IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

In the Matter of the Federal Bureau of Prisons' Execution Protocol Cases,	)	
LEAD CASE: *Roane et al. v. Barr*	)	Civil Action No. 19-mc-145 (TSC)
THIS DOCUMENT RELATES TO:	)	
ALL CASES	)	

CERTIFICATION OF THE ADMINISTRATIVE RECORD

Pursuant to 28 U.S.C. § 1746, I, Jeffrey E.E. Toenges, declare and state as follows:

1. I am an Assistant General Counsel at the Federal Bureau of Prisons (BOP), Office of General Counsel, in Washington, D.C. I have been employed with BOP since September 2016, and have been employed as an attorney in the Federal Government for over 27 years.
2. I am responsible for the compilation of the Administrative Record regarding the revised BOP Federal Execution Protocol.
3. I certify that the attached index is a true and accurate list of materials that comprise the Administrative Record.

I declare under penalty of perjury that the above information is true and correct to the best of my belief.

Executed on: 8/29/19

Jeffrey E.E. Toenges

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ADMINISTRATIVE RECORD SUMMARY
BOP USE OF SINGLE DRUG PROTOCOL

Introduction

The Federal Bureau of Prisons ("BOP") is responsible for implementing federal death sentences. *See* 28 C.F.R. Part 26. These regulations require the sentence be implemented by "intravenous injection of a lethal substance or substances in a quantity sufficient to cause death, such substance or substances to be determined by the Director of the Federal Bureau of Prisons . . . ." *See* 28 C.F.R. § 26.3(a)(4).

The BOP carried out the executions of Timothy McVeigh (2001), Juan Garza (2001), and Louis Jones (2003). At that time, the BOP lethal injection protocol consisted of three drugs: sodium pentothal, pancuronium bromide, and potassium chloride. The BOP has since been unable to acquire sodium pentothal.

In *Baze v. Rees*, 553 U.S. 35 (2008), the Supreme Court upheld Kentucky's use (along with at least 30 other states) of a three-drug combination, including sodium pentothal, pancuronium bromide, and potassium chloride. While *Baze* provided clear approval of a specific protocol for states to carry out the death penalty, practical obstacles soon emerged as pharmaceutical companies began refusing to supply the drugs used to implement the death sentences. *See Glossip v. Gross*, 135 S.Ct. 2726, 2733 (2015). Specifically, the sole American manufacturer of sodium pentothal stopped producing the drug because of its use in the death penalty. *Id.* Unable to obtain sodium thiopental, states explored alternatives and adopted use of pentobarbital, which was used in all of the 43 executions carried out by the states in 2012. *Id.* at 2733 (citing the Death Penalty Information Center online site at www.deathpenaltyinfo.org). However, pentobarbital also became difficult to obtain as anti-death-penalty advocates lobbied manufacturers to stop selling it for use in executions. *Id*.

States are unwilling to discuss or reveal the identity of entities that supply their lethal injection drugs because those entities often stop supplying the drugs once their identity is disclosed. *See In re: Missouri Department of Corrections*, 839 F.3d 732, 736 (8th Cir. 2016). Further, many states have enacted legislation precluding disclosure of entities that supply drugs necessary to carry out an execution and/or the identity of individuals who participate in executions. *See e.g.* Ga. Code Ann. § 42-5-36 (Georgia Lethal Injection Secrecy Act); Tex. Code Ann. § 552.1081 and Tex. Code Crim. Proc. Art. 43.14(b); Ark. Code Ann. § 5-4-617; Miss. Code Ann. § 99-19-51; Mo. Rev. Stat. § 546.720; Ohio Rev. Code Ann. § 2949.221; Okla. Stat. Ann. Title 22, § 1015; Tenn. Code Ann. § 10-7-504; S. D. Codified Laws § 23A-27A-31.2; and Va. Code Ann. § 53.1-234.

As sodium pentothal became unavailable, the BOP explored alternative drugs. The BOP benchmarked with state practices, reviewed case law, consulted with medical professionals, and reviewed available professional literature in this area. As a result of this review, the BOP has determined that a single-drug protocol, using pentobarbital, would be adopted as the execution protocol.

Benchmark with States

BOP personnel visited several state execution sites and reviewed state lethal injection protocols. The state lethal injection protocols were viewed on the corresponding state department of corrections' web sites and/or the Death Penalty Information Center website.

After the availability of sodium pentothal declined, states developed alternative drug combinations that replaced sodium pentothal with pentobarbital. *Glossip*, 135 S.Ct. at 2733. Some states incorporated pentobarbital as a one-drug protocol, and some states used pentobarbital in a three-drug protocol.

However, the availability of pentobarbital declined and states implemented other protocols. Due to challenges with availability of sodium pentothal and pentobarbital, several states have changed their protocols or adopted more than one lethal injection protocol to overcome shifting availability of various drugs. For example:

- In 2017, the State of Nevada adopted a three-drug execution protocol that includes fentanyl, diazepam, and cisatracurium. In June 2018, Nevada revised the protocol and replaced diazepam with midazolam, reportedly because Nevada's inventory of diazepam expired.
- From 2011 to 2013, Florida executed 10 individuals using a three-drug protocol wherein pentobarbital was the first drug administered. However, pentobarbital became unavailable for use in executions. In October 2013, Florida became the first state to substitute midazolam for pentobarbital as part of a three-drug protocol. *Glossip*, 135 S.Ct. at 2734. Florida executed 13 individuals using a lethal injection protocol with midazolam as the first drug without any reported problems. *Arthur v. Alabama Department of Corrections*, 840 F.3d 1268, 1304 (11th Cir. 2016). However, Florida encountered difficulties acquiring midazolam and in January 2017, Florida adopted a new three-drug protocol because it was unable to acquire midazolam. In that new protocol, Florida substituted etomidate for midazolam as the first drug, followed by rocuronium bromide and potassium acetate. The Florida Supreme Court upheld the use of etomidate as part of the lethal injection protocol. *Asay v. State of Florida*, 224 So.3d 695 (Fla. 2017). Florida has executed two individuals using that protocol.

Fourteen states have used pentobarbital in their lethal injection protocol, either as part of a three-drug combination or as a single-drug method. Georgia, Idaho, Missouri, South Dakota, and Texas administer a single-drug pentobarbital protocol. Both Missouri and Texas have extensive experience using the single-drug pentobarbital method, executing 20 and 78 inmates, respectively, since approximately 2012. Since 2010, pentobarbital was used as part of a single or three-drug combination in 208 executions. Of the ten executions in 2019, as of June 24, 2019, five used a single-drug pentobarbital protocol. https://deathpenaltyinfo.org/executions/lethal-injection/state-by-state-lethal-injection-protocols

Anticipating that the BOP would encounter the same obstacles that the states have encountered in obtaining pentobarbital, it also considered other lethal injection protocols. One alternative

protocol considered consists of three drugs: midazolam, sufentanil citrate, and potassium chloride.

The BOP determined that a one-drug protocol is preferred for several reasons. First, there are complications inherent in obtaining multiple drugs (availability obstacles) and navigating the respective expiration dates. Second, acquiring and storing one drug is administratively more efficient. Third, administering one drug reduces the risk of errors during administration, and eliminates the need to orchestrate the pace and sequence of administering multiple drugs and IV line management.

Professional Medical Expert Consultation

The BOP consulted with two medical experts to review whether the BOP's proposed pentobarbital protocol will produce a humane death. Both concluded that the protocol would produce a humane death.

Publically available expert testimony was also reviewed by the BOP. First, in January 2017, the expert addressed Ohio's lethal injection protocol, which entails midazolam, pancuronium bromide, and potassium chloride. Second, in February 2017, the expert provided testimony addressing Missouri's one drug lethal injection of pentobarbital.

In the Missouri case, the expert testified for the state on the efficacy of pentobarbital, and secondarily the use of nitrogen gas. When asked which option is better, the expert testified, "I don't offer an opinion about one being better than the other." The reason advanced was that medical ethics prevent him from so opining. Similarly, the inmate's expert declined to offer an opinion in that regard.

In the Missouri case, the inmate's attorney explored the expert's prior testimony regarding the efficacy of midazolam in the context of Ohio's 3-drug protocol. The inmate's attorney asked questions about the effects of each drug without directly asking which is better (e.g., the 3-drug protocol using midazolam vs pentobarbital). The expert testified that both are effective at producing unconsciousness (the intended effect), and then stated that pentobarbital achieves deeper levels of unconsciousness than midazolam.

In sum, the expert's prior testimony opined that both pentobarbital and midazolam in their respective protocols work to have the intended effect in this setting. He also testified that the properties of pentobarbital achieve a "deeper level" of unconsciousness than midazolam.

Review of After Action Report

The BOP reviewed the after action report of the widely publicized Oklahoma execution in 2015 involving state inmate Clayton Locket, which used a three drug protocol using midazolam, a paralytic agent, and then potassium chloride. As summarized by the Supreme Court in *Glossip*, 135 S.Ct. at 2734-35, that investigation concluded that the viability of the IV access point was the single greatest factor that contributed to the difficulty in administering the execution drugs.

Although various media outlets have reported complications with lethal injection executions, none of those executions appear to have resulted from the use of single-drug pentobarbital. This consideration included review of information provided by Death Penalty Information Center, *Botched Executions*, https://deathpenaltyinfo.org/some-examples-post-furman-botched-executions?scid=8&did=478.

Review of Case Law

The BOP reviewed case law addressing lethal injection protocols. Courts have held that the use of pentobarbital in executions does not violate the Eighth Amendment. *See, e.g.*, *Ladd v. Livingston*, 777 F.3d 286 (5th Cir. 2015); *Zink v. Lombardi*, 783 F.3d 1089, 1102 (8th Cir. 2015); *Jackson v. Danberg*, 656 F.3d 157 (3d Cir. 2011); *DeYoung v. Owens*, 646 F.3d 1319 (11th Cir. 2011); and *Pavatt v. Jones*, 627 F.3d 1336 (10th Cir. 2010). *See also Bucklew*, 139 S.Ct. at 1129-1132 (finding that death row inmate challenging Missouri's method of execution using a single-drug pentobarbital protocol failed to show a feasible and readily implemented alternative method of execution that would significantly reduce a substantial risk of severe pain).

Challenges to state lethal injection protocols frequently propose a single dose of pentobarbital rather than a three-drug protocol. *See, e.g.*, *McGehee v. Hutchinson*, 854 F.3d 488 (8th Cir. 2017); *In re Missouri Department of Corrections*, 839 F.3d 732 (2016); *Arthur v. Commissioner, Alabama Department of* Corrections, 840 F.3d 1268 (11th Cir. 2016); *In re Ohio Execution Protocol*, 860 F.3d 881, 890-91 (6th Cir. 2017); and *Glossip*, 135 S.Ct. at 2738. The common argument is that use of pentobarbital is an alternative method that would significantly reduce the substantial risk of pain from the challenged method. Two U.S. Supreme Court Justices dissented from denial of certirorari in two cases where the Petitioners' argued that state lethal injection protocols violated the Eighth Amendment. In both cases, the dissenting opinions indicated that the proposed alternative of a single-drug protocol consisting of pentobarbital did not carry the risks of the protocols being challenged. *See Zagorski v. Parker*, 139 S.Ct. 11 (2018) (challenge to the Tennessee lethal injection protocol consisting of midazolam, vecuronium bromide, and potassium chloride); and *Arthur v. Dunn*, 137 S.Ct. 725 (2017) (challenge to the Alabama lethal injection protocol consisting of midazolam, vecuronium bromide, and potassium chloride).

Based on review of case law, it is evident that use of pentobarbital is litigation tested, and courts across the country have held that the use of pentobarbital in executions does not violate the Eighth Amendment. Further, inmates and their advocates frequently cite to pentobarbital as a method that would significantly reduce the substantial risk of pain compared to the challenged method.

Source for Pentobarbital

The BOP has a viable source for obtaining pentobarbital. The manufacturer is properly registered as a bulk manufacturer of the active pharmaceutical ingredient ("API") for pentobarbital. The API was subjected to quality assurance testing, further supporting the reliability and qualification of this manufacturer.

The BOP has secured a compounding pharmacy to store the API and to convert the API into injectable form as needed. The BOP conferred with DEA to ensure the compounding pharmacy is properly registered. The compounding pharmacy has performed its own testing and the drug further passed quality assurance testing conducted by two independent laboratories.

The BOP confirmed with DEA that the BOP facility in Terre Haute, Indiana, meets the regulatory requirements for storage and handling of pentobarbital.

ATTACHMENTS

BENCHMARK

- Lethal Injection Protocol from:
  - Georgia
  - Idaho
  - Missouri
  - South Dakota
  - Texas

- State-by-state lethal injection summary from the Death Penalty Information Center website, https://deathpenaltyinfo.org/lethal-injection
- Internal talking points summarizing:
  - The State of Florida lethal injection protocol evolution
  - States that currently or previously used pentobarbital, and aggregated data.

CASE LAW

- *Bucklew v. Precythe*, 139 S.Ct. 1112 (2019)
- *Zagorski v. Parker*, 139 S.Ct. 11 (2018)
- *Arthur v. Dunn*, 137 S.Ct. 725 (2017)
- *Glossip v. Gross*, 135 S.Ct. 2726 (2015)
- *Baze v. Rees*, 553 U.S. 35 (2008)
- *Ladd v. Livingston*, 777 F.3d 286 (5th Cir. 2015)
- *Zink v. Lombardi*, 783 F.3d 1089 (8th Cir. 2015)
- *Jackson v. Danberg*, 656 F.3d 157 (3d Cir. 2011)
- *DeYoung v. Owens*, 646 F.3d 1319 (11th Cir. 2011)
- *Pavatt v. Jones*, 627 F.3d 1336 (10th Cir. 2010)
- *Price v. Commissioner, Alabama Dep't of Corrections*, 920 F.3d 1317 (11th Cir.2019)
- *Arthur v. Commissioner, Alabama Dep't of Corrections*, 840 F.3d 1268 (11th Cir. 2016)
- *In Re: Ohio Execution Protocol*, 860 F.3d 881 (6th Cir. 2017)
- *McGehee v. Hutchinson*, 854 F.3d 488 (8th Cir. 2017)

MEDICAL EXPERT DEPOSITIONS/REPORTS

- Rule 26(a)(2) Expert Report Declaration of Joseph F. Antoginini, M.D. (in the case of *Bucklew v. Lombardi*, 2016 WL 11258099 (W.D.Mo.))
- Expert Deposition of Joseph Antoginini, M.D. (2017 WL 9471457 (W.D. Mo.))
- Expert Report of Craig W. Lindsley, Ph.D., dated May 26, 2017
- Transcript of Preliminary Injunction Hearing dated January 5, 2017, in *In re: Ohio Execution Protocol Litigation*, in the U.S. District Court for the Southern District of Ohio.

JOURNALS, MEDIA, AND REPORTS

- Deborah W. Denno, *Lethal Injection Chaos Post-Baze*, 102 GEO. L.J. 1331, 1382 (2014)
- Hospira, Press Release, Hospira Statement Regarding Pentothal (sodium thiopental) Market Exit (Jan. 21, 2011).
- CNN article - *Death row inmate executed using pentobarbital in lethal injection*, December 16, 2010, *available at* http://www.cnn.com/2010/CRIME/12/16/oklahoma.execution
- Death Penalty Information Center, *Botched Executions*, https://deathpenaltyinfo.org/some-examples-post-furman-botched-executions?scid=8&did=478
- Oklahoma Department of Public Safety Report: The Execution of Clayton D. Lockett

BUREAU OF PRISONS AND DEPARTMENT OF JUSTICE CORRESPONDENCE

- November 27, 2017, memorandum from Director Mark S. Inch to the department (addressing proposed one-drug protocol).
- March 7, 2018, memorandum from Director Mark S. Inch to the department (addressing use of fentanyl).
- Addendum to BOP Execution Protocol (one drug pentobarbital).
- Draft memorandum from Acting Director to the department addressing anticipated adoption of one-drug protocol.
- Letter from various State Attorneys General dated January 25, 2011, to Attorney General Eric Holder, and the response letter from Attorney General Eric Holder dated March 4, 2011.
- Op. Off. Legal Counsel Volume 43 (May 3, 2019).

GEORGIA DEPARTMENT OF CORRECTIONS

GEORGIA DIAGNOSTIC AND CLASSIFICATION PRISON

LETHAL INJECTION PROCEDURES

July 17, 2012

GEORGIA DIAGNOSTIC AND CLASSIFICATION PRISON
LETHAL INJECTION PROCEDURES

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LETHAL INJECTION PROCEDURES

I. PRE-EXECUTION PROCEDURES

A. Designation and Notification of Staff

The individuals listed below shall be present at each execution. At least twelve (12) hours prior to the execution, the Warden or the Warden's designee will notify the following individuals of the time and date of execution and place to report for assignment. These individuals will then acknowledge receipt of the Warden's notification. The Warden has the authority to waive the twelve (12) hour requirement on an emergency basis.

1. Warden or Deputy Warden who shall ensure that the court ordered execution is carried out.

2. Two (2) Assistants or more as directed by the Warden.

3. Two (2) Physicians - to determine when death supervenes.

4. One (1) Physician - to provide medical assistance during the execution process (may be one of the Physicians identified in I.A.3 above).

5. IV Team - to consist of two (2) or more trained personnel, including at least one (1) Nurse, to provide intravenous access.

6. Six (6) Correctional Officers to serve as a Special Escort Team who will apply restraints to the condemned during the execution process.

7. Injection Team to consist of three (3) trained staff members to inject solutions into the intravenous port(s) during the execution process.

8. One (1) Chaplain to administer to the spiritual needs of the condemned and to provide a prayer on the condemned's behalf upon request.

9. Security personnel as appropriate.

B. Restrictions:

No photographic, audio, video, recording, or computerized equipment will be permitted in the Execution Chamber or Execution Witness Room except as

specifically authorized by the Warden. Only pencils, note pads, or other writing materials issued and controlled by designated GDC staff will be permitted.

II. DAY OF EXECUTION

A. Within Three (3) Hours of Execution

Within three (3) hours of the scheduled execution, the following tasks shall be performed:

1. A communications check will be performed.

2. Telephone circuits and private lines between the Command Center (CP1), Execution Chamber (CP2), and the Front Gate (CP3) will be checked.

3. The Execution Chamber and Execution Witness Room will be inspected as directed by the Warden.

4. A radio check between the Command Center, Execution Chamber, and Front Gate will be initiated.

B. Within Two (2) Hours of Execution

Within two (2) hours of the scheduled execution, the following tasks shall be performed:

1. Chemicals will be delivered to the H-5 Chemical Room by the Deputy Warden of Security or Correctional Major.

2. The IV Team will perform a check of all necessary equipment and instruments.

3. Communications Check - The same procedure will be followed as at three (3) hours prior to the execution as specified in Paragraph II.A.

4. The Execution Chamber and Execution Witness Room will be inspected as directed by Warden.

5. The condemned will be prepared in accordance with prior responsibilities previously designated by Warden.

6. The condemned may visit with clergy.

7. An opportunity for the condemned to make a last statement will be provided. Any such statement will be recorded by designated staff.

8. A shower and clean clothing will be provided to the condemned.

9. A designated staff member shall confirm the presence of witnesses required by O.C.G.A.§17-10-41 to attend the execution. Any final instructions will be issued by the Warden.

10. A designated staff member shall confirm the presence of the witnesses designated and approved by the Commissioner. Instructions will be issued to the witnesses to assure an understanding of their conduct in the Execution Witness Room and while being escorted to and from the Execution Witness Room. All witnesses are to have previously acknowledged, in writing, their understanding and agreement to abide by the rules, regulations, and procedures of the GDC.

C. Within One (1) Hour of Execution

Within one (1) hour of the scheduled execution, the following tasks shall be performed:

1. The IV Team will perform a check of all necessary equipment and instruments.

2. The designated staff members will prepare lethal injection syringes.

3. Medical staff will perform a test on the heart monitor.

4. The condemned will be offered a mild sedative by a Physician.

5. Special Escort Team members will ensure that all straps are in place and functional on the execution gurney.

6. Communications Check: The same communications check procedures specified in Paragraph II.A. above will be repeated. In addition, the telephone lines between the Command Center (CP1), the Execution Chamber (CP2), and the Front Gate (CP3) are to remain open beginning thirty (30) minutes prior to the scheduled execution.

7. The Execution Chamber and Execution Witness Room will be inspected as directed by the Warden.

8. Attendees and those required by O.C.G.A.§17-10-41 to attend executions will be issued additional instructions, and will be escorted to the Execution Chamber or Execution Witness Room as appropriate. Any witnesses for the condemned inmate, any media representatives, and the State's witnesses will be processed, instructed, and transported separately.

9. Upon arrival at the Execution Witness Room, witnesses and media representatives will be confirmed. The media representative designated to observe the preparation of the condemned will be identified and confirmed. The presence of witnesses requested by the condemned and those approved by the Commissioner, including media representatives, will be confirmed.

D. Preparation of the Condemned

1. The condemned inmate will be escorted to the lethal injection gurney by member(s) of the Special Escort Team approximately twenty (20) minutes prior to the time of the execution. The Special Escort Team will securely control the movements of the condemned from the holding cell to the execution chamber.

2. The Special Escort Team will secure the condemned to the gurney by attaching restraints to the arms, legs, and body of the condemned.

3. The IV Team will provide two (2) intravenous accesses into the condemned. If the veins are such that intravenous access cannot be provided, a Physician will provide access by central venous cannulation or other medically approved alternative.

4. Heart monitor leads will be applied to the condemned by a Nurse from the IV Team.

5. Witnesses will be escorted to the Execution Witness Room.

6. The Warden will introduce himself to witnesses and issue final instructions regarding the execution.

7. The Warden will ask the condemned if he has anything to add to the final statement. Any additional statement will be limited to two (2) minutes. The statement will be recorded by designated staff. A prayer will be offered if requested by the condemned. The prayer will be limited to two (2) minutes.

8. The condemned will be read the Execution Order of the Court.

9. Execution officials will take their places.

10. The Attorney General, or the Attorney General's designee, shall advise the Commissioner as to whether or not to proceed. The Commissioner then instructs the Warden as to whether or not to proceed.

E. Execution Process

Upon the Order of the Warden, the execution process will proceed as follows:

1. A staff member designated by the Warden will monitor the time when the injection process begins.

2. The first member of the Injection Team will inject one (1) syringe containing 2.5 grams of Pentobarbital (labeled #1). The second member of the Injection Team will inject an additional syringe containing 2.5 grams of Pentobarbital (labeled #2). The third member of the Injection Team will inject one (1) syringe containing 60 cubic centimeters of Saline (labeled #3), ensuring a steady, even flow of the chemical.

3. Throughout the lethal injection process, an IV Nurse will monitor the progress of the injection in the Execution Chamber to ensure proper delivery of chemicals and to monitor for any signs of consciousness. If the IV Nurse in the execution chamber observes a problem with intravenous flow, the Nurse will inform the attending Physician, who will inform the Warden as to whether or not using an alternative intravenous access is appropriate. The Warden will give the appropriate instructions to the Injection Team.

4. If, after a sufficient time for death to have occurred, the condemned individual exhibits visible signs of life, the Warden shall instruct the Injection Team to administer an additional 5 grams of Pentobarbital followed by 60 cubic centimeters of Saline as outlined in Subsection 2 of Section E. above.

5. Upon completion of the injection of the final syringe, the designated Physician will advise the Warden when the heart monitor indicates that the condemned inmate is deceased. The Warden and the two Physicians will then enter the Execution Chamber to determine if death has occurred.

6. If the condemned shows residual signs of life within a reasonable period after all injections have been completed, steps 1 through 5 above will be repeated upon the order of the Warden.

7. The Warden will then announce the fact of death to the witnesses. The

Execution Chamber curtains will then be closed.

F. Post Execution

1. The witnesses and media representatives will be escorted from the Execution Witness Room. Media representatives will be immediately escorted from the prison to the press area.

2. The IV lines will be detached by the IV Team, the straps will be removed by the Special Escort Team, and the body will be removed from the gurney. The body will be placed in a body bag and placed on a stretcher provided by the State Crime Lab. The body will then be taken by van to the State Crime Lab for a postmortem examination.

3. Press release: The Public Information Officer for the Department of Corrections will advise news media that the Order of the Court has been carried out.

G. Interment of Condemned.

1. The Warden or designee and attending physicians will prepare a certificate of execution and certify the fact of execution. The certificate will be forwarded to the Clerk of Superior Court of the county in which the sentence was pronounced. A copy shall be forwarded to the Commissioner.

2. The last statement of the condemned will be forwarded to the Central Office, as appropriate.

3. Interment: The body may be released to the relatives at their expense or should the nearest relative of the condemned so desire, the body will be carried to the former home of the person so executed, if in the State of Georgia. The expense of such transportation to the former home shall be paid by the Ordinary, County Commissioners, or person(s) having the charge of county funds in which the person was convicted. (O.C.G.A. § 17-10-43).

4. If the relatives do not claim the body of the executed person, interment will be in accordance with Board of Corrections Rule 125-2-4.20.

H. Critical Incident Debriefing

1. Staff participants will be seen by the Critical Incident Debriefing Team within seventy-two (72) hours of each execution or as soon as possible.

APPENDIX I

IV TEAM - INSTRUCTIONS

SET UP PROCEDURE:

1. The Warden or designee will have two (2) intravenous infusion devices placed in the veins of the condemned and a Saline solution available for an infusion medium. Those persons engaged in this activity will be referred to as the IV Team.

2. An IV administration set will be inserted into the outlet of the bag of Normal Saline IV solution. Two (2) IV bags will be set up in this manner.

3. The IV tubing shall be cleared of air and made ready for use.

4. The standard procedure for providing IV access will be used.

5. The IV tubing for both set-ups will be connected to the receiving port of the IV access; one for the primary vein, the other for the secondary vein.

6. At this point, the administration sets shall be running at a slow rate of flow (KVO), and ready for the insertion of syringes containing the lethal agents. The Warden or his designee shall maintain observation of both set-ups to ensure that the rate of flow is uninterrupted. **NO FURTHER ACTION** shall be taken until the prearranged signal to start the injection of lethal agents is given by the Warden or designee.

APPENDIX II

CONTROLLED CHEMICAL HANDLING PROCEDURES FOR EXECUTION BY LETHAL INJECTION

The following procedures will be utilized to obtain controlled chemicals, transport the chemicals to the Execution Chamber at the Georgia Diagnostic and Classification Prison (GDCP), dispose of and/or return unused chemicals to the GDCP Pharmacy.

A. The certificate issued by the Drug Enforcement Agency (DEA), United States Department of Justice will be posted in the medical room of the GDCP Execution Chamber. A copy of the certificate will be kept on file at the GDCP Pharmacy.

B. All controlled materials, blank "Controlled Chemical Disposition Record" forms, and a lockable transport case will be kept in the GDCP Pharmacy.

C. The designated key ring, located in the Tunnel Entrance Restricted Key Box, will be utilized to gain access to the chemical storage containers, transport case and the temporary chemical storage containers located in the Execution Chamber. Access to this key ring and the receipt and/or transportation of chemicals is restricted to: Deputy Warden for Security, Correctional Major, and designated Pharmacist. In an emergency, the Warden of GDCP may designate another official this duty.

D. On the day of a scheduled execution, one of the authorized staff members will draw the proper keys, proceed to the pharmacy and procure the appropriate amount of chemicals.

E. The appropriate amount of chemicals to be issued is as follows: Pentobarbital – a total of 15 grams of the chemical.

F. During the procedures outlined in step #4, the "Controlled Chemical Disposition Record" will be initiated at this time. The Pharmacy will keep a temporary copy upon issuance. The original will be kept with the chemicals in the transport case. The appropriate sections will be completed as needed.

G. Chemicals will be delivered to the Execution Chamber and locked in the chemical storage container.

H. Within one hour of the scheduled execution, the chemicals will be drawn into syringes to be used by the Injection Team by a trained staff member supervised by a nurse.

I. Chemicals will be drawn up as follows:

    1. Pentobarbital – 2.5grams – Syringe #1 .

2. Pentobarbital – 2.5 grams – Syringe # 2.
3. Saline Solution – 60 cubic centimeters each - Syringe # 3.

J. A secondary set of Syringe Numbers 1, 2 and 3 will be prepared in the manner outlined above in section I if an additional dosage of Pentobarbital is needed. The secondary set of Pentobarbital will not be drawn into Syringe Numbers 1 and 2 prior to the execution, but will be immediately available, together with the appropriate syringes, if an additional dosage of Pentobarbital is needed.

K. The remaining chemicals, along with appropriate syringes will be locked in the transport case and placed in the mechanical room in the event they are needed.

L. At the conclusion of the execution, the amount of each chemical injected into the condemned inmate is to be recorded on the Controlled Chemical Disposition Record form, along with the date, time, inmate name and number.

M. Any chemical loaded into a syringe that is not used will be destroyed by disposing of the chemicals in an appropriate manner. This must be witnessed and the section completed and signed on the Controlled Chemical Disposition form.

N. Any unused chemicals will be returned to the pharmacy via the transport case and the remainder of the Controlled Chemical Disposition Record form will be completed.

O. The original Controlled Chemical Disposition Record form will be retained by the Pharmacy. A copy will be sent to the Warden's office for inclusion into the Execution file.

P. An inventory will be kept by the Pharmacy of each chemical used and returned. The Controlled Chemical Disposition form and the inventory logs will be kept in a red binder attached to the chemical storage container.

Q. The attachments 1 through 2 will be completed and submitted as required.

Attachments: (1) Controlled Chemical Disposition Form
(2) Inventory Log for Pentobarbital

CONTROLLED CHEMICAL DISPOSITION RECORD (LETHAL INJECTION)

GEORGIA DEPARTMENT OF CORRECTIONS – GDCP

CHEMICALS DISPENSED BY GDCP PHARMACY

Name of Chemical – Amount	Date Issued	Lot #	Expiration	# of Vials
PENTOBARBITAL 15 GRAMS				

ISSUED BY: (SIGN AND PRINT NAME)	RECEIVED BY: (SIGN AND PRINT NAME)	DEPT/LOCATION

CHEMICALS ADMINISTERED BY INJECTION TEAM

DATE	TIME	INMATE NAME/NUMBER	CHEMICALS	QTY
			PENTOBARBITAL	

CHEMICALS DESTROYED

CHEMICALS DESTROYED	QTY	# OF SYRINGES	DATE DESTROYED	DEPT/LOCATION
PENTOBARBITAL				

DESTROYED BY: (SIGN AND PRINT NAME)	WITNESSED BY: (SIGN AND PRINT NAME)	DEPT/LOCATION

CHEMICALS RETURNED TO GDCP PHARMACY

DATE RETURNED	CHEMICAL RETURNED	QTY RETURNED	# OF VIALS
	PENTOBARBITAL		

RETURNED BY: (SIGN AND PRINT NAME)	RECEIVED BY: (SIGN AND PRINT NAME)	DEPT/LOCATION

CONTROLLED CHEMICAL INVENTORY LOG

GEORGIA DEPARTMENT OF CORRECTIONS – GDCP

DATE	PACKAGE SIZE	BEGINNING INVENTORY	AMOUNT DISPENSED	DATE DISPENSED	SUBTOTAL	AMOUNT RETURNED	DATE RETURNED	TOTAL INVENTORY	INITIALS

Idaho Department of Correction	Standard Operating Procedure Operations Division General Administration	**Control Number:** 135.02.01.001	**Version:** 3.6	**Page Number:** 1 of 35 **Adopted:** 5-18-1998 **Reviewed:** 1-6-2012 **Next Review:** 1-6-2014
		Title: Execution Procedures		

This document was approved by Kevin Kempf, chief of the Operations Division, on 1/6/12 (signature on file).

Open to the general public: ☒ Yes ☐ No

If no, is there a redacted version available: ☐ Yes ☐ No

BOARD OF CORRECTION IDAPA RULE NUMBER 135

Executions

POLICY CONTROL NUMBER 135

Executions

DEFINITIONS

Standardized Terms and Definitions List

None

PURPOSE

The purpose of this standard operating procedure (SOP) is to establish specific procedures for administration of capital punishment in accordance with the Idaho Code and the constitutions of the United States of America and the state of Idaho.

SCOPE

This SOP applies to all Idaho Department of Correction (IDOC) staff members involved in the administration of capital punishment and to offenders who are under death warrant and the execution of which has not been stayed.

Note: This SOP is subject to revision at the discretion of the chief of the Operations Division or the director of the IDOC. Either person may revise, suspend, or rescind any procedural steps, at any time, at his sole discretion.

RESPONSIBILITY

Director of the IDOC

The director of the IDOC shall be responsible for:

- Exercising overall control of the administrative policy, SOP, field memorandum, and of the execution process itself;
- Communicating with Idaho governor's office, Idaho Board of Correction, legislators, and Idaho Commission of Pardons and Parole;

- Determining execution method and ensuring that applicable chemicals are obtained; and
- Approving news media representatives for media center access.

Chief of the Operations Division

The chief of the Operations Division shall be responsible for:

- Approving all SOPs, field memorandums, and post orders related to the execution process;
- Contacting/notifying members of the victim's family;
- Contacting/notifying the state of Idaho's witnesses;
- Briefing the victim's family, the condemned offender's family, and the state of Idaho's witnesses before the execution; and
- Disseminating briefings as needed to staff following the issuance of a death warrant.

Deputy Chief of the Prisons Bureau

The deputy chief of the Prisons Bureau shall be responsible for:

- Appointing one or more staff member(s) within the bureau to assist the Idaho Maximum Security Institution (IMSI) warden;
- Coordinating the IDOC's south Boise complex activities as the Incident Command System (ICS) command center operations chief; and
- Activating the following teams and overseeing their activities:
  - Command;
  - Correctional Emergency Response Team (CERT);
  - Maintenance;
  - Critical Incident Stress Management (CISM);
  - Traffic Control Team;
  - Idaho State Correctional Institution (ISCI) media center; and
  - South Idaho Correctional Institution (SICI) grounds and perimeter security.

Administrative Team

The Administrative Team consists of the deputy chiefs of the Prisons Bureau, the IMSI warden, and the backup to the IMSI warden for the purpose of serving as the execution director. The Administrative Team is responsible for:

- Providing, planning, directing, and implementing all pre-execution and post-execution activities;
- Coordinating all processes associated with specialty team (section 5) personnel selection, equipment, supply acquisition, training, rehearsal, and performance;
- Conducting preparatory steps in order to ensure that the execution process is conducted in accordance with this SOP;

- Reviewing and ensuring that the department faithfully adheres to the letter and intent of Idaho Code, sections 19-2705, 19-2713, 19-2714, 19-2715, 19-2716, 19-2718;
- Selecting staff to serve on the Escort Team and Medical Team;
- Identifying a licensed physician to be on sight during the execution procedure;
- Ensuring that all of the equipment such as electrical, plumbing, heating and cooling units (HVAC) in the execution chamber are tested periodically to ensure they are in working order; and
- Ensuring that an annual training schedule is established and identifying dates for periodic for periodic on-site rehearsal sessions by the Escort Team, Medical Team, and command staff.

Idaho Maximum Security Institution (IMSI) Warden

The IMSI warden shall be responsible for:

- Serving the death warrant;
- Assigning to the condemned offender a warden's liaison;
- Creating and maintaining a log documenting the events leading up to the execution date;
- Issuing all the orders to facilitate an execution at IMSI;
- Approving the spiritual advisor for the offender if one is requested; and
- Creating a permanent record of the execution activities.

Idaho Maximum Security Institution (IMSI) Deputy Warden of Security

The IMSI deputy warden of security shall be responsible for internal security at IMSI. In addition to the regular posts, the IMSI deputy warden of security shall be responsible for scheduling staff for additional security to begin 48 to 24 hours prior to the execution up to and including a 'level C response' in accordance with the ICS.

Idaho State Correctional Institution (ISCI) Warden

The ISCI warden shall be responsible for establishing a field memorandum to identify authority and guidelines to coordinate media activity and providing logistical and communication support at the IDOC's south Boise complex.

Note: The chief of the Operations Division must approve the field memorandum.

South Idaho Correctional Institution (SICI) Warden

The SICI warden shall be responsible for establishing a field memorandum to identify authority and guidelines to coordinate and implement external security measures, including guidelines for other law enforcement and support agencies operating on the IDOC's south Boise complex.

Note: The chief of the Operations Division must approve the field memorandum.

Table of Contents

GENERAL REQUIREMENTS

1. Introduction

Execution of an offender under sentence of death is one of the most serious responsibilities of the agency and a high regard for the dignity of all involved must be maintained.

An execution generates public debate and attention. IDOC staff must be aware of the pressures an execution places on themselves and offenders. Extra security precautions are necessary and staff must be prepared and able to meet the situations that might arise.

All execution procedures, for both male and female offenders, will be conducted at IMSI.

No IDOC staff member or contractor, except as identified by Idaho Code or contract, will be forced to participate in an execution and can withdraw from the process at any time without prejudice.

The IDOC shall make every effort in the planning and preparation of an execution to ensure that the execution process:

- Faithfully adheres to the letter and intent of Idaho Code, sections 19-2705, 19-2713, 19-2714, 19-2715, 19-2716, and 19-2718;
- Is handled in a manner that minimizes its impact on the safety, security, and operational integrity of the prison in which it occurs;
- Reasonably addresses the right of the offender to not suffer cruelly during the execution;
- Accommodates the public's right to obtain certain information concerning the execution and strives to minimize the impact on the community and the state of Idaho;
- Reasonably addresses the privacy interests of victims and their families;
- Provides contingency planning to identify and address unforeseen problems;
- Maintains lines of communication for stays of execution, commutations, and other circumstances up to the time that the offender is executed;
- Provides opportunity for citizens to exercise their First Amendment rights to demonstrate for or against capital punishment in a lawful manner; and
- Ensures there is an appropriate response to unlawful civil disobedience, trespass and other violations of the law by any person attempting to impact the execution or the operation of the prison.

2. Monitoring Appellate Activities

The deputy chief of the Prisons Bureau, in conjunction with the deputy attorneys general (DAGs) who represent the IDOC, will monitor the appellate process of those offenders under the sentence of death. When it appears that an offender may be within one year or less of exhausting his appeals, the deputy chief of the Prisons Bureau will notify the director of the IDOC, chief of the Operations Division, and the IMSI warden of the possibility of the issuance of a death warrant within the next year.

The Administrative Team will begin the planning and preparation process when an offender is determined to be possibly within this one year timeframe.

3. Staff Conduct and Professionalism

All IDOC staff and contractors are responsible to maintain a high degree of professionalism regarding the execution process, to include all IDOC and contract facilities that are not involved in the execution process. Expectations demonstrating professionalism include, but are not limited to, the following:

- Restraint and courtesy when interacting with offenders, witnesses, demonstrators, attorneys, news media, state of Idaho and local law enforcement and any member of the public regarding the implementation of the death penalty;

- All assigned duties are performed proficiently and professionally; and
- Conduct that appropriately reflects the gravity of the execution process.

The names of the individuals serving on the escort and medical teams (see section 5) and the name of the on-site licensed physician (see section 6) will be treated with the highest degree of confidentiality. Any staff member who is aware of the identities of the individual team members and/or the on-site physician must maintain strict confidentiality of those identities. Any staff member who discloses the identities of any individual team member or the on-site physician will receive disciplinary action up to and including dismissal. (See SOP 205.07.01.001, *Corrective and Disciplinary Action*).

4. Attempted Disruption of Execution Process

The IDOC is required by Idaho Code to carry out the execution of an offender under sentence of death. The IDOC will take those actions necessary to fulfill this requirement and prevent the disruption of an execution or disruption to the safe and orderly operation of its correctional facilities to include, but not limited to the following:

- Filming, taping, broadcasting or otherwise electronically documenting the execution of an offender;
- Trespassing and otherwise entering upon IDOC property without authorization;
- Participating in unlawful demonstrations or unlawfully attempting to disrupt, prevent and otherwise interfere with an execution; and/or
- Unlawfully threatening, intimidating and otherwise attempting to influence authorized persons involved in the execution process.

These prohibitions apply to the offender population, contractors, IDOC staff, and members of the general public.

The IDOC will ensure that adequate law enforcement officers to include but not limited to the Boise Police Department, Ada County Sheriff's Department, and/or Idaho State Police are present to ensure the safe control of citizens on IDOC property, including officers stationed at the Execution Unit, if deemed necessary.

5. Specialty Teams and their Training and Practice Requirements

The execution process requires three (3) specialty teams: an Escort Team, a Medical Team, and an Administrative Team. The names of the individuals on the Escort Team and Medical Team will be treated with the highest degree of confidentiality (see section 3). The anonymity of all individuals (except those Administrative Team members who must participate as required by Idaho Code) participating in or performing any ancillary functions in the execution and any information contained in the records that could identify those individuals must remain confidential and are not subject to disclosure. The identities of escort and medical team members will be limited to the director of the IDOC, the chief of the Operations Division, and the Administrative Team.

Escort Team Members – Criteria and Selection Requirements

To serve on the Escort Team is strictly voluntary (staff may withdraw at any time without prejudice). Escort Team members must meet the following criteria:

- Has displayed a high degree of professionalism;
- Has displayed an ability to maintain confidentiality;

- Has had no personnel disciplinary action in the past 12 months;
- Has at least one year of satisfactory employment with the IDOC;
- Has no blood relationship or legal relationship to the victim's family; and
- Has no blood relationship or legal relationship to the condemned offender or offender's family.

The Administrative Team shall identify qualified personnel to serve on the Escort Team, verify their qualifications, and complete criminal background checks before approving their participation on the team.

The deputy chief of the Prisons Bureau will designate an Escort Team leader and at least one alternate Escort Team leader.

The Escort Team leader shall (a) report to and take direction from a designated Administrative Team member, and (b) ensure that all team members thoroughly understand all provisions of this SOP and are well-trained in the escort procedures.

Medical Team Members – Criteria and Selection Requirements

The Medical Team shall consist of volunteers whose training and experience include administering intravenous (IV) drips. The Medical Team shall be responsible for inserting IV catheters, ensuring the line is functioning properly throughout the procedure, mixing the chemicals, preparing the syringes, monitoring the offender (including the level of consciousness), and administering the chemicals as described in appendix A, *Execution Chemicals Preparation and Administration*.

The Medical Team can be comprised of any combination of the following disciplines:

- Emergency medical technician (EMT);
- Licensed practical nurse (LPN);
- Military corpsman;
- Paramedic;
- Phlebotomist;
- Physician assistant;
- Physician;
- Registered nurse (RN); or
- Other medically trained personnel including those trained in the United States military.

To serve on the Medical Team, individuals must meet the following criteria:

- Must have at least three (3) years of medical experience as an EMT, LPN, military corpsman, paramedic, phlebotomist, physician assistant, physician, RN, or other medically trained personnel including those trained in the United States military;
- Has no blood relationship or legal relationship to the victim's family; and
- Has no blood relationship or legal relationship to the condemned offender or offender's family.

The Administrative Team shall identify qualified personnel to serve on the Medical Team; verify their professional qualifications (to include professional license[s] and certification[s]), training, and experience; complete criminal background checks; and conduct personal interviews before approving their participation on the team.

Note: Licensing and/or certification, and criminal history reviews shall be conducted, prior to entering into an agreement. These reviews shall be conducted annually and upon the issuance of a death warrant.

The Administrative Team shall ensure that all Medical Team members thoroughly understand all provisions of this SOP and are well-trained in the execution procedures.

The deputy chief of the Prisons Bureau will designate a Medical Team leader and at least one alternate Medical Team leader.

The Medical Team leader shall (a) have direct oversight over the Medical Team, and (b) report to and take direction from a designated Administrative Team member

Training and Rehearsal Requirements

The Administrative Team shall (a) ensure an annual training schedule is established, and (b) identify dates for periodic on-site rehearsal sessions by the Escort Team, Medical Team, and command staff. All training and rehearsal sessions shall be documented and submitted to a designated Administrative Team member. The training schedule shall meet the following criteria:

- The schedule shall include a minimum of 10 annual training sessions for the escort and medical teams;
- After receiving a death warrant, the Escort Team, Medical Team, and command staff will train weekly before the scheduled execution date;
- The Escort Team, Medical Team, and command staff members must participate in a minimum of four (4) training sessions prior to participating in an actual execution;
- Prior to any scheduled execution, the Escort Team, Medical Team, and command staff shall conduct a minimum of two (2) rehearsal sessions during the 48 hours before the scheduled execution; and
- Training and rehearsal sessions for the Medical Team shall include the placing of IV catheters and establishing an IV drip in a minimum of two (2) live volunteers prior to each execution.

Note: If no execution is anticipated beyond the time required to assemble and adequately train the escort and medical teams, the director of the IDOC may suspend annual training.

6. Licensed Physician on Site during Execution

A licensed physician will be on-site and staged in or near the Execution Unit. The Administrative Team will verify the physician's professional licensure and will complete a criminal background check.

Note: The on-site physician will not be a member of any teams described herein this SOP and will not participate in the execution in any way.

Note: The on-site physician's identity shall remain anonymous and shall be protected from disclosure in the same manner described for the medical and escort team members. (See section 3 and section 4.)

The on-site physician will have access to an on-site medical crash cart, including applicable medications, and defibrillator. The physician must be a medical doctor licensed by the Idaho Board of Medicine.

The on-site physician will provide the following services:

- First Aid: Provide emergency care if needed to any person in the immediate area; and
- Resuscitation: Will assist in any necessary resuscitation effort of the offender should a problem occur with the execution process.

Emergency Medical Personnel and Ambulance Service

Emergency medical technicians and ambulance service will be staged near the Execution Unit as determined by the Administrative Team to provide emergency medical assistance and transport to anyone requiring such care during the process.

7. Death Warrants and Pregnant Females

If there is reason to believe that a female under death warrant is pregnant, the facility warden will require the offender to be examined by three (3) physicians. If the offender is found to be pregnant, the facility warden will immediately notify the prosecuting attorney of the county with jurisdiction, the Idaho governor's office, and the sentencing judge. The facility warden will suspend the execution, until the offender is no longer pregnant and the sentencing court has appointed a day for execution.

8. Stay of Execution

Upon receipt of notification that the court has issued a stay of execution, the director of the IDOC shall advise the chief of the Operations Division, deputy chief of the Prisons Bureau, and IMSI warden.

If the stay of execution is received immediately prior to the execution, the IMSI warden will advise the witnesses that a stay of execution has been issued. If it is anticipated that the stay will be for an extended period of time, have the witnesses escorted back to their specified staging areas.

Director of the IDOC

- Notify the state of Idaho governor's office; and
- Notify the executive director of the Idaho Commission of Pardons and Parole.

Chief of the Operations Division

- Provide a briefing to the state of Idaho's witnesses and the condemned offender's witnesses; and
- Provide a briefing to IDOC staff.

Administrative Team

Ensure that all chemicals and medical supplies are handled in accordance with appendix A, *Execution Chemicals Preparation and Administration*.

Deputy Chief of the Prisons Bureau

- Advise facilities that a stay of execution has been issued;
- Begin systematically deescalating the operation and when applicable instruct execution activities related operations to stand down; and
- When appropriate, return all IDOC and contract facilities to normal operations.

IDOC Public Information Officer (PIO)

Issue a press release to the media.

IMSI Warden

- If the stay is issued after the offender has been moved to the execution chamber and IV catheters have been inserted, and the stay is anticipated to be for more than two (2) hours, direct the Medical Team to remove the catheters;
- Direct the Escort Team to remove the offender from the Execution Unit and return him to a designated cell; and
- If applicable, return offender's property.

9. General Timelines

The processes described in this SOP are based on a timeline; however, the timeline is subject to change as needed to accommodate unforeseen events.

The timeline begins with issuance of a death warrant and concludes following the execution or stay of execution. The sequence of events is based on the following timeline:

- Issuance of the death warrant;
- 30 days prior to the execution;
- 21 days prior to the execution;
- Seven (7) days prior to the execution;
- Two (2) days prior to the execution;
- 24 hours prior to the execution;
- 12 hours prior to the execution;
- Execution procedures; and
- Post-execution activities.

10. Public Information and Media Access

The IDOC PIO is responsible to prepare and release information to the media. The IDOC PIO will clear each press release with the deputy chief of the Prisons Bureau before it is released to the media.

The IDOC PIO will act as the IDOC's liaison with all media agencies requesting access to the IDOC's south Boise complex or information regarding the execution. The IDOC PIO will notify all news media of the following IDOC rules that must be adhered to:

- Tobacco is not allowed within any IDOC facility;
- Weapons of any kind are not allowed on IDOC property;

- Cameras, video cameras, cellular telephones, and recording devices are not allowed inside IMSI or the execution chamber;
- Cameras, video cameras, and recording devices are allowed in the media center and at the area(s) designated for media on the IDOC's south Boise complex;
- Are subject to search (metal detector and random pat search);
- Must arrive at the facility at the designated time; and
- Must enter IDOC property as instructed.

Media Center

A media center will be established and will be located on property at the IDOC's south Boise complex.

The term "news media representative" shall be defined as a person whose primary employment is gathering or reporting news for:

- A newspaper as defined in Idaho Code, section 60-106;
- A news magazine having a national circulation being sold by newsstands and by mail circulation to the general public;
- Radio and television news programs of stations holding Federal Communication Commission licenses; and
- The Associated Press.

Because advances in information technology have blurred the definition of the term 'news media', resulting in there being no commonly accepted definition of the term, and because IDOC has an obligation to assure the orderly operation of the media center by regulating access to center, news organizations which distribute content primarily via a website will be admitted on a case-by-case basis. The IDOC PIO will verify that each web-based organization is a bona fide news media. The director of the IDOC will be the final authority to approve admittance of news media representatives from web-based news agencies.

Media Witnesses to the Execution

In addition to the media center where news media representatives will be provided information and briefings, the IDOC has allotted four (4) seats for news media representatives to witness the execution. News media organizations wishing to have reporters witness the execution must submit their representatives' names, birth dates and Social Security numbers at least 14 days prior to the scheduled execution for the purposes of undergoing a criminal background check and approval (see appendix B, *Media Notification and Agreement*). The four (4) media seats are comprised as follows:

- One media witness seat is allocated to the Associated Press. The Associated Press will select the reporter.

The following media witness seats are selected by random drawings:

- One media witness seat is allocated to media representing the region that serves the county of conviction. The director of the IDOC will determine which media agencies provide substantial coverage to the residents in the county of conviction for admittance into the pool for this seat;
- One seat is allocated for local print/internet; and

- One seat is allocated for local broadcast media.

Note: Local media is defined as a print/internet or broadcast media whose primary mission is to cover and deliver local news to the residents of Idaho. Each media organization may submit no more than one person as a possible media witness.

Random Drawing

Approximately one week before the scheduled execution, the IDOC PIO will conduct the random drawing for three (3) media seats. The drawing shall include selecting alternative representatives should the primary representative withdraw prior to the execution.

News media representatives requesting access to the media center must complete appendix B, *Media Notification and Agreement,* and agree to return directly to the media center following the execution and share their information with the other news media representatives. The IDOC PIO will facilitate that discussion and briefing.

Media Staging

The deputy chief of the Prisons Bureau will determine the schedule and location for media vehicle staging and the schedule when news media representatives who are not participating in the witness pool must arrive.

News media representatives who have been selected to witness the execution must arrive at the media center at the time designated by the IDOC PIO, which is approximately three (3) hours before the scheduled execution.

News media representatives will sign in at the designated media center.

ISCI will provide two (2) escort officers and a transport van to transport the news media representatives selected to be present at the execution from the media center to IMSI. The news media witnesses will join the other state of Idaho witnesses to be escorted to the Execution Unit.

The transport officers will remain in a pre-assigned area at IMSI until the execution is declared completed by the IMSI warden. The escort officers will then transport the media representatives back to the media center to participate in the news conference.

11. External Security

Temporary Flight Restriction

In consultation with local law enforcement and home land security, the deputy chief of the Prisons Bureau will assess any security threat or risk posed by air craft. If a security or safety risk involving aircraft is perceived, before the execution the deputy chief of the Prisons Bureau will request through appropriate channels that the Federal Aviation Administration (FAA) place a temporary flight restriction (TFR) surrounding the IDOC's south Boise complex consisting of the following (see section 16). An example of the TFR airspace would be as follows:

- **Radius:** Three (3) nautical miles
- **Altitude:** 500 feet from the surface

IDOC's South Boise Complex Security Zones

The IDOC property south of Boise known as IMSI, ISCI, SICI, and South Boise Women's Correctional Center (SBWCC) will be broken down into four (4) security areas:

- **Inner perimeter zone:** the respective facilities fences
- **Controlled perimeter zone**: an extended perimeter around the four (4) facilities
- **Restricted zones:** areas designated for the media
- **Extended zones:** areas designated for observers/demonstrators.

At the designated time, the SICI warden will control access to the IDOC's south Boise complex to include IMSI, ISCI, SICI, and SBWCC.

SBWCC will provide security staff as needed to the SICI warden to help support security of the controlled perimeter zone.

The SICI warden is responsible for establishing posts at strategic access and checkpoints in the controlled perimeter zone surrounding the facilities.

12. Those Present at Execution

The director of the IDOC (or designee) shall have the discretion to determine the number of persons allowed in the Execution Unit during the execution procedure. In exercising this discretion, the director of the IDOC (or designee) shall consider the safe and orderly operation of IMSI, the interests of the victim's family, and whether multiple death warrants are being executed concurrently. Persons allowed in the Execution Unit are as follows.

Note: Individual placement of attendees in the Execution Unit is subject to change at the discretion of the IMSI warden.

- The Administrative Team;
- The Escort Team (up to four [4] members total);
- The Medical Team;
- The on-site physician (one total);
- The director of the IDOC (or designee);
- An Idaho Board of Correction representative (one total);
- The chief of the Operations Division (or designee);
- The IMSI warden (or designee) (one total);
- The Ada County coroner (one total);
- The prosecuting attorney from the county of conviction (one total);
- The sheriff from the county of conviction (one total);
- The sentencing judge (one total);
- The Idaho governor (or his representative) (one total);
- The Idaho attorney general (or his representative) (one total);
- Members of the victim's family (two [2] total);
- A spiritual advisor of the offender's choosing (one total);
- Friends (approved visitors) or members of the offender's family (two [2] total);
- The offender's attorney of record (one total); and

- Members of the news media (up to four [4] total, see section 10).

The Execution Unit includes witness areas, the execution chamber, the Medical Team room, and staging areas. The persons in each area are as follows:

State of Idaho Witness Area

- An Escort Team member (one total);
- The chief of the Operations Division;
- Members of the victim's family (two [2] total);
- Members of the news media (up to four [4] total in accordance with section 10);
- The prosecuting attorney from the county of conviction (one total);
- The sheriff from the county of conviction (one total);
- The sentencing judge (one total);
- An Idaho Board of Correction representative (one total);
- The Idaho governor (or his representative) (one total); and
- The Idaho attorney general (or his representative) (one total).

Condemned Offender's Witness Area

- An Escort Team member (one total);
- IDOC liaison for offender's family;
- Friends (approved visitors) or members of the offender's family (two [2] total);
- The offender's attorney of record (one total); and
- A spiritual advisor of the offender's choosing (one total);

Execution Chamber

Other than the offender, the other individuals authorized to be in the execution chamber are:

- Escort Team members (up to two [2] total);
- Interpreter (if necessary):
- The director of the IDOC; and
- The IMSI warden (or designee).

Note: The Ada County coroner and the on-site physician (see section 6) will be located in a staging area near the execution chamber as determined by the IMSI warden.

Medical Team Room

- Only the Medical Team; and
- Only the Administrative Team.

13. Upon Receipt of a Death Warrant

Upon the receipt of a death warrant by the director of the IDOC, the following steps will be implemented.

Note: If the warrant is delivered to a facility warden instead of the director of the IDOC, the facility warden will implement step 4, and immediately notify the director, the chief of the Operations Division, and the deputy chief of the Prisons Bureau.

Functional Roles and Responsibilities	Step	Tasks
Director of the IDOC	**1**	• Immediately notify the warden of the facility in which the offender is housed **and** the IMSI warden; and • Immediately forward the death warrant to the warden of the facility in which the offender is housed.
Director of the IDOC	**2**	Notify the: • Idaho Board of Correction; • Executive director of the Idaho Commission of Pardons and Parole; • Idaho governor's office; and • IDOC PIO.
Facility Warden	**3**	Begin a log to provide a comprehensive chronological history of every aspect of the execution procedure.
Facility Warden	**4**	Serve the death warrant on the offender.
Facility Warden	**5**	Immediately segregate the offender from the general offender population (see section 15).
Facility Warden	**6**	Place the offender under constant observation by two (2) staff members for 24 hours a day, seven (7) days a week. **Note:** An observation logbook will be immediately established to record staff's observation of the offender's activities and behavior until the offender is executed or a stay of execution is received. Entries will be chronological. Each day will be recorded beginning at midnight as M/DD/YYYY. During the final four (4) hours before the execution, staff shall record each entry noting the time in hours and minutes, and make entries a minimum of once every 30 minutes.
Facility Warden	**7**	Notify the facility health authority **and** clinician that the offender has been placed in solitary confinement under a death warrant.
Facility Warden	**8**	• Notify the sentencing court that the death warrant has been served; • Retain the original death warrant; • Place a copy of the death warrant in the offender's central file; • Provide the offender with a copy of the death warrant; and • Forward a copy of the death warrant to the lead DAG who represents the IDOC.

Functional Roles and Responsibilities	Step	Tasks
Facility Warden	**9**	Within 24 hours after the death warrant is served, appoint a staff member (normally an IMSI deputy warden) to relieve the warden of all duties except those duties related to the execution procedure until there is a stay of execution **or** the execution process has been completed.
Facility Warden	**10**	Appoint a staff member to serve as liaison between the condemned offender, the offender's family, and the IMSI warden (if the offender does not speak English ensure an interpreter is obtained and available to communicate with offender);

14. Briefing and/or Communication: After the Death Warrant is Served

The facility warden shall ensure that at a minimum, a weekly briefing will occur for all involved staff commencing after the death warrant is served until the facility has returned to normal operations. The CISM team members will be available to speak with interested and affected staff, individuals, or groups who have been identified by the facility warden or other staff.

At a minimum, briefings and/or communication will be conducted as follows:

- Immediately after the death warrant is served;
- If any changes are made to the established execution timeline;
- As deemed necessary to keep staff well informed during the week prior to the execution; and
- The day after the execution.

15. Conditions of Confinement

Immediately following the service of a death warrant, the offender will be moved to a predetermined isolation cell in accordance with Idaho Code, section 19-2705. The isolation cell will be supplied a fresh mattress and pillow that has been thoroughly inspected, and clean bedding. An unclothed body search will be conducted and the offender will be given clean clothes and different shoes.

Identify any special accommodations that are required if the offender has a disability or other special need.

Until the execution has been stayed or completed, any movement of the offender will require that he be escorted in full restraints, by two (2) correctional staff.

The offender will be placed under 24-hour, constant observation by two (2) uniformed staff members until there is a stay of execution or the offender is transferred to the execution chamber.

The offender will be allowed daily outdoor exercise, showers, and telephone access.

The offender will be provided access to a television set.

Property

The offender's personal property will be handled as provided in this section.

The offender's personal property shall be inventoried. The offender will be allowed to keep not more than six (6) cubic feet of legal papers and religious materials, a pencil and paper, books or periodicals, and commissary food items. All remaining property will be boxed, sealed and removed from the cell. It will be stored pending receipt of written instructions from the offender regarding disposition of property or otherwise disposed of as outlined in directive 312.02.01.001, *Death of an Inmate*.

Commissary

The offender will be allowed to purchase food items from the commissary until the delivery date of commissary is within seven (7) days of the execution, the IMSI warden can extend this time frame at his discretion. Non-food purchases must be approved by the IMSI warden. The spending limit will be the same as established in SOP 320.02.01.001, *Property: State-issued and Offender Personal Property*. However, the IMSI warden can increase or decrease this amount with approval of the deputy chief of the Prisons Bureau. The offender may retain consumable commissary items as approved by the IMSI warden until completion of the last meal.

Last Meal

For the last meal, the offender can select a meal from the established IDOC menu. The last meal will be provided to the offender at approximately 1900 hours the day prior to the scheduled execution.

Hygiene Items

The offender shall receive limited hygiene supplies (bar soap, toothpaste and toothbrush) and a towel and washcloth. These items will be exchanged on a daily basis.

The offender will be issued a clean set of clothing and bedding daily.

The offender will be provided (issued by staff) a safety razor to shave. Staff will immediately remove the razor from the offender's possession after he has finished shaving.

Access to the Offender

Access will be limited to the following:

- Law enforcement personnel investigating matters within the scope of their duties;
- The offender's attorney of record;
- Agents of the offender's attorney of record; and
- Attending physician/healthcare staff.

Access is defined as those activities that are necessary for official business. Law enforcement personnel, attorneys of record and their agents, and attending physician/healthcare staff are considered as official business and such access will be a contact visit.

Visitation

Visitation will be limited to the following:

- Spiritual adviser of the offender's choosing;
- Approved visitors;
- Members of the offender's immediate family, specifically the offender's:

- Mother or father, including step parents;
- Brothers or sisters of whole or half (½) blood, by adoption or stepbrothers or stepsisters;
- Lawful spouse verified by marriage license or other operation of law;
- Natural children, adopted children, or stepchildren;
- Grandparents of blood relation; and
- Grandchildren of blood relation.

All visitations must be in accordance with SOP 604.02.01.001, *Visiting*, and the guidelines established herein this SOP.

The offender's attorney of record and his agents will be provided contact visits. Such contact visits will be under staff visual observation, but so that the staff members cannot hear the conversation.

Note: For the purposes of this section, 'agents of the attorney of record' means employees of the attorneys of record including investigators, paralegals, legal interns and mitigation specialists but does not include retained experts or other independent contractors of the attorneys of record.

Immediate family and approved visitors must be approved in accordance with SOP 604.02.01.001, *Visiting*. Normally, minor children will not be allowed to visit and any exception must be approved by the deputy chief of the Prisons Bureau.

Approved visitors and immediate family may be allowed non-contact visits until seven (7) days before the execution date. Any exception to this rule must be approved by the deputy chief of the Prisons Bureau. Between serving the death warrant until seven (7) days before the execution, all visits with immediate family, approved visitors, and spiritual advisor will be non-contact.

In the seven (7) days immediately before the execution, if there is no stay of execution, visits with approved visitors who are not immediate family will cease. This time frame can be extended by the IMSI warden in collaboration with the deputy chief of the Prisons Bureau.

In the seven (7) days immediately before the execution, approved immediate family and spiritual advisor may be granted contact visits with the offender. (The offender's attorney of record will continue to have contact visiting during the seven [7] days immediately before the execution.)

The IMSI warden shall establish the frequency and duration in which visits occur and shall have the authority to suspend or deny visits when public safety or the safe, secure and orderly operation of the prison could be compromised.

Note: If there is a stay of execution, the IMSI warden will determine housing in accordance with SOP 319.02.01.001, *Restrictive Housing*, and visiting in accordance with SOP 604.02.01.001, *Visiting*.

Spiritual Advisor

The offender can request a spiritual advisor of his choosing. The spiritual advisor must be approved by the facility warden before visitation can occur. The spiritual advisor cannot be an IDOC staff member or the staff member of a contract facility. The spiritual

advisor will normally be an approved religious volunteer or member of the clergy. The spiritual advisor may be a contract provider for volunteer and religious activities in accordance with the requirement of that contract.

Healthcare

The IMSI warden shall request that the facility health authority review the condemned offender's healthcare record and identify any prescribed medication(s) or health care issues.

Facility healthcare services staff shall dispense all medications in unit doses and when available, in liquid form. No medication including over-the-counter medications shall be provided or maintained by the offender as keep-on-person.

The facility health authority shall provide the offender an opportunity to complete an Idaho Physician Orders for Scope of Treatment form.

Facility healthcare services staff will take necessary steps to maintain the offender's health prior to the execution and shall respond appropriately to health care issues and emergencies including suicide attempts and will take reasonable steps to revive the offender in medical distress at all times prior to the execution, unless the offender has a "do not resuscitate" request on file.

Facility healthcare services staff will monitor the offender daily for significant changes in the offender's medical or mental health and if the offender's health changes, facility healthcare services staff must report the offender's condition immediately to the IMSI warden.

Note: All access, visits, etc. will be documented in the constant observation log.

16. Thirty (30) to 21 Days Prior to the Execution

After serving the death warrant until 21 days prior to the execution, the following activities will occur. If any of the activities identified in this section cannot be achieved within this timeframe, the responsible party will notify the director of the IDOC, chief of the Operations Division, and the deputy chief of the Prisons Bureau.

Unless a specific timeline is identified, the tasks outlined in this section are not required to be completed in a specific order.

Director of the IDOC

- Continue communication with the Idaho Board of Correction;
- Continue communication with the Idaho governor (or his representative);
- Communicate as needed with the executive director of the Idaho Commission of Pardons and Parole; and
- Meet with the chief of the Operations Division, the deputy chief of the Prisons Bureau, and other members of the IDOC Leadership Team as needed.

Chief of the Operations Division

- Continue to provide briefings to IDOC staff;
- Send appendix C, *State Witness Notification and Agreement,* to the following and establish a deadline for the return of all forms:
    - The Ada County Coroner;

- ♦ The prosecuting attorney from the county of conviction;
- ♦ The sheriff from the county of conviction;
- ♦ The sentencing judge;
- ♦ The Idaho governor;
- ♦ The Idaho attorney general;
- ♦ The Idaho Board of Correction; and

- Monitor planning related to the scheduled execution.

Administrative Team

- Finalize arrangements with the Ada County coroner's office for the disposition of the body, security for the Ada County medical examiner's vehicle, and the custodial transfer of the body;
- Evaluate the candidates to serve on the escort and medical teams (see section 5), approve or deny each candidate, review the current specialty team rosters, and make replacements if needed;
- Ensure the assigned Medical Team members physically evaluate the offender to predetermine appropriate venous access locations;
- Ensure that all of the equipment such as electrical, audio, plumbing, HVAC units in the execution chamber are tested periodically to ensure they are in working order;
- Contact licensed physician to ensure he is available to perform duties as identified herein;
- Assign a staff member to test and perform maintenance as needed to all utilities (HVAC units, plumbing, electrical etc.) in the Execution Unit and establish a schedule for testing and reporting unit status during the time leading up to the execution date;
- Ensure the Medical Team room and execution chamber are equipped with one synchronized clock each. The synchronized clocks will be the official time keeping devices for the execution procedures;
- Ensure that execution chemicals and other medical supplies have been purchased and/or that sources have been established. When chemicals are received, immediately start a chain of custody document, secure the chemicals, and monitor to ensure compliance with manufacturer specifications. Access to the chemicals must be limited the members of the Administrative Team;
- If chemicals are on site, check the expiration dates on each item to ensure they will not expire before the execution date. If any item will expire before the execution date, immediately dispose of it appropriately;
- Consult with Medical Team members regarding the equipment for the procedure and ensure all equipment necessary to properly conduct the procedure is on site, immediately available for use and functioning properly;
- Ensure that all backup medical equipment, including a backup electrocardiograph (EKG) machine and instruments, crash cart, and defibrillator are on site, immediately available for use and functioning properly;

- Check applicable sterilization dates on medical supplies to ensure they are useable on the execution date;
- Ensure that the Escort Team, Medical Team, and command staff are conducting training (see section 5) in preparation for the execution; and
- Ensure that communication devices with inter-operability capability and restricted frequencies are available and will be on site before the execution date.

Deputy Chief of the Prisons Bureau

- Notify facility heads at all IDOC correctional facilities of the pending execution and provide instruction to the facility heads regarding staff briefings and expectations;
- Request that all IDOC facility heads develop incident action plans (IAP) for their respective facilities for facility management during the period leading up to and following the execution. The IAPs must be submitted to the deputy chief of the Prisons Bureau at least 21 days before the scheduled execution date;
- Contact the IDOC contract monitor and Correctional Alternative Placement Program (CAPP) and Idaho Correctional Center (ICC) facility heads to discuss their respective IAPs for facility management during the period leading up to and following the execution. The CAPP and ICC facilities must submit their IAPs to the IDOC 21 days before the execution date;
- Identify and assign team leaders and members, and activate the teams;
- Establish the four (4) security areas of the IDOC's south Boise complex and provide that information to facility heads and other staff as needed see section 11;
- Confirm with the IMSI warden that the training schedule has been activated ensuring that staff members participating in the execution have received adequate training, written instruction and practice, and that all training has been documented;
- Discuss preparations at IMSI with the IMSI warden;
- Confirm with all IDOC south Boise complex facility wardens that the training schedule has been activated ensuring that staff members participating in the execution have received adequate training, written instruction and practice, and that all training has been documented;
- Contact the CISM team;
- Notify the IDOC victim services coordinator of the court's issuance of a death warrant;
- If warranted, request through the appropriate authority that the Federal Aviation Administration (FAA) place a 24 hour temporary flight restriction (TFR) surrounding the IDOC's south Boise complex consisting of the following:
    - **Radius:** Three (3) nautical miles
    - **Altitude:** 500 feet from the surface
- Ensure state of Idaho and local law enforcement is periodically briefed and adequately prepared for the execution;

- Establish the agenda, schedule meetings, and lead the discussion with state of Idaho and local law enforcement and applicable IDOC staff regarding community safety, traffic control, and crowd control;
- Ensure that personnel from law enforcement agencies who have not participated in training sessions or who have not previously been involved in the execution process are briefed and their responsibilities explained;
- Invite state of Idaho and local law enforcement liaisons to participate in periodic briefings about the execution and its impact on the community including access restrictions, crowd control, additional security precautions that may be warranted, and other pertinent information. Collaborate with each agency to determine each agency's role and each jurisdiction's responsibilities;
- Schedule tabletop and simulation exercises with state of Idaho and local law enforcement identifying areas and activities for improvement and incorporate the findings into future simulations; and
- If it is determined that any IDOC staff member, contractor, volunteer, or other offender under IDOC jurisdiction is a family member, has a legal or other significant relationship with the condemned offender, the condemned offenders' family, the victim, or the victim's family, contact the applicable manager to discuss potential issues and ensure that appropriate management and/or support plans are developed.

IDOC PIO

- Issue a news release announcing the date and time of the execution;
- Send appendix B, *Media Notification and Agreement,* to media liaisons and establish a deadline for the return of all forms; and
- Facilitate up to one telephone interview with the offender per day with Idaho media from the day the death warrant is issued until the day before the execution (excluding weekends and state of Idaho and federal holidays). The offender and his attorney of record may select the order in which the interviews occur. The offender may refuse any or all media requests for interviews.

IDOC Victim Services Coordinator

Determine if the IDOC has recorded victims who have requested notification. If such victims exist, obtain contact information for each victim (minor children will not be allowed to witness an execution). The victim service coordinator will provide the contact information to the chief of the Operations Division. If possible, the chief of the Operations Division will first make contact with the victim's family by telephone.

- Send each victim who has identified themselves to the IDOC appendix D, *Victim's Family Witness Notification and Agreement* using certified mail with a return receipt;
- The requests to be present at the execution must be received at least 14 days before the execution; and
- Notify the IDOC victim services coordinator in the county in which the crime originated.

IMSI Warden

- Begin an execution log to be kept in the IMSI warden's office. This log will provide a comprehensive and chronological history. The IMSI warden will document every aspect of the execution proceeding, including tasks and/or actions assigned to, or completed by an Administrative Team member, until the offender has been executed or has received a stay of execution order. When the process has been completed either by execution or stay, the log will be placed in the offender's central file;
- Ensure that the facility health authority provides the offender an opportunity to complete an Idaho Physician Order for Scope of Treatment form;
- Ensure that the facility healthcare service is providing medications in unit doses and when available, in liquid form; that no medication, including over-the-counter medication, is being provided to the offender as keep-on-person; and that any medication the offender has requested be discontinued is no longer being provided;
- Discuss with the offender the options available for the disposition of his body after it has been released by the Ada County coroner. Advise the offender that he cannot donate his body for organ donation;
- Inform the offender that he can request a spiritual advisor and ask if the offender would like to request a spiritual advisor now;
- Inform the offender that a total of two (2) adult family members or friends (approved visitors), his attorney of record, and a spiritual advisor may be present at the execution. The offender can decline any of these individuals who want to witness the execution. No minors (see section 16) or other offenders can witness the execution;
- Outline how conditions of confinement will be modified over the next 30 days and briefly describe the relevant aspects of the execution process;
- Offer the offender the opportunity to contact his attorney of record by phone and to speak with a facility volunteer and religion coordinator (VRC) or spiritual advisor;
- Advise the offender he may request a last meal. The meal can be his choice from the IDOC standard food service menu;
- Provide the offender with a copy of appendix E, *Summary of Procedures.* (Attach the signed original to the IMSI warden's execution log.);
- Ensure that the offender's file is reviewed thoroughly to determine if there are any IDOC staff members, contractors, or volunteers who are family members, have a legal relationship, or any other significant relationship with the condemned offender, the victim, or victim's family; or if there are any offenders under IDOC jurisdiction who are family members, have a legal relationship, or any other significant relationship with the condemned offender, the victim, or victim's family. If any such persons are identified, relay that information to the deputy chief of the Prisons Bureau;
- Notify the commissary provider of the restrictions placed on the offender's commissary purchases;
- Contact the condemned offender's family by telephone to inform them of the scheduled execution date, the name and contact information of the warden's liaison, and any other related issues;

- Within two (2) business days of receiving a death warrant, send appendix F, *Offender's Friend/Family Witness Notification and Agreement,* to the offender's family by certified mail citing the date of execution and informing them of their liaison person. The notification will inform them that if they choose to receive the remains that they are responsible for making arrangements for the offender's burial, or the state of Idaho will have the remains cremated;
- Inform the offender and the offender's family that disposition of remains information must be received seven (7) days before the execution date and that if the offender does not provide information for disposal of his remains, his remains will be disposed of in accordance with directive 312.02.01.001, *Death of an Inmate*. (Give the offender a copy of directive 312.02.01.001.);
- Request that the IDOC health authority develop a medical emergency response plan that provides adequate emergency response in the Execution Unit; and
- Ensure that healthcare services staff obtain the offender's current weight and enter that information into the IMSI warden's execution log.

IMSI Warden's Offender Liaison

Meet with the condemned offender at least once each working day and forward all of the offender's questions and concerns directly to the IMSI warden.

IMSI Deputy Warden (Acting as Facility Head)

- Establish a management plan including staffing, meals, and contingency plans to ensure the safe and orderly operation of the facility during the time leading up to the execution;
- Brief the deputy chief of the Prisons Bureau on the management plan; and
- Monitor IMSI activities and brief the deputy chief of the Prisons Bureau if any concerns or problems arise.

17. Twenty-one (21) to Seven (7) Days Prior to the Execution

Twenty-one (21) to seven (7) days prior to the execution, the following activities will occur. If any of the activities identified in this section cannot be achieved within this timeframe, the responsible party will notify the director of the IDOC, chief of the Operations Division, and the deputy chief of the Prisons Bureau.

Unless a specific timeline is identified, the tasks outlined in this section are not required to be completed in a specific order.

Chief of the Operations Division

- Continue to provide briefings to IDOC staff;
- Compile a list of state of Idaho and media witnesses including pool reporters, and submit the list and all completed state witness notification and agreements (appendix C) and media notification and agreements (appendix B) to the deputy chief of the Prisons Bureau; and
- Monitor planning related to the scheduled execution.

Administrative Team

- Ensure that the Escort Team, Medical Team, and command staff are conducting training (see section 5) in preparation of the execution;

- Contact the Ada County coroner's office and determine the protocol regarding the transfer of the offender's body to the coroner's possession following the execution and forward that information to the IMSI warden; and
- Take steps to resolve outstanding equipment and inventory issues.

Deputy Chief of the Prisons Bureau

- Brief director of the IDOC and chief of the Operations Division;
- Continue to conduct tabletop and live exercises with the previously identified teams;
- Review IDOC, CAPP, and ICC facility IAPs, and continue discussion and preparation with facility heads;
- Contact the CISM team leader and ensure the team is making appropriate preparations; and
- Convene a meeting with state of Idaho and local law enforcement agencies to discuss any changes or modifications to crowd control, traffic control, and community safety.

IDOC PIO

- Address media-specific inquiries;
- Forward all completed media notification and agreements (appendix B) to the deputy chief of the Prisons Bureau (or designee) for a criminal background check;
- Arrange telephone interviews with the offender up to one day prior to the execution; and
- Notify members of the media regarding the status of their witness applications.

IMSI Warden

- Visit with the condemned offender as needed;
- Retrieve the completed *Offender's Friend/Family Witness Notification and Agreement* (appendix F) and answer any questions the offender may have;
- Ensure the offender has provided directions for the handling of his remains. (If the offender provides no information or the information is insufficient or incorrect, the deceased shall be disposed of in accordance with directive 312.02.01.001, *Death of an Inmate*.);
- Ensure that the offender has had the opportunity to complete an Idaho Physician Orders for Scope of Treatment form;
- Ensure the offender has provided directions for the disposition of his property and offender trust fund; and
- Meet with the facility health authority and IDOC health authority to review plans for coverage and emergency response before and following the scheduled execution.

IMSI Warden's Offender Liaison

- Continue daily contact with the offender;
- Stay in contact with the condemned offender's family; and
- Update the IMSI warden on any issues, requests, or questions.

IMSI Deputy Warden (Acting as Facility Head)

- Ensure that the necessary action steps have been taken regarding the IMSI management plan including staffing, meals, and contingency plans to ensure the safe and orderly operation of the facility during the time leading up to the execution;
- Brief the deputy chief of the Prisons Bureau on the status of the management plan; and
- Continue to monitor IMSI activities and brief the deputy chief of the Prisons Bureau if any concerns or problems arise.

18. Seven (7) to Two (2) Days Prior to the Execution

Seven (7) to two (2) days prior to the execution, the following activities will occur. If any of the activities identified in this section cannot be achieved within this timeframe, the responsible party will notify the director of the IDOC, chief of the Operations Division, and the deputy chief of the Prisons Bureau.

Unless a specific timeline is identified, the tasks outlined in this section are not required to be completed in a specific order.

Chief of the Operations Division

- Continue to provide briefings to IDOC staff;
- Gather the names of those planning to be present in the Execution Unit; and
- Monitor planning related to the scheduled execution.

Administrative Team

- Ensure that the Escort Team, Medical Team, and command staff have completed adequate training sessions (see section 5);
- Confirm preventive maintenance of the execution chamber is current;
- Test equipment, lighting, audio, HVAC units, etc. in the execution chamber;
- Ensure that audio/video equipment is ready and operational if needed;
- Confirm that the inventory of equipment, necessary supplies, and backup materials are on-site;
- Recheck the medical supplies and chemicals to ensure that each item is ready, expiration dates have not been exceeded, items are properly packaged, and if applicable sterilized; and
- At least three (3) days before the scheduled execution date, obtain technical assistance for the purpose of reviewing the lethal substances, the amounts, the methods of delivery and injection, and the offender's physical and historical characteristics to evaluate compliance with this SOP. The individual(s) conducting the technical review will observe the Medical Team place IV catheters and establish an IV drip line in a live body. The individual(s) conducting the technical review will meet with the Administrative Team to review his findings. The director of the IDOC will make the final determination regarding compliance with this SOP.

Deputy Chief of the Prisons Bureau

- Brief director of the IDOC and chief of the Operations Division;

- Stand up the ICS center;
- Continue tabletop and live exercises;
- Confirm staffing levels and necessary vehicles for regular operations and the execution are appropriate and ready;
- Ensure local law enforcement agencies are fully briefed;
- Gather all information regarding media, potential media witnesses, and those who will be present at the execution; and
- In conjunction with the IDOC Leadership Team, ISCI, and IMSI wardens, finalize the media plan, potential media witnesses, and those who will be present at the execution.

IDOC PIO

- Conduct the random drawing, approximately seven (7) days prior to the execution, for three (3) media seats, to include alternate representatives should the primary representative withdraw prior to the execution;
- Complete a list of the media representatives that want to be on or near the IDOC's south Boise complex and/or be in the media center, but not present at the execution;
- Forward the lists of media agencies, media staff members, and potential media witnesses to the director of the IDOC, chief of the Operations Division, deputy chief of the Prisons Bureau, and IMSI warden; and
- Conduct a preliminary briefing with potential media witnesses and media representatives serving as pool reporters.

Medical Team Leader

- Ensure serviceability of all medical equipment including EKG machines (to include instruments) and/or defibrillator, and the availability of graph paper; and
- Ensure heart monitor lead lines are sufficient in length.

IMSI Warden

- Meet with the condemned offender as needed; and
- Address any unresolved questions or issues.

IMSI Warden's Offender Liaison

- Continue daily contact with the offender;
- Have the offender complete a withdrawal slip for any remaining funds in his trust account and designate to whom the funds should be sent;
- Stay in contact with the condemned's family; and
- Update the IMSI warden on any issues, requests, or questions.

IMSI Deputy Warden (Acting as Facility Head)

- Review staffing to ensure there is adequate coverage near the execution date;
- Review use of force inventories, less than lethal weapons and munitions to ensure that adequate supplies are in place if needed for emergency response;
- Brief shift commanders, unit sergeants, and case managers;

- Ensure that proper tool and key control procedures are being followed;
- Ensure that transportation vehicles that are not assigned to the execution process are available if needed for IMSI operational needs;
- Meet with maintenance staff to review any problems or concerns with infrastructure;
- Meet with the facility health authority to ensure that an adequate emergency response plan is in place for the time frame near the execution; and
- Brief the IMSI warden and the deputy chief of the Prisons Bureau regarding the emergency plan preparedness and any issues or concerns.

19. Two (2) Days Prior to the Execution

Two (2) days prior to the execution, the following activities will occur. If any of the activities identified in this section cannot be achieved within this timeframe, the responsible party will notify the director of the IDOC, chief of the Operations Division, and the deputy chief of the Prisons Bureau.

Unless a specific timeline is identified, the tasks outlined in this section are not required to be completed in a specific order.

Chief of the Operations Division

- Continue to provide briefings to IDOC staff; and
- Monitor planning related to the scheduled execution.

Administrative Team

- Conduct at least two (2) rehearsal sessions with the Escort Team, Medical Team, and command staff (see section 5);
- Confirm that escort and medical teams, a licensed physician (see section 6), emergency medical personnel, and the Ada County coroner are scheduled and will be on-site at the established time;
- Restrict access to the execution chamber to those with expressly assigned duties;
- Ready the execution chamber for the offender; and
- Verify execution inventory and equipment checks are completed and open issues resolved.

Deputy Chief of the Prisons Bureau

- Schedule and conduct IDOC south Boise complex simulation exercises, as necessary and modify practices if warranted;
- Ensure that contracted services have planned their activities to coincide with the incident action plans for modified operational status related to the scheduled execution;
- Contact IDOC, CAPP, and ICC facility heads to monitor their preparation and status;
- and
- Confirm adequate staffing, equipment, and materials are in place for regular operations and the execution.

20. Twenty-Four (24) to 12 Hours Prior To the Execution

Twenty-four (24) to 12 hours prior to the execution, the following activities will occur. If any of the activities identified in this section cannot be achieved within this timeframe, the responsible party will notify the director of the IDOC, chief of the Operations Division, and the deputy chief of the Prisons Bureau.

Unless a specific timeline is identified, the tasks outlined in this section are not required to be completed in a specific order.

Administrative Team

- Ensure the final preparation of Execution Unit is complete. Each room receives a final evaluation specific to its functions including security, climate control, lighting, sound and sanitation;
- Ensure that video monitoring and intercom systems are functioning properly;
- Ensure the Medical Team room and execution chamber clocks are accurately set and working;
- Ensure that appropriate restraints are ready;
- Ensure that communication devices are ready;
- Ensure that the Medical Team leader checks the EKG machine instruments to confirm they are functioning properly;
- Ensure that the crash cart and defibrillator are in place and functioning properly; and
- Check medical supply and chemical inventory.

Deputy Chief of the Prisons Bureau

- Activate the following teams:
    - Command
    - CERT
    - Maintenance
    - CISM
    - Traffic Control Team
- Ensure CISM is activated state-wide;
- Modify operation of the IDOC's south Boise complex;
- Contact IDOC, CAPP, and ICC facility heads to ensure they are prepared to activate their IAPs for modified operation; and
- Establish the ICS command center.

IDOC PIO

Establish the media center.

IDOC Health Authority

Conduct a review of the offender's healthcare.

IMSI Warden

- Ensure that all the offender's remaining property, except one religious item, is removed and inventoried, and that the offender has completed a disposition sheet for his property;
- Ensure that witness areas are in order;
- Ensure that transportation vehicles are ready; and
- Ensure that food service is prepared to serve offender his last meal request.

IMSI Deputy Warden (Acting as Facility Head)

- Activate the IMSI management plan;

  Note: the plan can be activated earlier if activities, behaviors, or other issues indicate it prudent to do so.

- Ensure that detailed staff briefings are provided; and
- Ensure that CISM is on-site at IMSI.

21. Twelve (12) Hours Prior To the Execution

Twelve (12) hours prior to the execution, the following activities will occur. If any of the activities identified in this section cannot be achieved within this timeframe, the responsible party will notify the director of the IDOC, chief of the Operations Division, and the Administrative Team.

Unless a specific timeline is identified, the tasks outlined in this section are not required to be completed in a specific order.

Deputy Chief of the Prisons Bureau

Contact IDOC, CAPP, and ICC facility heads to ensure they have activated their incident action plans for modified operation.

Restricting Access to IDOC Property

During the final twelve hours prior to the execution, access to the IDOC's south Boise complex is limited. Restrictions shall remain in effect until normal operations resume after the execution or a stay of execution is issued.

Access is limited to the following:

- On-duty personnel;
- On-duty contract personnel;
- Volunteers deemed necessary by the facility wardens;
- Approved delivery vehicles;
- Approved media;
- Approved execution witnesses;
- Law enforcement personnel on business-related matters; and
- Others as approved by the ICS operations chief.

Population Management

- The IDOC's south Boise complex and CAPP and ICC facilities shall go on secure status as defined and ordered by the ICS operations chief at conclusion of a formal count and not less than nine (9) hours prior to the scheduled execution; and
- After the conclusion of the execution or stay of execution, all IDOC and contract prison facilities shall return to regular operations at the direction of the ICS operations chief.

Condemned Offender Activities

- Ensure the offender receives the last meal by approximately 1900 hours prior to the scheduled execution. (All eating utensils and remaining food and beverage shall be removed upon completion of the meal.);
- Phone calls are concluded by 2100 hours. (Telephone calls shall be terminated at 2100 hours the day prior to the execution, excluding calls with the offender's attorney of record and others approved by the IMSI warden.);
- Visitation shall be terminated at 2100 hours the night prior to the execution, excluding visits from the offender's attorney of record and others as approved by the IMSI warden;
- No later than 2300 hours the night before the execution, the facility healthcare services staff will offer the offender a mild sedative;
- No later than five (5) hours prior to the execution, the offender shall be offered a light snack. (All eating utensils and remaining food, to include any remaining consumable commissary, shall be removed upon completion of the meal.); and
- No later than four (4) hours prior to the execution, the facility healthcare services staff will offer the offender another mild sedative.

22. Final Preparations

During the final preparations, the IMSI warden will be unavailable to address issues not directly related to the execution process. All other inquiries shall be directed to a member of the Administrative Team.

Witness Briefing

Prior to entering the execution witness area, the chief of the Operations Division will provide briefings of the execution process to those who will be present at the execution. The victim's family and offender's family will receive separate briefings.

Procedures to Carry out the Execution

The procedures for carrying out the execution are found in appendix A, *Execution Chemicals Preparation and Administration*.

Note: Total anonymity of personnel in the Medical Team room must be maintained. At no time will the personnel be addressed by name or asked anything that would require an oral response.

23. Pronouncement of Death

Idaho Code, section 19-2716, requires that the death of a condemned offender be pronounced by the Ada County coroner (or deputy coroner).

The Ada County coroner (or deputy coroner) will be staged in or near the Execution Unit during the execution process. When the execution process has been completed, the coroner will enter the execution chamber, examine the offender, and pronounce the offender's death to the IMSI warden. The IMSI warden will announce that the sentence of death has been carried out as ordered by the court and the execution has been completed.

24. Return of Service on the Death Warrant

After the execution, the IMSI warden must complete a return of service of the death warrant, showing the date, time, mode, and manner in which it was executed. The original death warrant will be returned to the sentencing court. A copy of the death warrant with the return of service information will be filed in the offender's central file. A copy of the original death warrant shall be forwarded to the DAG office.

25. Following the Execution

Administrative Team

- Ensure that the assigned members of the Medical Team will return all unused materials to the safe in the execution chamber;
- Gather all documents, logs, recordings, sequence of chemical forms (see appendixes A1 thru A4), EKG machine tape, list of identifiers, etc. and deliver them to the DAG who represents the IDOC for storage;
- Upon completion or long-term stay, inventory the items, complete the chain of custody, and secure the items in the administration safe;
- Retrieve all secured materials; and
- Destroy all used materials in accordance with safe disposal practices and document the disposition of each drug on the inventory sheet.

Deputy Chief of the Prisons Bureau

Contact all facility heads and determine each facilities' status and any issues that were experienced related to the execution process.

Execution Chamber and Condemned Isolation Cell Cleaning

Under the supervision of a person designated by the designated Administrative Team member, the execution chamber and condemned isolation cell shall be cleaned and secured. Facility staff trained in infectious diseases preventive practices will utilize appropriate precautions in cleaning the execution chamber.

Resuming Normal Operations

ICS command center shall determine when the prisons resume normal operations after receiving assessments from all facility wardens.

IDOC staff shall be deactivated at the direction of ICS command center.

Debriefing

Within 48 hours, the deputy chief of the Prisons Bureau and IMSI warden will debrief the director of the IDOC and chief of the Operations Division and other Leadership Team staff as the director deems appropriate regarding the process and if applicable make recommendations to revise the standard operation procedure or other related processes or documents.

REFERENCES

Appendix A, *Execution Chemicals Preparation and Administration*

Appendix A1, *Sequence of Chemical Form- Method 1*

Appendix A2, *Sequence of Chemical Form- Method 2*

Appendix A3, *Sequence of Chemical Form- Method 3*

Appendix A4, *Sequence of Chemical Form- Method 4*

Appendix B, *Media Notification and Agreement*

- Appendix B (Fill-in version)

Appendix C, *State Witness Notification and Agreement*

- Appendix C (Fill-in version)

Appendix D, *Victim's Family Witness Notification and Agreement*

- Appendix D (Fill-in version)

Appendix E, *Summary of Procedures*

- Appendix E (Fill-in version)

Appendix F, *Offender's Friend/Family Witness Notification and Agreement*

- Appendix F (Fill-in version)

Directive 312.02.01.001, *Death of an Inmate*

Idaho Code, Title 19, Chapter 27, Section 19-2705, *Death Sentence or Death Warrant and Confinement There under – Access to Condemned Person*

Idaho Code, Title 19, Chapter 27, Section 19-2713, *Proceedings When Female Supposed to be Pregnant*

Idaho Code, Title 19, Chapter 27, Section 19-2714, *Findings in Case of Pregnancy*

Idaho Code, Title 19, Chapter 27, Section 19-2715, *Ministerial Actions Relating to Stays of Execution, Resetting Execution Dates, and Order of Execution of Judgment of Death*

Idaho Code, Title 19, Chapter 27, Section 19-2716, *Infliction of Death Penalty*

Idaho Code, Title 19, Chapter 27, Section 19-2718, *Return of Death Warrant*

Idaho Code, Title 60, Chapter 1, Section 60-106, *Qualifications of Newspapers Printing Legal Notices*

Standard Operating Procedure 205.07.01.001, *Corrective and Disciplinary Action*

Standard Operating Procedure 319.02.01.001, *Restrictive Housing*

Standard Operating Procedure 320.02.01.001, *Property: State-issued and Offender Personal Property*

Standard Operating Procedure 604.02.01.001, *Visiting*

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IDAHO DEPARTMENT OF CORRECTION
Execution Chemicals Preparation and Administration

A. Modifications to Protocols and Procedures

There shall be no deviation from the procedures, protocols, and chemicals in this procedure without prior consent from the director of the IDOC. A member of the Administrative Team shall monitor and ensure compliance with protocols and procedures related to the preparation and administration of chemicals.

B. Preparation of Chemicals

At the appropriate time, the IMSI warden shall transfer custody of the chemicals to the Medical Team leader so the Medical Team can complete chemical and syringe preparation.

The Medical Team leader will supervise the syringe preparation, assigning a Medical Team member to prepare each chemical and the corresponding syringe. The assigned Medical Team members shall prepare their designated chemical and syringes for two (2) complete sets of chemicals to be used in the implementation of the death sentence. A third set of syringes shall be available and ready for use as backup.

The assigned Medical Team member shall be responsible for preparing and labeling the assigned sterile syringes in a distinctive manner identifying the specific chemical contained in each syringe by (a) assigned number, (b) chemical name, (c) chemical amount and (d) the designated color, as set forth in the chemical chart below. This information shall be preprinted on a label, with two (2) labels affixed to each syringe to ensure a label remains visible.

There shall be sufficient lighting and physical space in the Medical Team room and the execution chamber to enable team members to function properly and to observe the offender. The offender will be positioned to enable the Medical Team leader to view the offender, the offender's arms (or other designated intravenous [IV] location) and face with the aid of a color camera and a color monitor.

After the Medical Team prepares all syringes with the proper chemicals and labels as provided in the applicable chemical chart, the Medical Team leader shall place three (3) complete sets of the prepared and labeled syringes in the color-coded and labeled syringe trays in the order in which the chemicals are to be administered. The syringes will be placed in the color-coded and labeled syringe trays in a manner to ensure there is no crowding, with each syringe resting in its corresponding place in the shadow box which is labeled with the name of the chemical, color, chemical amount and the designated syringe number.

The syringes shall be placed in such a manner to ensure the syringe labels are clearly visible. Prior to placing the syringes in the color-coded and labeled syringe trays, the flow shall be checked by the Medical team leader running heparin/saline solution through the line to confirm there is no obstruction.

After all syringes are prepared and placed in color-coded and labeled syringe trays in proper order, the Medical Team leader shall confirm that all syringes are properly labeled and placed in the color-coded and labeled syringe trays in the order in which the chemicals are to be administered as designated by the applicable chemical chart. Each chemical shall be administered in the predetermined order in which the syringes are placed in the tray.

C. Approved Chemicals

The IDOC has four (4) options for lethal injection methods. Which option is used is dependent upon the availability of chemicals.

The director of the IDOC has approved the following lethal injection chemicals and methods as described in Chemical Chart 1, Chemical Chart 2, Chemical Chart 3, and Chemical Chart 4:

Method 1

CHEMICAL CHART 1	
Primary SET A	
Syringe No.	Label
1A (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
2A (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
3A (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
4A (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
5A (flush)	60mL Heparin/Saline, **BLACK**
6A (complete 6-7)	60mg Pancuronium Bromide, **BLUE**
7A (complete 6-7)	60mg Pancuronium Bromide, **BLUE**
8A (flush)	60mL Heparin/Saline, **BLACK**
9A (complete 9-10)	120mEq Potassium Chloride, **RED**
10A (complete 9-10)	120mEq Potassium Chloride, **RED**
11A (flush)	60mL Heparin/Saline, **BLACK**

CHEMICAL CHART 1		CHEMICAL CHART 1	
Backup Set B		**Backup Set C**	
Syringe No.	Label	Syringe No.	Label
1B (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**	1C (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
2B (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**	2C (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
3B (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**	3C (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
4B (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**	4C (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
5B (flush)	60mL Heparin/Saline, **BLACK**	5C (flush)	60mL Heparin/Saline, **BLACK**
6B (complete 6-7)	60mg Pancuronium Bromide, **BLUE**	6C (complete 6-7)	60mg Pancuronium Bromide, **BLUE**
7B (complete 6-7)	60mg Pancuronium Bromide, **BLUE**	7C (complete 6-7)	60mg Pancuronium Bromide, **BLUE**
8B (flush)	60mL Heparin/Saline, **BLACK**	8C (flush)	60mL Heparin/Saline, **BLACK**
9B (complete 9-10)	120mEq Potassium Chloride, **RED**	9C (complete 9-10)	120mEq Potassium Chloride, **RED**
10B (complete 9-10	120mEq Potassium Chloride, **RED**	10C (complete 9-10)	120mEq Potassium Chloride, **RED**
11B (flush)	60mL Heparin/Saline, **BLACK**	11C (flush)	60mL Heparin/Saline, **BLACK**

Syringe Preparation (Method 1)

Syringes 1A, 2A, 3A, 4A, 1B, 2B, 3B, 4B, 1C, 2C, 3C and 4C each contain 1.25 gm/50ml. of sodium pentothal / 1 in 50 ml. of sterile water in four (4) 60 ml. syringes for a total dose of 5 grams of sodium pentothal in each set. Each syringe containing sodium pentothal shall have a **GREEN** label which contains the name of chemical, chemical amount, and the designated syringe number.

Syringes 5A, 8A, 11A, 5B, 8B, 11B, 5C, 8C and 11C each contain 60 ml. of a heparin/saline solution, at a concentration of 10 units of heparin per milliliter, and shall have a **BLACK** label which contains the name of the chemical, chemical amount, and the designated syringe number.

Syringes 6A, 7A, 6B, 7B, 6C and 7C each contain 60 mg of pancuronium bromide for a total of 120 mg of pancuronium bromide in each set. Each syringe containing pancuronium bromide shall have a **BLUE** label which contains the name of the chemical, chemical amount, and the designated syringe number.

Syringes 9A, 10A, 9B, 10B, 9C and 10C each contain 120 milliequivalents of potassium chloride for a total of 240 milliequivalents of potassium chloride in each set. Each syringe containing potassium chloride shall have a **RED** label which contains the name of the chemical, chemical amount, and the designated syringe number.

After the Medical Team prepares all syringes with the proper chemicals and labels as provided in the applicable chemical chart, the Medical Team leader shall ensure the IV setup is completed.

Method 2

CHEMICAL CHART 2	
Primary SET A	
Syringe No.	Label
1A (compete 1-2)	2.5 g Pentobarbital **GREEN**
2A (complete 1-2)	2.5 g Pentobarbital **GREEN**
3A (flush)	60mL Heparin/Saline, **BLACK**
4A (complete 4-5)	60mg Pancuronium Bromide, **BLUE**
5A (complete 4-5)	60mg Pancuronium Bromide, **BLUE**
6A (flush)	60mL Heparin/Saline, **BLACK**
7A (complete 7-8)	120mEq Potassium Chloride, **RED**
8A (complete 7-8)	120mEq Potassium Chloride, **RED**
9A (flush)	60mL Heparin/Saline, **BLACK**

CHEMICAL CHART 2		CHEMICAL CHART 2	
Backup Set B		**Backup Set C**	
Syringe No.	Label	Syringe No.	Label
1B (complete 1-2)	2.5 g Pentobarbital **GREEN**	1C (complete 1-2)	2.5 g Pentobarbital **GREEN**
2B (complete 1-2)	2.5 g Pentobarbital **GREEN**	2C (complete 1-2)	2.5 g Pentobarbital **GREEN**
3B (flush)	60mL Heparin/Saline, **BLACK**	3C (flush)	60mL Heparin/Saline, **BLACK**
4B (complete 4-5)	60mg Pancuronium Bromide, **BLUE**	4C (complete 4-5)	60mg Pancuronium Bromide, **BLUE**
5B (complete 4-5)	60mg Pancuronium Bromide, **BLUE**	5C (complete 4-5)	60mg Pancuronium Bromide, **BLUE**
6B (flush)	60mL Heparin/Saline, **BLACK**	6C (flush)	60mL Heparin/Saline, **BLACK**
7B (complete 7-8)	120mEq Potassium Chloride, **RED**	7C (complete 7-8)	120mEq Potassium Chloride, **RED**
8B (complete 7-8)	120mEq Potassium Chloride, **RED**	8C (complete 7-8)	120mEq Potassium Chloride, **RED**
9B (flush)	60mL Heparin/Saline, **BLACK**	9C (flush)	60mL Heparin/Saline, **BLACK**

Syringe Preparation (Method 2)

Syringes 1A, 2A, 1B, 2B, 1C, and 2C each contain 2.5 gm of pentobarbital for a total of 5 grams in each set. Each syringe containing pentobarbital shall have a **GREEN** label which contains the name of chemical, chemical amount and the designated syringe number.

Syringes 3A, 6A, 9A, 3B, 6B, 9B, 3C, 6C and 9C each contain 60 ml. of a heparin/saline solution, at a concentration of 10 units of heparin per milliliter, and shall have a **BLACK** label which contains the name of the chemical, chemical amount and the designated syringe number.

Syringes 4A, 5A, 4B, 5B, 4C and 5C each contain 60 mg of pancuronium bromide for a total of 120 mg of pancuronium bromide in each set. Each syringe containing pancuronium bromide shall have a **BLUE** label which contains the name of the chemical, chemical amount and the designated syringe number.

Syringes 7A, 8A, 7B, 8B, 7C and 8C each contain 120 milliequivalents of potassium chloride for a total of 240 milliequivalents of potassium chloride in each set. Each syringe containing potassium chloride shall have a **RED** label which contains the name of the chemical, chemical amount and the designated syringe number.

After the Medical Team prepares all syringes with the proper chemicals and labels as provided in the applicable chemical chart, the Medical Team leader shall ensure the IV setup is completed.

Method 3

CHEMICAL CHART 3	
Primary Set A	
Syringe No.	Label
1A (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
2A (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
3A (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
4A (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
5A (flush)	60mL Heparin/Saline, **BLACK**

CHEMICAL CHART 3		CHEMICAL CHART 3	
Backup Set B		**Backup Set C**	
Syringe No.	Label	Syringe No.	Label
1B (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**	1C (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
2B (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**	2C (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
3B (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**	3C (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
4B (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**	4C (complete 1-4)	1.25 g Sodium Pentothal, **GREEN**
5B (flush)	60mL Heparin/Saline, **BLACK**	5C (flush)	60mL Heparin/Saline, **BLACK**

Syringe Preparation (Method 3)

Syringes 1A, 2A, 3A, 4A, 1B, 2B, 3B, 4B, 1C, 2C, 3C, and 4C each contain 1.25 gm/50ml. of sodium pentothal / 1 in 50 ml. of sterile water in four (4) 60 ml. syringes for a total dose of 5 grams of sodium pentothal in each set. Each syringe containing sodium pentothal shall have a **GREEN** label which contains the name of chemical, chemical amount, and the designated syringe number.

Syringes 5A, 5B, and 5C each contain 60 ml. of a heparin/saline solution, at a concentration of 10 units of heparin per milliliter, and shall have a **BLACK** label which contains the name of the chemical, chemical amount, and the designated syringe number.

After the Medical Team prepares all syringes with the proper chemicals and labels as provided in the applicable chemical chart, the Medical Team leader shall ensure the IV setup is completed.

Method 4

CHEMICAL CHART 4	
Primary Set A	
Syringe No.	Label
1A (complete 1-2)	2.5 g Pentobarbital **GREEN**
2A (complete 1-2)	2.5 g Pentobarbital **GREEN**
3A (flush)	60mL Heparin/Saline, **BLACK**

CHEMICAL CHART 4	
Backup Set B	
Syringe No.	Label
1B (complete 1-2)	2.5 g Pentobarbital **GREEN**
2B (complete 1-2)	2.5 g Pentobarbital **GREEN**
3B (flush)	60mL Heparin/Saline, **BLACK**

CHEMICAL CHART 4	
Backup Set C	
Syringe No.	Label
1C (complete 1-2)	2.5 g Pentobarbital **GREEN**
2C (complete 1-2)	2.5 g Pentobarbital **GREEN**
3C (flush)	60mL Heparin/Saline, **BLACK**

Syringe Preparation (Method 4)

Syringes 1A, 2A 1B, 2B, 1C, and 2C each contain 2.5 gm of pentobarbital for a total of 5 grams in each set. Each syringe containing pentobarbital shall have a **GREEN** label which contains the name of chemical, chemical amount and the designated syringe number.

Syringes 3A, 3B, and 3C each contain 60 ml. of a heparin/saline solution, at a concentration of 10 units of heparin per milliliter, and shall have a **BLACK** label which contains the name of the chemical, chemical amount and the designated syringe number.

After the Medical Team prepares all syringes with the proper chemicals and labels as provided in the applicable chemical chart, the Medical Team leader shall ensure the IV setup is completed.

Note: The chemical amounts as set forth in chemical charts 1, 2, 3, and 4 are designated for the execution of persons weighing 500 pounds or less. The chemical amounts will be reviewed and may be revised as necessary for an offender exceeding this body weight.

Note: The quantities of chemicals prepared and administered may not be changed in any manner without prior approval of the director of the IDOC.

Note: The full dose contained in each syringe shall be administered to the offender and subsequently documented by the designated recorder. The quantities of the chemicals prepared and administered may not be changed in any manner without prior approval of the director of the IDOC after consultation with the Medical Team leader. If all electrical activity of the heart ceases prior to administering all of the chemicals, the Medical Team members shall continue to follow this protocol and administer all remaining chemicals in the order and amounts set forth in the applicable chemical chart.

IV Setup Procedure

After all syringes are prepared and placed in proper order, the Medical Team leader shall confirm that all syringes are properly labeled and placed in the order in which the chemicals are to be administered as designated by the chemical chart. Each chemical shall be administered in the predetermined order in which the syringes are placed in the color-coded and labeled syringe trays.

Note: All of the prepared chemicals shall be used or properly disposed of no later than 24 hours after the time designated for the execution to occur.

Note: Should a stay delay the execution beyond 24 hours of the scheduled execution, another primary set of syringes shall be prepared when the execution is rescheduled in accordance with the process set forth in this procedure.

D. Chemical Delivery Procedures

The Medical Team recorder is responsible for completing the applicable sequence of chemical form (see appendixes A1 thru A4). The recorder shall document on the form the amount of each chemical administered and confirm that it was administered in the order set forth in the chemical chart. Any deviation from the written procedure shall be noted and explained on the form.

E. Preparation, Movement, and Monitoring of Offender

Prior to moving the offender from the isolation cell to the execution table, the director of the IDOC will confer with the Idaho attorney general (or designee) and the Idaho governor (or designee) to confirm there is no legal impediment to proceeding with the lawful execution and there are no motions pending before a court which may stay further proceedings.

The offender will be offered a mild sedative based on the offender's need. The sedative shall be provided to the offender no later than four (4) hours prior to the execution, unless it is determined medically necessary.

At the designated time, the Escort Team will escort the offender to the execution room secured on the table by the prescribed means with the offender's arms positioned at an angle away from the offender's side.

After the offender has been secured to the execution table, the Escort Team leader will personally check the restraints which secure the offender to the table to ensure they are not so restrictive as to impede the offender's circulation, yet sufficient to prevent the offender from manipulating the catheters and IV lines.

Once the offender is secured, the Medical Team leader will attach the leads from the electrocardiograph (EKG) machine to the offender's chest and confirm that the EKG machine is functioning properly and that the proper graph paper is used. A backup EKG machine shall be on site and readily available if necessary.

A Medical Team member shall be assigned to monitor the EKG machine, and mark the EKG graph paper at the commencement and completion of the administration of each chemical. The assigned identifier of the Medical Team member monitoring the EKG machine shall be noted at each juncture.

Throughout the procedure, the Medical Team members shall continually monitor the offender's level of consciousness and EKG machine readings, maintaining constant observation of the offender using one or more of the following methods: direct observation, audio equipment, camera, and television monitor as well as any other medically approved method(s) deemed necessary by the Medical Team leader. The Medical Team leader shall be responsible for monitoring the offender's level of consciousness.

The assigned Medical Team members will insert the catheters and attach the IV lines.

The witnesses will be brought in to the applicable witness areas.

Once all witnesses are secured in the witness rooms, the IMSI warden shall read aloud a summary of the death warrant.

A microphone will be positioned to enable the Medical Team leader to hear any utterances or noises made by the offender throughout the procedure. The Medical Team leader will confirm the microphone is functioning properly, and that the offender can be heard in the Medical Team room.

The IMSI warden shall ensure there is a person present in the execution chamber throughout the execution who is able to communicate with the offender in the offender's primary language. This person will be positioned to clearly see, hear and speak to the offender throughout the execution. If the IMSI warden can communicate with the offender in the offender's primary language, he may serve in that capacity.

The IMSI warden will ask the offender if he wishes to make a last statement and provide an opportunity to do so.

The IMSI warden will offer the offender an eye covering.

F. Intravenous Lines

The assigned Medical Team members shall determine the best sites on the offender to insert a primary IV catheter and a backup IV catheter in two (2) separate locations in the peripheral veins utilizing appropriate medical procedures. The insertion sites in order of preference shall be: arms, hands, ankles and feet, as determined medically appropriate by the Medical Team leader. Both primary and backup IV lines will be placed unless in the opinion of the Medical Team leader it is not possible to reliably place two (2) peripheral lines. In the event that it is not possible to reliably place two (2) peripheral lines, the Medical Team leader will direct Medical Team members to place an IV catheter in a central line for the purpose of administering the chemicals.

At the discretion of the Medical Team leader, a localized anesthetic may be used to numb the venous access site.

To ensure proper insertion in the vein, the assigned Medical Team members should watch for the flashback of blood at the catheter hub in compliance with medical procedures.

The assigned Medical Team members shall ensure the catheter is properly secured with the use of tape or adhesive material, properly connected to the IV line and out of reach of the offender's hands. A flow of heparin/saline shall be started in each line and administered at a slow rate to keep the line open.

The primary IV catheter will be used to administer the chemicals and the backup catheter will be reserved in the event of the failure of the first line. Any failure of a venous access line shall be immediately reported to the IMSI warden.

The IV catheter in use shall not be covered and shall remain visible throughout the procedure.

The IMSI warden shall physically remain in the execution chamber with the offender throughout the administration of the chemicals in a position sufficient to clearly observe the offender and the primary and backup IV sites for any potential problems and shall immediately notify the Medical Team leader and director of the IDOC should any issue occur. Upon receipt of such notification, the director of the IDOC will stop the proceedings and take all steps necessary in consultation with the Medical Team leader prior to proceeding further with the execution.

Should it be determined that the use of the backup IV catheter is necessary, a complete set of backup chemicals will be administered in the backup IV as set forth in the applicable chemical chart.

Should it become necessary to use an alternate means of establishing an IV line because, in the opinion of the Medical Team leader, it is not possible to reliably place a peripheral line in the offender, a Medical Team member may utilize a central line catheter if, in the opinion of the Medical Team leader, such a line may be reasonably placed. The Medical Team member responsible for placing a central line

catheter shall have at least one year of regular and current professional experience conducting that procedure. The Medical Team member will place the central line catheter utilizing appropriate medical procedures. The Medical Team member shall ensure the catheter is properly secured with the use of tape or adhesive material, properly connected to the IV line and out of reach of the offender's hands. This line shall be utilized for the administering of all chemicals.

Upon successful insertion of the catheter into a central line, a Medical Team member will inject a solution of heparin/saline into the catheter to ensure patency of the catheter.

G. Administration of Chemicals Methods 1 and 2

At the time the execution is to commence and prior to administering the chemicals, the director of the IDOC will reconfirm with the Idaho attorney general (or designee) and the Idaho governor (or designee) that there is no legal impediment to proceeding with the execution. Upon receipt of oral confirmation that there is no legal impediment, the director of the IDOC will instruct the IMSI warden to commence the process to carry out the sentence of death. The IMSI warden will then order the administration of the chemicals to begin. If there is a legal impediment to the execution, the director of the IDOC shall instruct the IMSI warden to **stop the process**, and to notify the offender and witnesses that the execution has been stayed or delayed. The IMSI warden (or designee) shall also notify the IDOC PIO and other pertinent staff.

Upon receiving the order to commence the execution process from the director of the IDOC, the IMSI warden will instruct the Medical Team leader to begin administrating the chemicals. The Medical Team leader will instruct the assigned Medical Team member to begin dispensing the first chemical.

Upon direction from the Medical Team leader, the assigned Medical Team member will visually and verbally confirm the chemical name on the syringe and then administer the full dose of sodium pentothal/or pentobarbital immediately followed by the heparin/saline flush. The heparin/saline is administered as a secondary precaution to further ensure the line is functioning properly and flushed between each chemical.

After the sodium pentothal/or pentobarbital and heparin/saline have been administered and before the Medical Team members begin administering the pancuronium bromide, the Medical Team leader shall confirm the offender is unconscious by direct examination of the offender. The Medical Team leader, dressed in a manner to preserve his anonymity, will enter into the room where the IMSI warden and offender are located to physically confirm the offender is unconscious by using all necessary medically appropriate techniques such as giving verbal stimulus, soliciting an auditory response, touching the eyelashes, and/or conducting a sternal rub. The Medical Team leader will also confirm that the IV line remains affixed and functioning properly.

No further chemicals shall be administered until the Medical Team leader has confirmed the offender is unconscious. After three (3) minutes have elapsed since the administration of the sodium pentothal/or pentobarbital, the Medical Team leader will assess and confirm that the offender is unconscious. The Medical Team leader will verbally advise the IMSI warden of the offender's status.

In the unlikely event that the offender is conscious, the Medical Team shall assess the situation to determine why the offender is conscious. The Medical Team leader shall communicate this information to the IMSI warden, along with all Medical Team input. The IMSI warden will determine how to proceed or, if necessary, to start the procedure over at a later time or stand down. The IMSI warden may direct the curtains to the witness viewing room be closed, and, if necessary, for witnesses to be removed from the execution unit.

If deemed appropriate, the IMSI warden may instruct the Medical Team to administer an additional 5 grams of sodium pentothal/or pentobarbital followed by the heparin/saline flush from backup set B.

Upon administering the sodium pentothal/or pentobarbital and heparin/saline from backup set B, the Medical Team leader will again physically confirm the offender is unconscious using proper medical

procedures and verbally advise the IMSI warden of the same. Throughout the entire procedure, the Medical Team members and the IMSI warden shall continually monitor the offender using all available means to ensure that the offender remains unconscious and that there are no complications.

Only after receiving oral confirmation from the Medical Team leader that the offender is unconscious and three (3) minutes have elapsed since commencing the administration of the sodium pentothal/or pentobarbital and heparin/saline from backup set B, will the IMSI warden instruct the Medical Team leader to proceed with administering the next chemicals.

When instructed, the Medical Team leader will instruct the assigned Medical Team members to begin administering the full doses of the remaining chemicals (pancuronium bromide and potassium chloride), each followed by a heparin/saline flush as set forth in the applicable chemical chart.

If after administering the potassium chloride and subsequent heparin/saline flush, the electrical activity of the offender's heart has not ceased, the additional potassium chloride and heparin/saline flush contained in backup set B shall be administered.

The full dose contained in each syringe shall be administered to the offender and subsequently documented by the designated recorder. The quantities of the chemicals prepared and administered may not be changed in any manner without prior approval of the director of the IDOC after consultation with the Medical Team leader.

If all electrical activity of the heart ceases prior to administering all the chemicals, the Medical Team members shall continue to follow this protocol and administer all remaining chemicals in the order and amounts set forth in the applicable chemical chart.

When all electrical activity of the heart has ceased as shown by the EKG machine, the Medical Team leader will advise the Ada County coroner and the IMSI warden that the procedure has been completed. The Medical Team leader will ensure that the EKG machine runs a print-out strip for two (2) minutes after the last chemical injection.

The Ada County coroner will enter the execution chamber, examine the offender, and pronounce the offender's death to the IMSI warden. The IMSI warden will then announce that the sentence of death as been carried out as ordered by the court.

The witnesses will be escorted from the Execution Unit back to the respective staging and/or exit locations.

Note: Backup set C will be used if (1) electrical activity of the heart has not ceased after administration of sets A and B, or (2) either primary set A or backup set B are damaged or otherwise deemed unusable.

H. Administration of Chemicals Methods 3 and 4

At the time the execution is to commence and prior to administering the chemicals, the director of the IDOC will reconfirm with the Idaho attorney general (or designee) and the Idaho governor (or designee) that there is no legal impediment to proceeding with the execution. Upon receipt of oral confirmation that there is no legal impediment, the director of the IDOC will instruct the IMSI warden to commence the process to carry out the sentence of death. The IMSI warden will then order the administration of the chemicals to begin. If there is a legal impediment to the execution, the director of the IDOC shall instruct the IMSI warden to **stop the process**, and to notify the offender and witnesses that the execution has been stayed or delayed. The IMSI warden (or designee) shall also notify the IDOC PIO and other pertinent staff.

Upon receipt of the director of the IDOC's order and under observation of the Medical Team leader, the IMSI warden will advise the Medical Team leader to begin the administration of chemicals. The Medical Team leader will instruct the assigned Medical Team member to begin dispensing the first chemical.

Upon direction from the Medical Team leader, the assigned Medical Team member will visually and verbally confirm the chemical name on the syringe and then administer the full dose of sodium pentothal/or pentobarbital immediately followed by the heparin/saline flush.

If after administering the sodium pentothal/or pentobarbital, subsequent heparin/saline flush, and 10 minutes have elapsed, and the electrical activity of the offender's heart has not ceased, the additional sodium pentothal/or pentobarbital and heparin/saline flush contained in backup set B shall be administered.

The full dose contained in each syringe shall be administered to the offender and subsequently documented by the designated recorder. The quantities of the chemicals prepared and administered may not be changed in any manner without prior approval of the director of the IDOC after consultation with the Medical Team leader.

If all electrical activity of the heart ceases prior to administering all the chemicals, the Medical Team members shall continue to follow this protocol and administer all remaining chemicals in the order and amounts set forth in the applicable chemical chart.

When all electrical activity of the heart has ceased as shown by the EKG machine, the Medical Team leader will advise the Ada County coroner that the procedure has been completed. The Medical Team leader will ensure that the EKG machine runs a print-out strip for two (2) minutes after the last chemical injection.

The Ada County coroner will enter the execution chamber, examine the offender, and pronounce the offender's death to the IMSI warden. The IMSI warden will then announce that the sentence of death as been carried out as ordered by the court.

The witnesses will be escorted from the Execution Unit back to the respective staging and/or exit locations.

Note: Backup set C will be used if (1) electrical activity of the heart has not ceased after administration of sets A and B, or (2) either primary set A or backup set B are damaged or otherwise deemed unusable.

I. Documentation of Chemicals and Stay

In the event that a pending stay results in more than a two (2) hour delay, the catheter will be removed, if applicable, and the offender shall be returned to the isolation cell until further notice.

The Medical Team recorder shall account for all chemicals that were not administered and document, in the applicable sequence of chemical form (see appendixes A1 thru A4), the chemical name, syringe identification code, amount, date, and the time. Time will be marked based on the approved Medical Team room clock. The Medical Team leader and the Medical Team recorder each will sign the applicable sequence of chemical form (see appendixes A1 thru A4). And will give the unused chemicals to a member of the Administrative Team.

All logs, the applicable sequence of chemical forms (see appendixes A1 thru A4), the list of identifiers, and the EKG machine tape shall be submitted to the deputy attorney general who represents the IDOC for storage.

Upon completion of the execution or when a stay exceeding 24 hours is granted the Administrative Team shall be responsible for the appropriate disposal of all medical waste and supplies to include unused, drawn chemicals in accordance with state of Idaho and federal law.

J. Contingency Procedure

A portable cardiac monitor/defibrillator will be readily available on site in the event that the offender goes into cardiac arrest at any time prior to dispensing the chemicals; trained medical staff shall make every

effort to revive the offender should this occur, unless the offender has signed a do not resuscitate (DNR).

Trained medical personnel and emergency transportation, neither of which is involved in the execution process, shall be available in proximity to respond to the offender should any medical emergency arise at any time before the order to proceed with the execution is issued by the director of the IDOC.

If at any point any Medical Team members determine that any part of the execution process is not going according to procedure, they shall advise the Medical Team leader who shall immediately notify the IMSI warden. The IMSI warden, in consultation with the director of the IDOC may consult with persons deemed appropriate and will determine to go forward with the procedure, start the procedure over at a later time within the 24-hour day, or stand down.

IDAHO DEPARTMENT OF CORRECTION
Sequence of Chemical Form- Method 1

Offender: _____ Number: _____
Court Case #: _____
Warrant of Death Issued By: _____

Chemical Chart 1: PRIMARY SET A			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1A	1.25 g Sodium Pentothal, **GREEN**		
2A	1.25 g Sodium Pentothal, **GREEN**		
3A	1.25 g Sodium Pentothal, **GREEN**		
4A	1.25 g Sodium Pentothal, **GREEN**		
5A	60mL Heparin/Saline, **BLACK**		
6A	60mg Pancuronium Bromide, **BLUE**		
7A	60mg Pancuronium Bromide, **BLUE**		
8A	60mL Heparin/Saline, **BLACK**		
9A	120mEq Potassium Chloride, **RED**		
10A	120mEq Potassium Chloride, **RED**		
11A	60mL Heparin/Saline, **BLACK**		

Chemical Chart 1: BACKUP SET B			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1B	1.25 g Sodium Pentothal, **GREEN**		
2B	1.25 g Sodium Pentothal, **GREEN**		
3B	1.25 g Sodium Pentothal, **GREEN**		
4B	1.25 g Sodium Pentothal, **GREEN**		
5B	60mL Heparin/Saline, **BLACK**		
6B	60mg Pancuronium Bromide, **BLUE**		
7B	60mg Pancuronium Bromide, **BLUE**		
8B	60mL Heparin/Saline, **BLACK**		
9B	120mEq Potassium Chloride, **RED**		
10B	120mEq Potassium Chloride, **RED**		
11B	60mL Heparin/Saline, **BLACK**		

Chemical Chart 1: BACKUP SET C			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1C	1.25 g Sodium Pentothal, **GREEN**		
2C	1.25 g Sodium Pentothal, **GREEN**		
3C	1.25 g Sodium Pentothal, **GREEN**		
4C	1.25 g Sodium Pentothal, **GREEN**		
5C	60mL Heparin/Saline, **BLACK**		
6C	60mg Pancuronium Bromide, **BLUE**		
7C	60mg Pancuronium Bromide, **BLUE**		
8C	60mL Heparin/Saline, **BLACK**		
9C	120mEq Potassium Chloride, **RED**		
10C	120mEq Potassium Chloride, **RED**		
11C	60mL Heparin/Saline, **BLACK**		

IDAHO DEPARTMENT OF CORRECTION
Sequence of Chemical Form- Method 2

Offender: _____ Number: _____
Court Case #: _____
Warrant of Death Issued By: _____

Chemical Chart 2: PRIMARY SET A			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1A	2.5 g Pentobarbital **GREEN**		
2A	2.5 g Pentobarbital **GREEN**		
3A	60mL Heparin/Saline, **BLACK**		
4A	60mg Pancuronium Bromide, **BLUE**		
5A	60mg Pancuronium Bromide, **BLUE**		
6A	60mL Heparin/Saline, **BLACK**		
7A	120mEq Potassium Chloride, **RED**		
8A	120mEq Potassium Chloride, **RED**		
9A	60mL Heparin/Saline, **BLACK**		

Chemical Chart 2: BACKUP SET B			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1B	2.5 g Pentobarbital **GREEN**		
2B	2.5 g Pentobarbital **GREEN**		
3B	60mL Heparin/Saline, **BLACK**		
4B	60mg Pancuronium Bromide, **BLUE**		
5B	60mg Pancuronium Bromide, **BLUE**		
6B	60mL Heparin/Saline, **BLACK**		
7B	120mEq Potassium Chloride, **RED**		
8B	120mEq Potassium Chloride, **RED**		
9B	60mL Heparin/Saline, **BLACK**		

Chemical Chart 2: BACKUP SET C			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1C	2.5 g Pentobarbital **GREEN**		
2C	2.5 g Pentobarbital **GREEN**		
3C	60mL Heparin/Saline, **BLACK**		
4C	60mg Pancuronium Bromide, **BLUE**		
5C	60mg Pancuronium Bromide, **BLUE**		
6C	60mL Heparin/Saline, **BLACK**		
7C	120mEq Potassium Chloride, **RED**		
8C	120mEq Potassium Chloride, **RED**		
9C	60mL Heparin/Saline, **BLACK**		

IDAHO DEPARTMENT OF CORRECTION
Sequence of Chemical Form- Method 3

Offender: _____ Number: _____
Court Case #: _____
Warrant of Death Issued By: _____

Chemical Chart 3: PRIMARY SET A			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1A	1.25 g Sodium Pentothal, **GREEN**		
2A	1.25 g Sodium Pentothal, **GREEN**		
3A	1.25 g Sodium Pentothal, **GREEN**		
4A	1.25 g Sodium Pentothal, **GREEN**		
5A	60mL Heparin/Saline, **BLACK**		

Chemical Chart 3: BACKUP SET B			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1B	1.25 g Sodium Pentothal, **GREEN**		
2B	1.25 g Sodium Pentothal, **GREEN**		
3B	1.25 g Sodium Pentothal, **GREEN**		
4B	1.25 g Sodium Pentothal, **GREEN**		
5B	60mL Heparin/Saline, **BLACK**		

Chemical Chart 3: BACKUP SET C			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1C	1.25 g Sodium Pentothal, **GREEN**		
2C	1.25 g Sodium Pentothal, **GREEN**		
3C	1.25 g Sodium Pentothal, **GREEN**		
4C	1.25 g Sodium Pentothal, **GREEN**		
5C	60mL Heparin/Saline, **BLACK**		

IDAHO DEPARTMENT OF CORRECTION
Sequence of Chemical Form- Method 4

Offender: _____ Number: _____
Court Case #: _____
Warrant of Death Issued By: _____

Chemical Chart 4: PRIMARY SET A			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1A	2.5 g Pentobarbital **GREEN**		
2A	2.5 g Pentobarbital **GREEN**		
3A	60mL Heparin/Saline, **BLACK**		

Chemical Chart 4: BACKUP SET B			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1B	2.5 g Pentobarbital **GREEN**		
2B	2.5 g Pentobarbital **GREEN**		
3B	60mL Heparin/Saline, **BLACK**		

Chemical Chart 4: BACKUP SET C			
Syringe No.	**Label**	**Date and Time Administered**	**Comments**
1C	2.5 g Pentobarbital **GREEN**		
2C	2.5 g Pentobarbital **GREEN**		
3C	60mL Heparin/Saline, **BLACK**		

MISSOURI DEPARTMENT OF CORRECTIONS
PREPARATION AND ADMINISTRATION OF CHEMICALS
FOR LETHAL INJECTION

A. Execution Team Members

The execution team consists of department employees and contracted medical personnel including a physician, nurse, and pharmacist. The execution team also consists of anyone selected by the department director who provides direct support for the administration of lethal chemicals, including individuals who prescribe, compound, prepare, or otherwise supply the chemicals for use in the lethal injection procedure.

B. Preparation of Chemicals

Medical personnel shall prepare the lethal chemicals. The quantities of these chemicals may not be changed without prior approval of the department director. The chemicals shall be prepared and labeled as follows:

1. Syringes 1 and 2: Five (5) grams of pentobarbital (under whatever name it may be available from a manufacturer, distributor or compounding pharmacy), 100 ml of a 50 mg/mL solution, shall be withdrawn and divided into syringes labeled “1” and “2.”

2. Syringe 3: 30 cc of saline solution.

3. Syringes 4 and 5: Five (5) additional grams of pentobarbital (under whatever name it may be available from a manufacturer, distributor or compounding pharmacy), 100 ml of a 50 mg/mL solution, shall be withdrawn into syringes labeled “4” and “5.”

4. Syringe 6: 30 cc of saline solution. This syringe is prepared in the event that additional flush is required.

C. Intravenous lines

1. Medical personnel shall determine the most appropriate locations for intravenous (IV) lines. Both a primary IV line and a secondary IV line shall be inserted unless the prisoner’s physical condition makes it unduly difficult to insert more than one IV. Medical personnel may insert the primary IV line as a peripheral line or as a central venous line (e.g., femoral, jugular, or subclavian) provided they have appropriate training, education, and experience for that procedure. The secondary IV line is a peripheral line.

2. A sufficient quantity of saline solution shall be injected to confirm that the IV lines have been properly inserted and that the lines are not obstructed.

D. Monitoring of Prisoner

1. The gurney shall be positioned so that medical personnel can observe the prisoner's face directly or with the aid of a mirror.

2. Medical personnel shall monitor the prisoner during the execution.

E. Administration of Chemicals

1. Upon order of the department director, the chemicals shall be injected into the prisoner by the execution team members under the observation of medical personnel. The lights in the execution support room shall be maintained at a sufficient level to permit proper administration of the chemicals.

2. The pentobarbital from syringes 1 and 2 shall be injected.

3. The saline solution from syringe 3 shall be injected.

4. Following a sufficient amount of time for death to occur after the injection of syringe 3, medical personnel shall examine the prisoner to determine if death has occurred. If the prisoner is still breathing, the additional five grams of pentobarbital will injected from syringes 4 and 5 followed by the saline from syringe 6.

5. At the completion of the process and after a sufficient time for death to have occurred, medical personnel shall evaluate the prisoner to confirm death. In the event that the appropriate medical personnel cannot confirm that death has occurred, the curtain shall be reopened until an appropriate amount of time has passed to reevaluate the prisoner.

F. Documentation of Chemicals

1. Medical personnel shall properly dispose of unused chemicals.

2. Before leaving ERDCC, all members of the execution team present at the execution shall complete and sign the "Sequence of Chemicals" form thereby verifying that the chemicals were given in the order specified in this protocol.

3. Before leaving ERDCC, one of the medical personnel present at the execution shall complete and sign the "Chemical Log" indicating the quantities of the chemicals used and the quantities of the chemicals discarded during the execution.

4. Within three days of the execution, the ERDCC warden shall submit the Sequence of Chemicals and the Chemical Log to the director of the Division of Adult Institutions (DAI). The DAI division director and the department director shall review the records. If they do not detect any irregularities, they shall approve the two documents. If any irregularities are noted, the DAI division director shall promptly determine whether there were any deviations from this protocol and shall report his findings to the department director.

1.3.D.3 Execution of an Inmate

I Policy Index:

Date Signed:	***07/27/2018***
Distribution:	***Public***
Replaces Policy:	***N/A***
Supersedes Policy Dated:	***02/09/2017***
Affected Units:	***All Institutions***
Effective Date:	***07/31/2018***
Scheduled Revision Date:	***July 2019***
Revision Number:	***14***
Office of Primary Responsibility:	***DOC Administration***

II Policy:

The Department of Corrections (DOC) will carry out the execution of an inmate in accordance with SDCL Chapter § 23A-27A. The execution will be conducted in a professional, humane and dignified manner.

III Definitions:

Lethal Injection:
The intravenous injection (IV) of a substance or substances in a lethal quantity (See SDCL § 23A-27A-32).

Witnesses:
People authorized to attend an execution as referenced in SDCL §§ 23A-27A-34 and 23A-27A-34.2.

Staff Member:
For the purposes of this policy, a staff member is any person employed by the Department of Corrections (DOC), full or part time, including an individual under contract assigned to the DOC or an employee of another State agency assigned to the DOC.

IV Procedures:

1. General Provisions:

A. Inmate executions are carried out by means of lethal injection (See SDCL § 23A-27A-32).

1. At no time will any medical professional(s) employed at a South Dakota Department of Corrections facility participate in the execution process.

2. Lethal injection is not the practice of medicine in South Dakota (See SDCL § 23A-27A-32).

3. The inmate who is to be executed will be connected to two (2) IV lines, normally one (1) in each arm. One (1) IV line will be the primary line for the lethal injection and the other IV line is designated as a backup.

4. The lethal injection process involves the administration of drugs, each in a lethal quantity, pursuant to a 3-Drug, 2-Drug, or 1-Drug protocol, depending on the date of the inmate's conviction and the availability of the necessary drugs:

   a. 3-Drug Protocol

      1) The first drug, Sodium Pentothal (aka Sodium Thiopental) or Pentobarbital, is administered in a quantity sufficient to ensure the inmate is not subjected to the unnecessary and wanton infliction of pain.
      2) The second drug, Pancuronium Bromide, stops the inmate's breathing.
      3) The third drug, Potassium Chloride, stops the inmate's heart.

   b. 2- Drug Protocol
      1) The first drug, Sodium Pentothal, (aka Sodium Thiopental) or Pentobarbital, is administered in a quantity sufficient to ensure the inmate is not subjected to the unnecessary and wanton infliction of pain.
      2) The second drug, Pancuronium Bromide, stops the inmate's breathing.

   c. 1- Drug Protocol- Sodium Pentothal (aka Sodium Thiopental) or Pentobarbital is administered in a lethal quantity sufficient to ensure the inmate is not subjected to the unnecessary and wanton infliction of pain.

5. Any person convicted of a capital offense or sentenced to death prior to July 1, 2007, may choose to be executed in the manner provided in this policy, or in the manner provided by South Dakota law at the time of the person's conviction or sentence (SDCL § 23A-27A-32.1).

   a. The inmate will indicate his/her choice in writing to the Warden of either the South Dakota State Penitentiary (SDSP) or the South Dakota Women's Prison (SDWP), not less than seven (7) days prior to the scheduled week of execution.

   b. If the inmate fails or refuses to choose a manner of execution in the time provided, the inmate will be executed as provided in SDCL § 23A-27A-32 (See SDCL § 23A-27A-32.1).

B. Executions are conducted under the direction of the Warden of either the SDSP or the SDWP.

1. The Warden will select qualified staff to participate in the execution.

2. The Warden will identify one (1) or more individuals trained to administer intravenous injections to carry out the lethal injection.

   a. The Warden will present information regarding the individual's(s') qualifications to the Secretary of Corrections for final approval (See SDCL § 23A-27A-32).

   b. The individual's(s') qualifications must demonstrate adequate training to competently carry out each technical step of the lethal injection (*See Baze v. Rees*, 553 U.S. 35 (2008) and *Taylor v. Crawford*, 487 F. 3d 1072 (8th Cir. 2007).

   c. The name, address, qualifications and other identifying information relating to the identity of any person or entity supplying drugs for use in intravenous injections under SDCL § 23A-27A is confidential. Disclosure of such information is a Class 1 Misdemeanor under state law (See SDCL § 23A-27A-31.2).

   d. The name, address, qualifications and other identifying information relating to the identity of any person administering the intravenous injections under SDCL § 23A-27A is confidential. Disclosure of such information may not be authorized or ordered. Disclosure

of such information is a Class 1 Misdemeanor under state law (See, SDCL § 23A-27A-31.2).

C. Male inmates sentenced to death will be housed in the South Dakota State Penitentiary (SDSP) or Jameson Prison Annex. Female inmates sentenced to death will be housed in the South Dakota Women's Prison (See DOC policy 1.3.D.2 - *Capital Punishment Housing*).

1. Inmates sentenced to death are segregated from other inmates and single-celled (See SDCL § 23A-27A-31.1).

2. Physical access to an inmate sentenced to death is limited to staff members, the inmate's legal counsel, members of the clergy if requested by the inmate, and members of the inmate's family approved to access the facility. No other person may be allowed access to the inmate without an order of the trial court (See SDCL § 23A-27A-31.1).

3. If the inmate to be executed is female, the Warden of SDWP will notify the Warden of SDSP to arrange for the transfer of the female inmate when the execution date is set.

D. The Governor may investigate the circumstances of the case of the inmate sentenced to death in a manner he/she deems appropriate and may require the assistance of the Attorney General (See SDCL § 23A-27A-19). The Governor has the power to reprieve or suspend the execution for up to ninety (90) days to complete his/her investigation (See SDCL § 23A-27A-20).

E. If there is a question on an inmate's mental competence to proceed with the execution, the Warden of the state penitentiary will notify the Governor, Secretary of Corrections and the sentencing court. If the sentencing court determines there is a substantial threshold showing of incompetence to be executed, the sentencing court will conduct hearings and order mental examinations. (See SDCL § 23A-27A-22, through § 23A-27A-26). As long as the inmate is considered incompetent, the inmate may not be executed (See SDCL §§ 23A-27A-24 and 23A-27A-26).

F. The death penalty cannot be imposed on a inmate who was mentally retarded at the time of the commission of the offense and whose condition was manifested and documented before the age of eighteen (18) (See SDCL §§ 23A-27A-26.1 through 23A-27A-26.7).

G. A pregnant inmate may not be executed (See SDCL §§ 23A-27A-27 through 23A-27A-29).

H. The death penalty cannot be imposed on an inmate who committed an act punishable by death while under eighteen (18) years of age (See SDCL § 23A-27A-42).

I. Inmate appeals regarding the death penalty are outside the responsibility of the DOC. Inquiries on the status of any inmate appeal(s) should be directed to the Office of the Attorney General or the defense attorney(s).

2. Warrant of Execution:

A. The sentencing judge (or his/her successor in office) will have a signed and certified Warrant of Death Sentence and Execution provided to the Warden of the state penitentiary (See SDCL §§ 23A-27A-15 and 23A-27A-16).

B. The Warrant of Death Sentence and Execution will set the week within which the inmate is to be executed (See SDCL § 23A-27A-15).

C. The Warden of the state penitentiary may carry out the execution at any time within the week stated in the Warrant of Death Sentence and Execution. (See, SDCL §§ 23A-27A-15 and 23A-27A-16).

3. Time and Place of Execution:

A. All executions will take place at the SDSP (See SDCL § 23A-27A-32).

B. Advance notice of the day and hour set by the Warden of the state penitentiary for the execution will be kept secret and only divulged to those invited or requested to be present at the execution (See SDCL § 23A-27A-37).

C. No person may divulge the day and hour set for the execution prior to the Warden's public announcement (See SDCL § 23A-27A-37).

D. The Warden of the state penitentiary will publicly announce the day and hour of the execution not less than forty-eight (48) hours in advance (See SDCL § 23A-27A-17). The release of information to the media outlets shall be coordinated with the DOC Communications and Information manager. All other DOC staff is expressly prohibited from providing information about the execution not readily available in the public domain.

4. Selection of Witnesses:

A. No person under the age of eighteen (18) will be allowed to witness an execution (See SDCL § 23A-27A-36).

B. Only persons authorized by the Warden of the state penitentiary, and those authorized by SDCL §§ 23A-27A-32, 23A-27A-34, 23A-27A-34.1, 23A-27A-34.2 and 23A-27A-36 are allowed to attend the execution.

1. The following witnesses are required to be invited to witness the execution by state law (See SDCL § 23A-27A-34):

   a. The Attorney General of South Dakota.

   b. The trial judge before whom the conviction was had or his /her successor in office.

   c. The State's Attorney of the county where the crime was committed.

   d. The Sheriff of the county where the crime was committed.

   e. Representatives of the victim.
      1) There are no specific statutory requirements for how the Warden selects which representatives of the victim(s) may witness the execution.
      2) The victim's(s') family(ies) may suggest the names of individuals who they would like to attend.
      3) In the event the victim's(s') family(ies) cannot or will not prioritize their list of individuals, the Warden will make the choice in the following manner:

         i. Close relatives of the victim(s) will be given preference to witness the execution. The order of preference is: spouse, parents/stepparents, adult children/stepchildren, siblings, and other family members (grandparents, aunts, uncles, nieces, nephews, cousins, etc.)

         ii. Friends of the victim(s)

   f. At least one member of the news media.
      1) The Warden will select two (2) members of the media. (See section on Media Relations).

g. A number of reputable citizens to be determined by the warden.

C. Space and seating for witnesses is limited by the size of the rooms, the viewing windows, and concerns for the safety and security of the witnesses.

D. Preference will be given to accommodating as many representatives of the victim as possible, given the space constraints and the requirements in state law that other persons also serve as witnesses.

E. The Warden of the state penitentiary has final approval of all witnesses not specifically required by law to be invited.

F. All witnesses other than the Attorney General, trial judge, States Attorney and Sheriff are subject to the same background check as a regular visitor to the facility, unless exempted by the Warden of the state penitentiary.

G. The inmate is allowed to request the attendance of up to five (5) persons to serve as witnesses. These persons may include but are not limited to legal counsel, members of the clergy, relatives or friends (See SDCL § 23A-27A-34.2). All the requested witnesses shall be on the inmate's visit list and at least eighteen (18) years of age (See DOC policy 1.5.D.1 *Inmate Visiting*).

5. Witness Behavior:

A. Because the execution will take place inside a facility where many other inmates and staff will be present or in close proximity, all witnesses are expected to follow the rules and procedures of the SDSP and the orders of escorting staff for the safety and security of all involved.

1. Failure by a witness to comply with the rules and procedures of SDSP or the orders of escorting staff may result in denial of entry or removal of the witness from the facility.

2. Witnesses shall follow the approved dress code for visitation. The witnesses will be provided this specific dress code information in advance of the execution (See DOC policy 1.5.D.1 *Inmate Visiting*).

3. Witnesses are subject to search by electroninc device and/or a hand-held metal detector and pat searches by DOC staff (See DOC policy 1.3.A.5 *Searches - Institutions*).

   a. Witnesses may be searched more than one (1) time prior to the execution.

4. Most personal property items are not allowed inside the SDSP.

   a. For example, purses, cameras, pictures, pocketknives, pagers, watches, cell phones, signs, recording devices, other electronic equipment, etc. are not permitted. These items should be left in the vehicle or lockers that are available for storage of personal property in the SDSP lobby.

   b. No drugs, alcohol, tobacco products or firearms are allowed inside SDSP. Anyone suspected of being under the influence of drugs or alcohol will be denied entry or removed from the facility.

B. All witnesses are cautioned to refrain from verbal outbursts or inappropriate action while inside the SDSP.

C. No cameras or recording devices of any type are allowed inside the SDSP, the witness area or the area surrounding the execution chamber (See DOC policy 1.1.A.4 *Relationship with News Media, Public and Other Agencies*).

6. Media Relations:

A. Requests for execution information (other than appeal issues) or interviews from media representatives are to be made to the DOC Communications and Information Manager or respective Warden (See DOC policy 1.1.A.4 *Relationship with News Media, Public and Other Agencies*). Reasonable efforts will be made to accommodate representatives of the news media before, during and after a scheduled execution; however, the DOC reserves the right to regulate media access to ensure the orderly and safe operations of the facility.

1. The Warden of the state penitentiary (or his/her designee) can discuss procedures under the control of SDSP that affect an execution. Examples of procedures which may be discussed:

   a. The timelines of the execution, from issuance of the warrant of execution to the certificate of execution, return of the deceased inmate's body and the burial.

   b. The various steps that go along with the execution; i.e. sequence of events, last meal, last words, etc.

   c. Witness information (See sections on Selection of Witnesses and Witness Behavior).

   d. A description of the regular visit procedures inside the security perimeter.

2. Questions regarding the process for the Governor to investigate the circumstances of the case will be directed to the Governor's Office or Attorney General's Office.

B. The decision to grant tours of the execution chamber is at the discretion of the Warden of the state penitentiary.

C. The decision to grant photo/video of the execution chamber is subject to the approval of the Secretary of DOC.

D. Two (2) media witnesses will be selected to attend the execution.

1. The first media representative will be selected from the Associated Press.

2. The second media representative will be selected from a media outlet located in the proximity of where the crime took place.

E. Media witnesses shall not possess cameras or recording devices of any type while in the witness area or surrounding area of the execution chamber.

1. Each media witness attending the execution may have writing material in the waiting area but must leave those materials behind when moved to the witness area.

2. Each media witness attending the execution will be given paper and a pencil by a DOC official when he/she arrives in the witness area.

7. Final Visit Arrangements:

A. Reasonable accommodations for visits by immediate family will be made after the inmate has been moved to a holding cell near the execution chamber.

1. Visits are allowed between 8:00 AM and 8:00 PM, except for the day of the execution (See item **"**E**"** in this section).

2. All personal visits will be Class II (non-contact) (See DOC policy 1.5.D.1 *Inmate Visiting*).

3. Telephone calls may be substituted for personal visits.

B. Visits will be supervised by DOC staff and must be arranged in advance through the Warden of the state penitentiary or Deputy Warden of the state penitentiary.

1. Visitors are subject to search by both a stationary and hand-held metal detector, and pat searches at any time (See DOC policy 1.3.A.5 *Searches - Institutions*).

2. Visitors must abide by the rules and regulations of the SDSP and the DOC.

3. Failure to abide by the rules and regulations of the SDSP and the DOC may result in termination of a current visit and denial of future visits.

C. Visitors will be escorted and supervised at all times.

D. The following members of the inmate's immediate family are allowed Class II visits with the inmate: father, mother, stepfather, stepmother, brother(s), sister(s), stepbrother(s), stepsister(s), biological/legally adopted children and spouse.

E. Visits with immediate family will cease at least six (6) hours prior to the scheduled time of execution.

F. Attorney access will be accommodated as much as possible.

1. Attorneys are subject to all the visit arrangements/restrictions listed in this section.

2. Any documents to be shared with the inmate will be passed to SDSP staff and inspected for contraband. Approved documents will be given to the inmate.

3. Attorney(s) must leave the holding cell area at least one (1) hour before the scheduled execution time.

G. Clergy will be allowed additional visits with the inmate until one (1) hour before the scheduled execution time.

8. The Execution:

A. An execution involves strict security procedures that are intended to protect the witnesses, staff, other inmates and the public at large. These security procedures are confidential and will not be discussed.

B. The Governor, Attorney General and Chief Justice of the State Supreme Court or designee will be provided with the telephone numbers of the Warden's Office, the chemical room and multiple backup telephone numbers, including personal cell phone numbers of the Warden of the state penitentiary and Deputy Warden of the state penitentiary for the purpose of emergency or last minute notification. The Warden of the state penitentiary and Deputy Warden of the state penitentiary will also be equipped with SDSP-issued radios.

C. After confirming with the Governor's Office, the Attorney General and the Chief Justice of the State Supreme Court that no last minute appeals have been initiated and no stays have been ordered, the inmate will be moved to the execution chamber and secured to the table.

D. Two (2) intravenous injection (IV) sites will be prepared and inserted, normally one (1) in each of the inmate's arms.

E. A bag of sterile saline solution will be connected to each IV site. Each IV will be checked and verified as running properly before witnesses are escorted into the viewing rooms.

F. The witnesses will be brought into the respective witness rooms one (1) group at a time.

G. The curtains outside the witness rooms will remain closed until the Warden of the state penitentiary is satisfied everything is ready and orders them opened.

H. The Warden of the state penitentiary will give the inmate an opportunity to make a final statement. A transcript will be made of the inmate's statement and the transcript will be made public.

I. For 3-Drug or 2-Drug protocol executions, the Sodium Pentothal or Pentobarbital will be administered and allowed to take effect prior to administering the subsequent drugs.

J. After the lethal injections have been administered, the Warden will wait a brief period before summoning a person capable of examining the inmate for the presence of respirations and heartbeat and, if appropriate, to pronounce death, including the time of death.

1. If the county coroner is on the premises, the Warden of the state penitentiary will ask the county coroner to certify death, including the time of death and then take charge of the body.

2. If the county coroner is not on the premises, the Warden will direct the inmate's body to be taken to a nearby morgue, where the county coroner will be summoned to examine it and certify death.

K. After death has been pronounced, the curtains of the witness rooms will be closed and the witness groups will be escorted away from the area separately.

9. Post-Execution Procedures:

A. The certificate of execution will be prepared and signed by the Warden. The certificate of execution document shall also be signed by each of the witnesses of the execution attending as allowed in § 23A-27A-34 and § 23A-27A-34.2. (See SDCL §§ 23A-27A-34, 23A-27A-34.2 and 23A-27A-40.1).

B. The Warden will ensure the county coroner is permitted to investigate the death pursuant to SDCL §§ 23-14-18(3) and 24-1-27

1. If the county coroner is on the premises, the body of the executed inmate will not be removed from the execution chamber until after the county coroner has certified the death of the inmate.

C. After the county coroner has completed the investigation, the body of the executed inmate (unless claimed by a relative or personal representative), will be interred in a cemetery within Minnehaha County (Also see SDCL § 23A-27A-39 and DOC policy 1.4.E.6 *Death of an Offender or Unresponsive Offender*).

D. After the execution has been completed, the DOC Communication and Information Manager will announce the fact in a press briefing that will be conducted on the SDSP grounds.

E. Media representatives present at the execution are required to attend the post-execution press conference to share information about the execution with other media.

F. Within ten (10) days following the execution, the certificate of execution and return will be filed with the Clerk of Courts of the county where the offense occurred. (See SDCL § 23A-27A-40.1)

V Related Directives:

SDCL chapter 23-14, chapter 23A-27A and 24-1-27
Baze v. Rees, 217 S. W. 3d 207, (May 7, 2008)
Taylor v. Crawford, 487 F. 3d 1072 (8th Cir. 2007)
DOC policy 1.1.A.4 *Relationship with News Media, Public and Other Agencies*
DOC policy 1.3.A.5 -- *Searches - Institutions*
DOC policy 1.3.D.2 – *Capital Punishment Housing*

DOC policy 1.5.D.1 -- *Inmate Visiting*
DOC policy 1.4.E.6 – *Death of an Offender or Unresponsive Offender*

VI Revision Log:

August 2006: New policy.
June 2007: **Revised** the policy statement. **Revised** the definition of lethal injection. **Removed** medical doctors as witnesses required to be invited to the execution. **Deleted** references and procedures related to SDCL § 23A-27A-38. **Revised** the post-execution procedures. **Moved** some information from the section on Media Relations and placed it in a new section titled The Execution. **Added** a reference to DOC policy 1.3.A.10. **Added** language about death penalty appeals. **Added** a statement regarding security measures. **Added** the circumstances in which an inmate may choose the current lethal injection procedures or revert back to existing law at the time of conviction or sentence. **Clarified** which individuals the victim's family may request as witnesses. **Added** a statement on the trained individuals' experience and qualifications. **Added** more specific procedures on administering the lethal dosages. **Added** a reference to *Taylor v. Crawford*.
August 2007: **Changed** "medical procedure" to "technical procedure" to avoid any possibility of confusion regarding an execution being considered the practice of medicine. **Updated** the procedures involving the county coroner in the section on The Execution.
June 2008: **Revised** formatting of policy in accordance with 1.1.A.2. **Changed** policy because of recent law changes to the capital punishment chapter, SDCL 23A-27A by the SD Legislature, 2008, SB 53 and the United States Supreme Court in **Baze v. Rees**, ___ US _____, (2008). **Revised** definition of Lethal Injection. **Changed** "through" to "and" and "36" to "34-2" in definition of Witnesses. **Deleted** reference to DOH policy in subsection (ss) (A1), **revised** wording in ss (A2), **added** "each in a lethal quantity" in ss (A4), **deleted** comment about remaining unconscious in ss (A4a), **replaced** "person" with "inmate" in ss (5A and B), **added** comment about state statue and statute 32-1 in ss (5B), **replaced** "at least two (2)" to "one (1) or more" in ss (B2), **revised** section reading properly trained to read adequately trained and referenced court cases in ss (B2b), **clarified** on the information that is to remain confidential for those assisting with administering the intravenous injection in ss (b2c), **revised** wording of how inmates are housed and **replaced** statute 16 with 31.1 in ss (C1), **replaced** statute 16 with 31.1 in ss (C2), **added** that the Secretary of DOC and sentencing court will be notified regarding any question regarding an inmate's mental competence and **replaced** statement regarding a commission may be appointed with language from statute 22 through 26, and **replaced** statutes in ss (E) and **deleted** "/exaction" and "and/" in ss (I), of General Provisions section. **Revised** statement regarding sentencing judge in ss (A), **replaced** "delivered" with "provided in ss (A), **added** "Death Sentence and" to "Execution" regarding the certified Warrant in ss (A, B and C) and **added** statute 16 in ss (A and C) of Warrant of Execution section. **Replaced** "the witnesses" with "those" in ss (B), **revised** ss (C) to state no person will divulge within Time and Place of Execution section. **Added** statute 36 in ss (A), **replaced** "DOC staff, law enforcement officers" with "persons", **added** statute 32, 24-2, 36 and **replaced** 35 with 34.1 in ss (B), **deleted** former ss (B2), **replaced** "no more than ten (10)" with "a number of" in ss (C), **deleted** ss (C1), **moved** ss (C2) to above ss (C), **added** new ss (C1 and C2)**, revised** wording regarding selection of witnesses in ss (D, D1, D2 and D2a), **deleted** former ss (D2c) regarding multiple victims, **deleted** "(Attorney General, trial judge, states attorney and sheriff)" in ss (E) and **added** ss (G) in Selection of Witnesses section **Clarified** that no cameras or recording devices are allowed inside SDSP or area surrounding the execution chamber in ss (C) of Witness Behavior section. **Revised** wording in ss (A), **deleted** statement regarding photo requests of the execution chamber in ss (B) and **added** a new ss (C) regarding requests to take photos of the execution chamber, of the Media Relations section **Deleted** statement regarding pursuant to SDCL 23A-27A-35 in ss (G) of Final Visit Arrangements section. **Revised** ss (D) to include two intravenous injection (IV) sites will be prepared and inserted, **added** "site" when referencing IV in ss (E), **added** "the transcript" in ss (H), **deleted** "to render the inmate unconscious" in ss (I), **replaced** "EMT" with "a person capable of examining" and **added** "for the presence of respirations and heartbeat and if appropriate" to ss (J), **deleted** statement about county coroner examining the inmate and **added** statement about taking charge of the body in ss (J2) and **deleted** statement regarding EMT and county coroner and **added** statement about death being pronounced ss (K) of The Execution section.

Replaced "persons" with "witnesses", **deleted** statute 40, **added** statutes 34, 34.2, 40.1 in ss (A), **added** statute 24-1-27 in ss (B), **replaced** "declared" with "certified" in ss (B1) **added** statute 40.1 in ss (F) and **revised** bullets to read accordingly within the Post-Execution Procedures section. **Added** Baze v. Rees, _____ US _____, (May 7, 2008), Taylor v. Crawford, 487 F. 3d 1072 (8th Cir., 2007) and DOC policy when referencing policies throughout policy **Revised** other grammatical, spacing and sentence structure throughout policy.

July 2009: **Added** site code to Baze v Rees throughout policy **Added** hyperlinks throughout policy. **Deleted** SDCL 23A-27A-30 in ss (G of General Provisions).

July 2010: **Revised** formatting of Section 1 **Replaced** SDSP with SD DOC in ss (A1 of General Provisions.

September 2011: **Reviewed with no changes.**

October 2011: **Deleted** "a" in IV.1.A. **Added** 3-Drug, 2-Drug, and 1-Drug protocol descriptions in Part IV.1.A.4.**Added** IV.1.B.1.c. moved former IV.1.B.2.c. to IV.1.B.2.d. **Updated** Baze cites to published U.S. citation throughout. **Deleted** "Pancuronium Bromide" and "Potassium Chloride" from IV.8.1 and **added** "For 3-Drug or 2-Drug protocol executions" and "subsequent drugs." **Deleted** "dosages of Sodium Pentothal, Pancuronium Bromide and Potassium Chloride" from IV.8.J and **added** "injections".

February 2013: **Added** "the Warden, subject to the approval of the Secretary of Corrections, shall determine the substances and the quantity of substances to be used for the execution" in Section 1 A. 5. b. **Deleted** "warden" and **Replaced** with "Warden of the state penitentiary" within the policy. **Deleted** "may not be authorized except pursuant to the terms of a court order" and **Replaced** with "is a class 1 misdemeanor under state law" in Section 1 B. 2. c. **Deleted** "Class 2" and **Replaced** with "Class 1" in Section 1 B. 2. d. **Deleted** "attorney's, clergy, DOC staff, other state or contractual staff stationed at the respective prison, people authorized by the respective Warden or any other person authorized to access the inmate through a court order" and **Replaced** with "penitentiary staff, Department of Corrections staff, inmate's counsel, member of the clergy if requested by the inmate, and members of the inmate's family. No other person may be allowed access to the inmate without an order of the trial court." in Section 1 C. 2. **Added** 3. to Section 1 C. **Added** "The release of information to the media outlets shall be coordinated with the DOC Communications and Information manager. All other DOC staff are expressly prohibited from providing information about the execution not readily available in the public domain" in Section 3 D. **Added** "Reasonable efforts will be made to accommodate representatives of the news media before, during and after a scheduled execution however; the DOC reserves the right to regulate media access to ensure the orderly and safe operations of its facilities." to Section 6 A.

July 2013: **Deleted** "the state penitentiary" and **Replaced** with "either the South Dakota State Penitentiary or the South Dakota Women's Prison" in Section 1 A. 5. a. **Deleted** "by state law at the time of the execution, the Warden, subject to the approval of the Secretary of Corrections, shall determine the substances and the quality of substances to be used for the execution" and **Replaced** with "in SDCL 23A027A-32) in Section 1 A.5 b. **Deleted** "the state penitentiary" and **Replaced** with either the SDSP or SDWP" in Section 1 B. **Added** e. "Representatives of the victim" to Section 4. Added 1)-3) and 3) a. to Section 4 B. 1.**Added** F. "At least one member of the news media" to Section 4 B. 1. **Added** G. "A number of reputable citizens to be determined by the Warden" to Section 4 B. 1. **Deleted** The Warden of the state penitentiary will select a number of reputable adult citizens to witness the execution and two (2) members of the media (See section on Media Relations)." in Section 1 C. **Deleted** " 1. Space and seating for witnesses is limited by the size of the rooms, the viewing windows and concerns for the safety and security of the witnesses" in Section 4 C. **Deleted** 2. "Preference will be given to accommodating as many representatives of the victim as possible give the space constraints and the requirements in state law that other persons also serves as witnesses" in Section 4. **Deleted** "There are no specific statutory requirements for how the Warden of the state penitentiary selects which representatives of the victim(s) may witness the execution" in Section 4. **Deleted** 1. "The victims family or families may suggest the names of the individuals who should attend" in Section 4 D. **Deleted** 2. "In the event the victim's family or families cannot or will not prioritize their list of individuals, the Warden of the state penitentiary will make the choice in the following manner:" and **Deleted** 1 (1-6) referencing the list of family in Section 4 D. **Renumbered**

items that followed **Added** new C. "Spaced and seating for witnesses is limited by the size of the rooms, the viewing windows and concerns for the safety and security of the witnesses" in Section 4 **Added** new D. "Preference will be given to accommodating as many representatives of the victim as possible given the space constraints and the requirements in state law that other persons also service as witnesses" in Section 4.
July 2014: **Reviewed** with no changes.
July 2015: **Added** definition of "Staff Members". **Added** "approved to access the facility" in Section 1 C. 1. **Deleted** "Department of Corrections staff" and **Replaced** with "staff members" in Section 1 C. 2.
January 2017: **Reveiwed** with no changes.
July 2018: **Reveiwed** with no changes.

Denny Kaemingk (original signature on file)	*07/27/2018*
Denny Kaemingk, Secretary of Corrections	Date

TEXAS DEPARTMENT OF CRIMINAL JUSTICE

Correctional Institutions Division

EXECUTION PROCEDURE

April 2019

ADOPTION OF EXECUTION PROCEDURE

In my duties as Division Director of the Correctional Institutions Division, I hereby adopt the attached Execution Procedure for use in the operation of the Texas Department of Criminal Justice Death Row housing units and perimeter functions. This Procedure is in compliance with Texas Board of Criminal Justice Rule §152.51; §§492.013(a), 493.004, Texas Government Code, and Article 43.14 – 43.20, Code of Criminal Procedure.

Lorie Davis

Lorie Davis
Director, Correctional Institutions Division

4·2·19
Date

EXECUTION PROCEDURES

PROCEDURES

I. Procedures Upon Notification of Execution Date

A. The clerk of the trial court pursuant to Tex Code of Criminal Procedure art. 43.15 shall officially notify the Correctional Institutions Division (CID) Director, who shall then notify the Death Row Unit Warden, and the Huntsville Unit Warden of an offender's execution date. Once an execution date is received, the Death Row Unit Warden's office shall notify the Unit Classification Chief, and the Death Row Supervisor.

B. The Death Row Supervisor shall schedule an interview with the condemned offender and provide him with the Notification of Execution Date (Form 1). This form provides the offender with a list of the information that shall be requested from him (2) two weeks prior to the scheduled execution.

C. The condemned offender may be moved to a designated cell. Any keep-on-person (KOP) medication shall be confiscated and administered to the offender as needed by Unit Health Services staff.

II. Stays of Execution

A. Official notification of a stay of execution shall be delivered to the CID Director, the Death Row Unit Warden, and the Huntsville Unit Warden through the Huntsville Unit Warden's Office. **Staff must not accept a stay of execution from the offender's attorney.** After the official stay is received, the Death Row Unit Warden's office shall notify the Unit Classification Chief and Death Row Supervisor.

B. Designated staff on the Death Row Unit shall notify the offender that a stay of execution has been received.

III. Preparation of the Execution Summary and Packet

A. Two Weeks (14 days) Prior to the Execution

1. The Death Row Unit shall begin preparation of the Execution Summary. The Execution Summary (Form 2) and the Religious Orientation Statement (Form 3) shall be forwarded to the Death Row Supervisor or Warden's designee for completion. A copy of the offender's current visitation list and recent commissary activity shall also be provided.

2. The Death Row Supervisor shall arrange an interview with the condemned offender to gather the information necessary to complete the Execution Summary and Religious Orientation Statement.

3. An offender may request to have his body donated to the Texas State Anatomical Board for medical education and research. The appropriate paperwork shall be supplied to the offender upon request.

4. The Execution Summary must be completed and returned by the Death Row Supervisor or Warden's designee in sufficient time to be forwarded to the CID Director's Office by noon of the 14th day. After approval by the CID Director, the summary shall be forwarded to the Death Row Unit Chaplain, the Huntsville Unit Warden's Office, and the Communications Department.

5. If the offender wishes to change the names of his witnesses, and it is less than fourteen (14) days prior to the scheduled execution, the offender shall submit a request in writing to the CID Director through the Death Row Unit Warden, who shall approve or disapprove the changes.

6. The Death Row Unit is responsible for completion of the Execution Packet which shall include:
   a. Execution Summary;
   b. Religious Orientation Statement;
   c. Copy of the Offender Travel Card;
   d. Current Visitation List;
   e. Execution Watch Notification;
   f. Execution Watch Logs;
   g. I-25 Offender's Request for Trust Fund Withdrawal;
   h. Offender Property Documentation (PROP-05 and PROP-08); and
   i. Other documents as necessary.

7. The Death Row Supervisor or the Warden's designee shall notify staff (Form 4) to begin the Execution Watch Log (Form 5).

8. The Execution Watch Log shall begin at 6:00 a.m. seven (7) days prior to the scheduled execution. The seven (7) day timeframe shall not include the day of the execution. The offender shall be observed, logging his activities every 30 minutes for the first six (6) days and every 15 minutes for the remaining 36 hours. The Communications Department may request information from the Execution Watch Log on the day of execution.

9. The original Execution Packet and the offender's medical file shall be sent with the condemned offender in the transport vehicle to the Huntsville Unit or the Goree Unit for a female offender. The Death Row Unit Warden shall maintain a copy of the Execution Packet on the Death Row Unit.

10. If there are any changes necessary to the Execution Packet, staff shall notify the CID Director's Office and the Huntsville Unit Warden's Office.

B. The Day of Execution

1. On the morning of the day of the execution prior to final visitation, all of the offender's personal property shall be packed and inventoried. The property officer shall complete an "Offender Property Inventory" (PROP-05) detailing each item of the offender's property. The property officer shall also complete a "Disposition of Confiscated Offender Property" (PROP-08) indicating the offender's choice of disposition of personal property.

    a. If disposition is to be made from the Huntsville Unit a copy of the property forms should be maintained by the Death Row Unit Property Officer and the originals forwarded to the Huntsville Unit with the property.

    b. If disposition is to be made from the Death Row Unit a copy of the property forms will be placed in the Execution Packet and the original forms maintained on the Death Row Unit through the completion of the disposition process.

    c. The Mountain View Unit Warden shall ensure that a female offender brings personal hygiene and gender-specific items to the Huntsville Unit as appropriate.

2. Designated staff shall obtain the offender's current Trust Fund balance and prepare the Offender's Request for Trust Fund Withdrawal (I-25) for completion by the offender.

    a. The following statement should be written or typed on the reverse side of the I-25, "In the event of my execution, please distribute the balance of my Inmate Trust Fund account as directed by this Request for Withdrawal." The offender's name, number, signature, thumbprint, date, and time should be below this statement. Two (2) employees' names and signatures should be below the offender's signature as witnesses that the offender authorized the form.

    b. This Request for Withdrawal form shall be delivered to the Inmate Trust Fund for processing by 10:00 a.m. CST the next business day following the execution.

3. A female offender may be transported to the Goree unit prior to the day of the execution. The Execution Transport Log for Female Offenders (Form 7) shall be initiated at the Mountain View Unit. The Goree Unit staff will initiate the Execution Watch Log upon arrival on the Goree Unit, permit visitation as appropriate and transport the offender to the Huntsville Unit.

The Transport Log shall resume when the offender departs the Goree Unit.

4. The condemned offender shall be permitted visits with family and friends on the morning of the day of the scheduled execution. No media visits shall be allowed at the Goree Unit.

   NOTE: Special visits (minister, relatives not on the visitation list, attorney, and other similar circumstances) shall be approved by the Death Row or Goree Unit Warden or designee. Exceptions may be made to schedule as many family members to visit prior to the offender's scheduled day of execution. These are considered to be special visits. No changes shall be made to the offender's visitation list.

5. The Execution Watch Log shall be discontinued when the Execution Transport Log for Male Offenders (Form 6) is initiated.

6. When appropriate the offender shall be escorted to 12 building at the Polunsky or the designated area at the Mountain View or Goree Unit and placed in a holding cell. The appropriate Execution Transport Log shall be initiated and the offender shall be prepared for transport to the Huntsville Unit. The offender shall be removed from the transport vehicle at the Huntsville Unit and escorted by Huntsville Unit security staff into the execution holding area.

7. Any transportation arrangements for the condemned offender between units shall be known only to the Wardens involved, the CID Director, as well as those persons they designate as having a need to know. No public announcement shall be made concerning the exact time, method, or route of transfer. The CID Director's Office and the Communications Department shall be notified immediately after the offender arrives at the Huntsville Unit

8. When the offender enters the execution holding area the Execution Watch Log shall immediately resume. The restraints shall be removed and the offender strip-searched.

9. The offender shall be fingerprinted, placed in a holding cell, and issued a clean set of TDCJ clothing.

10. The Warden shall be notified after the offender has been secured in the holding cell. The Warden or designee shall interview the offender and review the information in the Execution Packet.

11. Staff from the Communications Department shall also visit with the offender to determine if he wishes to make a media statement and to obtain authorization, if necessary, to release the statement.

12. The offender may have visits with a TDCJ Chaplain(s), a Minister/Spiritual Advisor who has the appropriate credentials and his attorney(s) on the day of execution at the Huntsville Unit; however, the Huntsville Unit Warden must approve all visits.

13. There shall be no family or media visits allowed at the Huntsville Unit.

IV. Drug Team Qualifications and Training

A. The drug team shall have at least one medically trained individual. Each medically trained individual shall at least be certified or licensed as a certified medical assistant, phlebotomist, emergency medical technician, paramedic, or military corpsman. Each medically trained individual shall have one year of professional experience before participating as part of a drug team, shall retain current licensure, and shall fulfill continuing education requirements commensurate with licensure. Neither medically trained individuals nor any other members of the drug team shall be identified.

B. Each new member of the drug team shall receive training before participating in an execution without direct supervision. The training shall consist of following the drug team through at least two executions, receiving step-by-step instruction from existing team members. The new team member will then participate in at least two executions under the direct supervision of existing team members. Thereafter, the new team member may participate in executions without the direct supervision of existing team members.

C. The Huntsville Unit Warden shall review annually the training and current licensure, as appropriate, of each team member to ensure compliance with the required qualifications and training.

V. Pre-execution Procedures

A. The Huntsville Unit Warden's Office shall serve as the communication command post and entry to this area shall be restricted.

B. Inventory and Equipment Check

1. Designated staff on the Huntsville Unit are responsible for ensuring the purchase, storage, and control of all chemicals used in lethal injection executions for the State of Texas.

2. The drug team shall obtain all of the equipment and supplies necessary to perform the lethal injection from the designated storage area.

3. An inventory and equipment check shall be conducted.

4. Expiration dates of all applicable items are to be checked on each individual item. Outdated items shall be replaced immediately.

C. Minister/Spiritual Advisor and attorney visits shall occur between 3:00 and 4:00 p.m. CST unless exceptional circumstances exist. Exceptions may be granted under unusual circumstances as approved by the Huntsville Unit Warden.

D. The offender shall be served his last meal at approximately 4:00 p.m. CST.

E. The offender shall be afforded an opportunity to shower and shall be provided with clean clothes at some time prior to 6:00 p.m. CST.

F. Only TDCJ security personnel shall be permitted in the execution chamber. The CID Director or designee and the Huntsville Unit Warden or designee shall accompany the offender while in the Execution Chamber. TDCJ Chaplains and Ministers/Spiritual Advisors designated by the offender may observe the execution only from the witness rooms.

VI. Set up Preparations for the Lethal Injection

A. One (1) syringe of normal saline shall be prepared by members of the drug team.

B. The lethal injection drug shall be mixed and syringes shall be prepared by members of the drug team as follows:

Pentobarbital - 100 milliliters of solution containing 5 grams of Pentobarbital.

C. The drug team shall have available a back-up set of the normal saline syringe and the lethal injection drug in case unforeseen events make their use necessary.

VII. Execution Procedures

A. After 6:00 p.m. CST and after confirming with the Office of the Attorney General and the Governor's Office that no further stays, if any, will be imposed and that imposition of the court's order should proceed, the CID Director or designee shall give the order to escort the offender into the execution chamber.

B. The offender shall be escorted from the holding cell into the Execution Chamber and secured to the gurney.

C. A medically trained individual shall insert intravenous (IV) catheters into a suitable vein of the condemned person. If a suitable vein cannot be discovered in an arm, the medically trained individual shall substitute a suitable vein in another part of the body, but shall not use a "cut-down" procedure to access a suitable vein. The medically trained individual shall take as much time as is needed to properly insert the IV lines. The medically trained individual shall connect an IV administration set, and start a normal saline solution to flow at a slow rate through

one of the lines. The second line is started as a precaution and is used only if a potential problem is identified with the primary line. The CID Director or designee, the Huntsville Unit Warden or designee, and the medically trained individual shall observe the IV to ensure that the rate of flow is uninterrupted.

D. Witnesses to the execution shall be brought into the appropriate viewing area ONLY AFTER the Saline IV has been started and is running properly, as instructed by the Huntsville Unit Warden or designee.

E. The CID Director or designee shall give the order to commence with the execution.

F. The Huntsville Unit Warden or designee shall allow the condemned person to make a brief, last statement.

G. The Huntsville Unit Warden or designee shall instruct the drug team to induce, by syringe, substances necessary to cause death.

H. The flow of normal saline through the IV shall be discontinued.

I. The lethal dose of Pentobarbital shall be commenced. When the entire contents of the syringe have been injected, the line shall be flushed with an injection of normal saline.

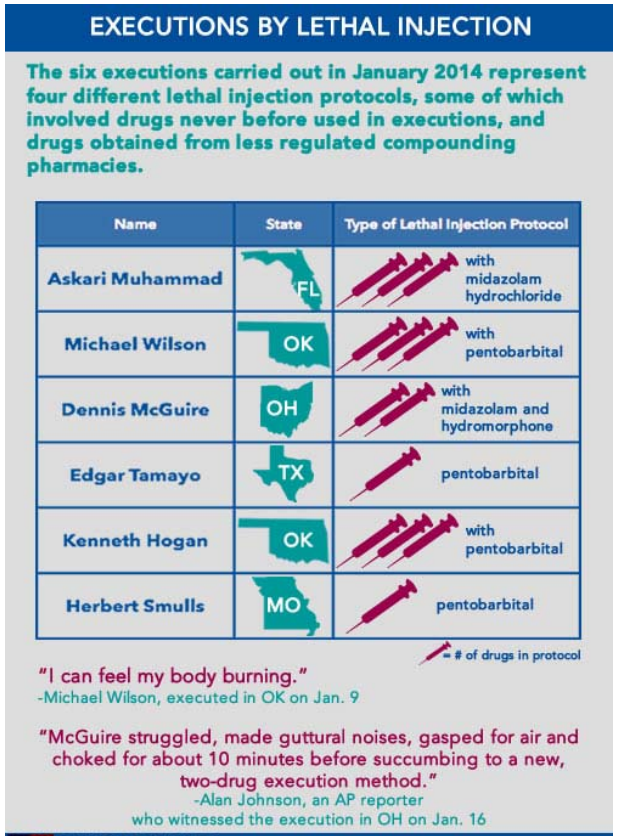
J. The CID Director or designee and the Huntsville Unit Warden or designee shall observe the appearance of the condemned individual during application of the Pentobarbital. If, after a sufficient time for death to have occurred, the condemned individual exhibits visible signs of life, the CID Director or designee shall instruct the drug team to administer an additional 5 grams of Pentobarbital followed with a saline flush.

K. At the completion of the process and after a sufficient time for death to have occurred, the Warden shall direct the physician to enter the Execution Chamber to examine the offender, pronounce the offender's death, and designate the official time of death.

L. The body shall be immediately removed from the Execution Chamber and transported by a coordinating funeral home. Arrangements for the body should be concluded prior to execution.

VIII. Employee participants in the Execution Process shall not be identified or their names released to the public. They shall receive an orientation with the Huntsville, Goree, Polansky, or Mountain View Unit Wardens, who shall inform the employees of the TDCJ ED-06.63, "Crisis Response Intervention Support Program" (CRISP). The employees shall be encouraged to contact the Regional CRISP Team Leader following the initial participation in the execution process.

State by State Lethal Injection



Until 2009, most states used a three-drug combination for lethal injections: an anesthetic (usually sodium thiopental, until pentobarbital was introduced at the end of 2010), pancuronium bromide (a paralytic agent, also called Pavulon), and potassium chloride (stops the heart and causes death). Due to drug shortages, states have adopted new lethal-injection methods, including:

ONE DRUG: Eight states have used a single-drug method for executions--a lethal dose of an anesthetic (Arizona, Georgia, Idaho, Missouri, Ohio, South Dakota, Texas, and Washington). Six other states have at one point or another announced plans to use a one-drug protocol, but have not carried out such an execution (Arkansas, California, Kentucky, Louisiana, North Carolina, and Tennessee).

PENTOBARBITAL: Fourteen states have used **pentobarbital** in executions: Alabama, Arizona, Delaware, Florida, Georgia, Idaho, Mississippi, Missouri, Ohio, Oklahoma, South Carolina, South Dakota, Texas, and Virginia. Five additional states plan to use pentobarbital: Kentucky, Louisiana, Montana, North Carolina, and Tennessee. Colorado includes pentobarbital as a backup drug in its lethal-injection procedure.

MIDAZOLAM: Seven states have used **midazolam** as the first drug in the three-drug protocol: Florida, Ohio, Oklahoma, Alabama, Virginia, Arkansas, and Tennessee. Oklahoma used midazolam in the botched execution fo Clayton Lockett in April 2014, and Lockett died after the procedure was halted. Alabama's use of midazolam in the execution of Ronald Smith in December 2016, resulted in nearly fifteen minutes of Smith heaving and gasping for breath. Arkansas's use of use midazolam in four executions in April 2017 raised concerns and in the execution of Kenneth Williams, witnesses reported coughing, convulsing, lurching and jerking. In January 2017, Florida abandoned its use of midazolam as the first drug in its three-drug protocol and replaced it with etomidate. Two states have

used midazolam in a two-drug protocol consisting of midazolam and hydromorphone: Ohio (Dennis McGuire) and Arizona (Joseph Wood). Both of those executions, which were carried out in 2014, were prolonged and accompanied by the prisoners' gasping for breath. After its botched execution of McGuire, Ohio abandoned its use of midazolam in a two-drug protocol, but then in October 2016 decided to keep midazolam in a three-drug protocol. In December 2016, Arizona abandoned its use of midazolam in either a two-drug or a three-drug protocol. Three states have, at some point, proposed using midazolam in a two-drug protocol (Louisiana, Kentucky, and Oklahoma) but none of those states has followed through with that formula. Some states have proposed multiple protocols. Missouri administered midazolam to inmates as a sedative before the official execution protocol began.

FENTANYL: Nebraska first used fentanyl in the August 14, 2018 execution of Carey Dean Moore. Nevada has also announced that it will use fentanyl in combination with other drugs to carry out executions.

COMPOUNDING PHARMACIES: At least ten states have either used or intend to use compounding pharmacies to obtain their drugs for lethal injection. **South Dakota** carried out 2 executions in October 2012, obtaining drugs from compounders. **Missouri** first used pentobarbital from a compounding pharmacy in the November 20, 2013 execution of Joseph Franklin. **Texas** first used pentobarbital from a compounding pharmacy in the execution of Michael Yowell on October 9, 2013. **Georgia** used drugs from an unnamed compounding pharmacy for an execution on June 17, 2014. **Oklahoma** has used drugs from compounding pharmacies in executions, including in the botched execution of Lockett. **Virginia** first used compounded pentobarbital obtained through the Texas Department of Criminal Justice in the execution of Alfredo Prieto on October 1, 2015. **Ohio** announced plans to obtain drugs from compounding pharmacies in October, 2013. In March 2014, **Mississippi** announced plans to use pentobarbital from a compounding pharmacy. Documents released in January 2014, show that **Louisiana** had contacted a compounding pharmacy regarding execution drugs, but it is unclear whether the drugs were obtained there. **Pennsylvania** may have obtained drugs from a compounder, but has not used them. **Colorado** sent out inquiries to compounding pharmacies for lethal injection drugs, but all executions are on hold.

ALTERNATE METHODS: Six states have laws allowing for alternative execution methods if lethal-injection drugs are unavailable. **Alabama** (effective July 2018), **Mississippi (**effective April 2017), and **Oklahoma** (effective November 2015) all have laws that allow for use of nitrogen hypoxia. **Tennessee**'s law allows for the use of the electric chair. **Utah**'s law allows the firing squad to be used if the state cannot obtain lethal-injection drugs 30 days before an execution. **New Hampshire** allows for hanging "if for any reason the commissioner [of corrections] finds it to be impractical to carry out the punishment of death by administration of the required lethal substance or substances." For detailed information about states' methods of executions, **see Methods of Execution**.

In **federal** executions, the method is lethal injection, which was the method used in all three of the federal executions in the modern era have been by lethal injection carried out in a federal facility in Indiana. Apparently, a three-drug combination was used, though prison officials did not reveal the exact ingredients. (See Washington Post, Dec. 5, 2000). The **U.S. Military** has not carried out any executions since reinstatement. It plans to use lethal injection.

LETHAL INJECTION "FIRSTS"

First state to use lethal injection: **Texas**, December 7, 1982

First state to use one-drug method: **Ohio**, December 8, 2009 (single drug was sodium thiopental)

First state to use pentobarbital in three-drug protocol: **Oklahoma**, December 16, 2010

First state to use pentobarbital in one-drug protocol: **Ohio**, March 10, 2011

First state to use midazolam in three-drug protocol: **Florida**, October 15, 2013

First state to use midazolam in two-drug protocol: **Ohio**, January 16, 2014

First state to use etimodate in three-drug protocol: **Florida**, August 24, 2017

First state to use fentanyl in four-drug protocol: **Nebraska**, August 14, 2018

For the specific drug formulas used in individual executions, see: Executions in 2009, Executions in 2010, Executions in 2011, Executions in 2012, Executions in 2013, Executions in 2014, Executions in 2015, Executions in 2016, Executions in 2017, Executions in 2018, and Executions in 2019.

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
Alabama	Not publicly available	3-drug, beginning with midazolam (1/21/16-2/7/19, 8 executions)	3-drug, beginning with pentobarbital (5/19/11-7/25/13, 5 executions) 3-drug, beginning with sodium thiopental (12/12/02-3/31/11, 27 executions)	Litigation ongoing, but executions may proceed	There is no statute that requires secrecy, but it is the position of the Department generally that the lethal-injection protocol is confidential and outside the purview of a public records request.
Arizona	Eff. June 17, 2017	2-drug, midazolam and hydromorphone (7/23/14, 1 execution)	1-drug pentobarbital (2/29/12-10/23/13, 8 executions) 3-drug, beginning with pentobarbital (5/25/11-7/19/11, 3 executions)	Lawsuit settled, and court dismissed case on June 22, 2017.	The protocol states, in part: "The anonymity of any person, as defined in A.R.S. § 1-215(28) and A.R.S. § 13-105(30), who participates in or performs any ancillary function(s) in the execution, including the source of the execution chemicals, and any information contained in records that would identify those persons are, as required by statute, to remain confidential and are not subject to disclosure. A.R.S. § 13-757 (C)." (First appeared in protocol dated March 26, 2014)

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
			3-drug, beginning with sodium thiopental (3/3/93-3/29/11, 24 executions)		
Arkansas	Eff. Aug. 6, 2015	3-drug, beginning with midazolam (4/20/17-4/27/17, 4 executions)	3-drug, beginning with sodium thiopental (6/25/90-11/28/05, 26 executions)	Litigation ongoing, but executions may proceed	Ark. Code Ann. §5-4-617 states, in part: "(i)(1) The procedures under subdivision (g)(1) of this section, the implementation of the procedures under subdivision (g)(1) of this section, and the identities of the entities and persons who participate in the execution process or administer the lethal injection are not subject to disclosure under the Freedom of Information Act of 1967, § 25-19-101 et seq."
California	Eff. March 2018	3-drug, beginning with sodium thiopental (2/23/96-1/17/06, 11 executions)	None	Litigation ongoing	
Colorado	Eff. May 2013	3-drug, beginning with sodium thiopental (10/13/97, 1 execution)	None	Executions on hold	
Florida	Eff. Jan. 4, 2017	3-drug beginning with etomidate (8/24/17-12/13/18, 5 executions)	3-drug, beginning with midazolam (10/15/13-1/7/16, 13 executions) 3-drug, beginning with pentobarbital (9/28/11-10/1/13, 10 executions)	Florida Supreme Court upheld the use of January 4, 2017 protocol, which uses the drug etomidate	Fla. Stat. Ann. §945.10 states, in part: "(1) Except as otherwise provided by law or in this section, the following records and information held by the Department of Corrections are confidential and exempt from the provisions [of public records act]. . . (g) Information which identifies an executioner, or any person prescribing, preparing, compounding, dispensing, or administering a lethal injection."

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
			3-drug, beginning with sodium thiopental (2/23/00-2/16/10, 25 executions)		
Georgia	Eff. July 17, 2012	1-drug pentobarbital (2/21/13-5/4/18, 20 executions)	3-drug, beginning with pentobarbital (6/23/11-9/21/11, 3 executions) 3-drug, beginning with sodium thiopental (10/25/01-1/25/11, 26 executions)		Ga. Code Ann. §42-5-36(d)(2) states, in part: "The identifying information of any person or entity who participates in or administers the execution of a death sentence and the identifying information of any person or entity that manufactures, supplies, compounds, or prescribes the drugs, medical supplies, or medical equipment utilized in the execution of a death sentence shall be confidential and shall not be subject to disclosure under Article 4 of Chapter 18 of Title 50 or under judicial process. Such information shall be classified as a confidential state secret."
Idaho	Eff. Jan 6, 2012	1-drug pentobarbital (6/12/12, 1 execution)	3-drug, beginning with pentobarbital (11/18/11, 1 execution) 3-drug, beginning with sodium thiopental (1/6/94, 1 execution)		Idaho Administrative Code 06.01.01.135 states, in part: "The Department will not disclose (under any circumstance) the identity of the on-site physician; or staff, contractors, consultants, or volunteers serving on escort or medical teams; nor will the Department disclose any other information wherein the disclosure of such information could jeopardize the Department's ability to carry out an execution."
Indiana	Eff. Jan. 22, 2014	3-drug, beginning with sodium thiopental (7/18/96-12/11/09, 17 executions)	None	On February 13, 2018, the **Indiana Supreme Court** ruled that the Department of Corrections	Ind. Code §35-38-6-1 states, in part: "(f)The following are confidential, are not subject to discovery, and may not be introduced as evidence in any civil or criminal proceeding: (1) The identity of [a pharmacist, a pharmacy, a wholesale drug distributor, or an outsourcing facility that provides a lethal substance to the

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
				can make changes to drugs used in lethal-injection protocol without having to follow rules under the Administrative Procedures Act, which would require—among other things—public comment before a new protocol could take effect.	department of correction] . . . necessary to carry out an execution by lethal injection. (2) The identity of an officer, an employee, or a contractor of a person described in subdivision (1). (3) The identity of a person contracted by a person described in subdivision (1) to obtain equipment or a substance to facilitate the compounding of a lethal substance described... (4) Information reasonably calculated to lead to the identity of a person described in this subsection"
Kansas	No current protocol in place	No executions carried out.	None		Kan. Stat. Ann. §22-4001 states, in part: "The identity of executioners and other persons designated to assist in carrying out the sentence of death shall be confidential."
Kentucky	Proposed Protocol Jan. 12. 2018 (subject to approval)	3-drug, beginning with sodium thiopental (5/25/99-11/21/08, 2 executions)	None	Litigation ongoing	Ky. Rev. Stat. §45A.720 states, in part: "Agreements with an individual to provide the services of executioner for the Department of Corrections shall not be subject to the provisions of KRS 45A.690 to 45A.725. The identity of an individual performing the services of executioner shall remain confidential and shall not be considered as public record for the purposes of KRS 61.870 to 61.884."
Louisiana	Not publicly available	3-drug, beginning with sodium thiopental (3/5/93-1/7/10, 8 executions)	None	Litigation ongoing; court order blocking executions extended indefinitely on January 5, 2018.	La. Rev. Stat. §15:570 states, in part: "G. The identity of any persons other than the persons specified in Subsection F of this Section who participate or perform ancillary functions in an execution of the death sentence, either directly or indirectly, shall remain strictly confidential and the identities of those persons and information

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
					about those persons which could lead to the determination of the identities of those persons shall not be subject to public disclosure in any manner. Any information contained in records that could identify any person other than the persons specified in Subsection F of this Section shall remain confidential, shall not be subject to disclosure, and shall not be admissible as evidence nor discoverable in any proceeding before any court, tribunal, board, agency, or person."
Mississippi	Eff. Nov. 15, 2017	3-drug, beginning with pentobarbital (5/10/11-6/20/12, 8 executions)	3-drug, beginning with sodium thiopental (7/17/02-7/21/10, 9 executions)	Litigation ongoing	Miss. Code Ann. §99-19-51 states, in part: "The identities of all members of the execution team, a supplier of lethal injection chemicals, and the identities of those witnesses listed in Section 99-19-55(2) who attend as members of the victim's or the condemned person's immediate family shall at all times remain confidential, and the information is exempt from disclosure under the provisions of the Mississippi Public Records Act of 1983.1"
Missouri	Eff. Oct. 18, 2013	1-drug pentobarbital (11/20/13-1/31/17, 20 executions)	3-drug, beginning with sodium thiopental (1/6/89-2/9/11, 68 executions)		Mo. Rev. Stat. 546.720 states, in part: "The identities of members of the execution team, as defined in the execution protocol of the department of corrections, shall be kept confidential. Notwithstanding any provision of law to the contrary, any portion of a record that could identify a person as being a current or former member of an execution team shall be privileged and shall not be subject to discovery, subpoena, or other means of legal compulsion for disclosure to any person or entity, the remainder of such record shall not be privileged or closed unless protected from disclosure by law."

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
					Protocol was amended in October 2013 to expand the definition of execution team: "The execution team consists of department employees and contracted medical personnel including a physician, nurse, and pharmacist. The execution team also consists of anyone selected by the department director who provides direct support for the administration of lethal chemicals, including individuals who prescribe, compound, prepare, or otherwise supply the chemicals for use in the lethal injection procedure."
Montana	Eff. Jan. 16, 2013	3-drug, beginning with sodium thiopental (5/10/95-8/11/06, 3 executions)	None	In October 2015, judge found the 2013 protocol violated state law. No updated protocol; litigation ongoing.	Mont. Code Ann. § 46-19-103 states, in part: "The identity of the executioner must remain anonymous. Facts pertaining to the selection and training of the executioner must remain confidential."
Nebraska	2016; announced 4-drug protocol on Nov. 9, 2017	4-drug: diazepam, fentanyl citrate, cisatracurium besylate, potassium chloride (8/14/18, one execution)	None		Neb. Rev. St. § 83-967 states, in part: "(2) The identity of all members of the execution team, and any information reasonably calculated to lead to the identity of such members, shall be confidential and exempt from disclosure pursuant to sections 84-712 to 84-712.09 and shall not be subject to discovery or introduction as evidence in any civil proceeding unless extraordinary good cause is shown and a protective order is issued by a district court limiting dissemination of such information."
Nevada	Eff. June 11, 2018.	3-drug, beginning with sodium thiopental	None	Litigation challenging protocol ongoing	

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
		(12/6/85-4/26/06, 11 executions)			
New Hampshire		No executions carried out.	None		
New Mexico		3-drug, beginning with sodium thiopental (11/6/01, 1 execution)	None		
North Carolina	Eff. Oct. 24, 2013	3-drug, beginning with sodium thiopental (3/16/84-8/18/06, 41 executions)	None	Litigation ongoing	N.C. Gen Stat. Ann. § 132-1.2 states, in part: "Nothing in this Chapter shall be construed to require or authorize a public agency or its subdivision to disclose any information that: . . . (7) Reveals name, address, qualifications, and other identifying information of any person or entity that manufactures, compounds, prepares, prescribes, dispenses, supplies, or administers the drugs or supplies obtained for any purpose authorized by Article 19 of Chapter 15 of the General Statutes."
Ohio	Eff. Oct. 7, 2016	3-drug, beginning with midazolam (7/27/17-7/18/18, 3 executions)	2-drug, midazolam and hydromorphone (1/16/14, 1 execution) 1-drug pentobarbital (3/10/11-9/25/13, 10 executions) 1-drug sodium thiopental (12/8/09-2/17/11, 10 executions) 3-drug, beginning with sodium thiopental	Litigation ongoing; On 6/28/2017, the Sixth Circuit Court of Appeals (en banc) reversed the lower court's issuance of a preliminary injunction regarding lethal-injection protocol.	Ohio Rev. Code Ann. § 2949.221 states, in part: "(B) If, at any time prior to the day that is twenty-four months after the effective date of this section, a person manufactures, compounds, imports, transports, distributes, supplies, prescribes, prepares, administers, uses, or tests any of the compounding equipment or components, the active pharmaceutical ingredients, the drugs or combination of drugs, the medical supplies, or the medical equipment used in the application of a lethal injection of a drug or combination of drugs in the administration of a death sentence by lethal injection as provided for in division (A) of section 2949.22 of the Revised Code, notwithstanding any provision of law to the

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
			(2/19/99-8/18/09, 32 executions)		contrary, all of the following apply regarding any information or record in the possession of any public office that identifies or reasonably leads to the identification of the person and the person's participation in any activity described in this division: (1) The information or record shall be classified as confidential, is privileged under law, and is not subject to disclosure by any person, state agency, governmental entity, board, or commission or any political subdivision as a public record under section 149.43 of the Revised Code or otherwise."
Oklahoma	No current protocol in place	3-drug: midazolam, pancuronium bromide, potassium acetate (1/15/15, 1 execution)	3-drug, beginning with midazolam (4/29/14, 1 execution) 3-drug, beginning with pentobarbital (12/16/10-1/23/14, 16 executions) 3-drug, beginning with sodium thiopental (9/10/90-10/14/10, 93 executions)	Executions placed on hold per court order during pending lethal injection litigation.	Okla. Stat. Ann. tit. 22, §1015 states: "(B) . . . . The identity of all persons who participate in or administer the execution process and persons who supply the drugs, medical supplies or medical equipment for the execution shall be confidential and shall not be subject to discovery in any civil or criminal proceedings. The purchase of drugs, medical supplies or medical equipment necessary to carry out the execution shall not be subject to the provisions of the Oklahoma Central Purchasing Act."
Oregon	Eff. March 2017	3-drug, beginning with sodium thiopental (9/6/96-5/16/97, 2 executions)	None	Governor-imposed moratorium	"(3) Selection of Executioner(s): The selection of the executioner(s) will be the responsibility of the Superintendent. The identity of the executioner(s) will remain confidential." Oregon Admin. Rule 291-024-0016
Pennsylvania			None		

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
	Eff. Aug. 28, 2012; revision Eff. Nov. 7, 2012	3-drug, beginning with sodium thiopental (5/2/95-7/6/99, 3 executions)		Governor-imposed moratorium	"(c) Confidentiality.--The identity of department employees, department contractors or victims who participate in the administration of an execution pursuant to this section shall be confidential." 61 Pa. Stat. and Cons. Stat. Ann. § 4305
South Carolina	Not publicly available	3-drug, beginning with pentobarbital (5/6/11, 1 execution)	3-drug, beginning with sodium thiopental (8/18/95-5/8/09, 35 executions)		S.C. Code §24-3-580 states, in part: "A person may not knowingly disclose the identity of a current or former member of an execution team or disclose a record that would identify a person as being a current or former member of an execution team."
South Dakota	Eff. Oct. 15, 2015	1-drug pentobarbital (10/15/12-10/29/18, 3 executions)	3-drug, beginning with sodium thiopental (7/11/07, 1 execution)		S.D. Codified Law §23A-27A-31.2 states, in part: "The name, address, qualifications, and other identifying information relating to the identity of any person or entity supplying or administering the intravenous injection substance or substances under chapter 23A-27A are confidential. Disclosure of the foregoing information may not be authorized or ordered."
Tennessee	Eff. Jan. 8, 2018	3-drug, beginning with midazolam (8/9/18, one execution)	3-drug, beginning with sodium thiopental (4/19/00-12/02/09, 5 executions)	Litigation ongoing.	Tenn. Code Ann. §10-7-504 states, in part: "(h) (1) Notwithstanding any other law to the contrary, those parts of the record identifying an individual or entity as a person or entity who or that has been or may in the future be directly involved in the process of executing a sentence of death shall be treated as confidential and shall not be open to public inspection. For the purposes of this section “person or entity” includes, but is not limited to, an employee of the state who has training related to direct involvement in the process of executing a sentence of death, a contractor or employee of a contractor, a volunteer who has direct involvement in the process of executing a

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
					sentence of death, or a person or entity involved in the procurement or provision of chemicals, equipment, supplies and other items for use in carrying out a sentence of death."
Texas	Eff. July 2012	1-drug pentobarbital (7/18/12-2/28/19, 78 executions)	3-drug, beginning with pentobarbital (5/3/11-4/26/12, 16 executions) 3-drug, beginning with sodium thiopental (12/7/82-2/22/11, 466 executions)		Tex. Crim. Proc. Code Ann. art. 43.14 states, in part: "(b) The name, address, and other identifying information of the following is confidential and excepted from disclosure under Section 552.021, Government Code: (1) any person who participates in an execution procedure described by Subsection (a), including a person who uses, supplies, or administers a substance during the execution; and (2) any person or entity that manufactures, transports, tests, procures, compounds, prescribes, dispenses, or provides a substance or supplies used in an execution."
Utah	Eff. June 10, 2010	3-drug, beginning with sodium thiopental (8/28/87-10/15/99, 4 executions)	None		There is no statute that requires secrecy, but it is the position of the Department generally that the lethal-injection protocol is confidential and outside the purview of a public records request.
Virginia	Eff. Feb. 7, 2017	3-drug, beginning with midazolam (1/18/17-7/6/17, 2 executions)	3-drug, beginning with pentobarbital (8/18/11-10/1/15, 2 executions) 3-drug, beginning with sodium thiopental (1/24/95-9/23/10, 78 executions)		Va. Code. §53.1-234 states, in part: "The identities of any pharmacy or outsourcing facility that enters into a contract with the Department for the compounding of drugs necessary to carry out an execution by lethal injection, any officer or employee of such pharmacy or outsourcing facility, and any person or entity used by such pharmacy or outsourcing facility to obtain equipment or substances to facilitate the compounding of such drugs and any information reasonably calculated to lead to the identities of such persons or entities, including their names, residential and office addresses, residential and office telephone numbers, social security

State	Link to current protocol	Most recently-used execution protocol	Previous protocols (Dates used, # of executions)	Status of protocol	Secrecy policies or statutes
					numbers, and tax identification numbers, shall be confidential, shall be exempt from the Freedom of Information Act (§ 2.2-3700 et seq.), and shall not be subject to discovery or introduction as evidence in any civil proceeding unless good cause is shown."
Washington		1-drug sodium thiopental (9/10/10, 1 execution)	3-drug, beginning with sodium thiopental (10/13/98-8/28/01, 2 executions)	Governor-imposed moratorium	
Wyoming		3-drug, beginning with sodium thiopental (1/22/92, 1 execution)	None		Wyo. Code § 7-13-916 (2015): “The identities of all persons who participate in the execution of a death sentence as a member of the execution team or by supplying or manufacturing the equipment and substances used for the execution are confidential. Disclosure of the identities made confidential by this section may not be authorized or ordered.”
U.S. Government	No current protocol in place	3-drug, beginning with sodium thiopental (6/11/01-3/18/03, 3 executions)	None		
U.S. Military	Eff. Jan. 2007	No executions carried out	None		

Prior Protocols

- **Arizona:** Jan. 11, 2017 protocol
- **California:** May 15, 2007 proposed protocol
- **Delaware**: Aug. 31, 2007 protocol
- **Florida:** Sept. 9, 2013 protocol; May 9, 2007 protocol
- **Georgia:** June 7, 2007 protocol
- **Louisiana:** June 17, 2013 protocol
- **Oklahoma:** Sept. 30, 2014 protocol
- **Ohio:** June 29, 2015 protocol; Sept. 18, 2011 protocol; Nov. 30, 2009 protocol
- **Kentucky's execution protocol**, issued in three parts: pre-execution procedures, protocol for medical and psychological evaluations prior to an execution, and change to one-drug protocol, allowing for use of either sodium thiopental or pentobarbital (July 20, 2012, public hearing to be held September 25, 2012)
- **Missouri:** May 15, 2012 protocol
- **Montana:** Jan. 16, 2013 protocol
- **Nevada:** Nov. 7, 2017 protocol
- **Tennessee:** June 25, 2015 protocol; Apr. 30, 2007 protocol
- **U.S. Military**: Jan. 2007 protocol

Related Links:

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FLORIDA

Current Protocol

Florida's current three-drug protocol:

1. etomidate,
2. rocuronium bromide, and
3. potassium acetate.

Etomidate is administered by intravenous injection for the induction of general anesthesia and sedation. In this context, it sedates the individual rendering them unconscious. Etomidate is also known by its brand name "Amidate."

Context

From 2000 to 2010, Florida executed 25 individuals using a three-drug protocol whereby the first drug used was sodium thiopental. However, that drug became unavailable as anti-death-penalty advocates pressured pharmaceutical companies to refuse to supply the drugs for use in executions.

Florida and other states then replaced sodium thiopental with pentobarbital. From 2011 to 2013, Florida executed 10 individuals using a three-drug protocol wherein pentobarbital was the first drug administered. However, pentobarbital became unavailable for use in executions.

In October 2013, Florida became the first state to substitute midazolam for pentobarbital as part of a three-drug protocol. Florida executed 13 individuals using a lethal injection protocol with midazolam as the first drug without any reported problems. Arthur v. Alabama Department of Corrections, 840 F.3d 1268, 1304 (11th Cir. 2016). However, Florida encountered difficulties acquiring midazolam.

In January 2017, Florida adopted a new three-drug protocol because it was unable to acquire midazolam. In its new protocol, Florida substituted etomidate for midazolam as the first drug, followed by rocuronium bromide and potassium acetate. The Florida Supreme Court upheld the use of etomidate as part of the lethal injection protocol. Asay v. State of Florida, 224 So.3d 695 (Fla. 2017). Florida has executed two individuals using this protocol.

- Fourteen states have used pentobarbital in their lethal injection protocol, either as part of a three-drug combination or as a single-drug method.

- The following states currently use a single-drug pentobarbital protocol:

    - Georgia
    - Idaho
    - Missouri
    - South Dakota
    - Texas

- The following states currently have lethal injection protocols that use pentobarbital as part of a three-drug combination:

    - Mississippi
    - South Carolina

- The following states previously used pentobarbital, either as part of a three-drug combination or by itself, in executions:

    - Alabama
    - Arizona
    - Delaware (state declared death penalty unconstitutional in 2016)
    - Florida
    - Ohio
    - Oklahoma
    - Virginia

- Since 2010, pentobarbital was used as part of a single or three-drug combination in 208 executions.

- Of the 25 executions in 2018, 16 used a single-drug pentobarbital protocol.

- Of the ten executions thus far in 2019, five used a single-drug pentobarbital protocol.

Source: https://deathpenaltyinfo.org/executions/lethal-injection/state-by-state-lethal-injection-protocols

KeyCite Yellow Flag - Negative Treatment
Distinguished by Price v. Commissioner, Department of Corrections, 11th Cir.(Ala.), April 10, 2019

139 S.Ct. 1112
Supreme Court of the United States.

Russell BUCKLEW, Petitioner
v.
Anne L. PRECYTHE, Director, Missouri Department of Corrections, et al.

No. 17-8151
|
Argued November 6, 2018
|
Decided April 1, 2019

Synopsis

Background: State death-row inmate brought § 1983 action challenging the constitutionality of Missouri's lethal injection method of execution, a single-drug protocol using the sedative pentobarbital. The United States District Court for the Western District of Missouri, Beth Phillips, J., 2014 WL 2736014, denied inmate's motion for a preliminary injunction and stay of execution, and dismissed his complaint for failure to state a claim. Inmate appealed. On rehearing en banc, the United States Court of Appeals for the Eighth Circuit, Loken, Circuit Judge, 783 F.3d 1120, reversed and remanded. On remand, the District Court, Beth Phillips, J., granted summary judgment in favor of defendants. Inmate appealed. The Court of Appeals, Loken, Circuit Judge, 883 F.3d 1087, affirmed. Certiorari was granted.

Holdings: The Supreme Court, Justice Gorsuch, held that:

[1] a state death-row inmate asserting an as-applied constitutional challenge to a State's method of execution must meet the same standard that would apply to a facial challenge;

[2] inmate failed to offer evidence that his proposed alternative method of execution, which would use nitrogen hypoxia as a lethal gas, was feasible and readily implemented; and

[3] inmate failed to offer evidence that his proposed alternative method of execution would significantly reduce the allegedly substantial risk of severe pain.

Affirmed.

Justice Thomas filed a concurring opinion.

Justice Kavanaugh filed a concurring opinion.

Justice Breyer filed a dissenting opinion, in which Justices Ginsburg, Sotomayor, and Kagan joined in part.

Justice Sotomayor filed a dissenting opinion.

West Headnotes (24)

[1] Constitutional Law
Capital Punishment;Death Penalty
Sentencing and Punishment
Constitutionality of death penalty

The Constitution allows capital punishment, because death was the standard penalty for all serious crimes at the time of the founding, the later addition of the Eighth Amendment did not outlaw the practice, and the Fifth Amendment, added to the Constitution at the same time as the Eighth Amendment, expressly contemplates that a defendant may be tried for a capital crime and deprived of life as a penalty, so long as proper procedures are followed. U.S. Const. Amends. 5, 8.

Cases that cite this headnote

[2] Constitutional Law
Capital Punishment;Death Penalty
Sentencing and Punishment
Constitutionality of death penalty

The same Constitution that permits States to authorize capital punishment also allows them to outlaw it, and that means that the judiciary bears no license to end a debate reserved for the people and their representatives. U.S. Const. Amends. 5, 8.

Cases that cite this headnote

[3] **Sentencing and Punishment**
Mode of execution

"Cruel and unusual punishments," which are prohibited by the Eighth Amendment, include dragging a prisoner to the place of execution, disemboweling, quartering, public dissection, and burning alive. U.S. Const. Amend. 8.

Cases that cite this headnote

[4] **Sentencing and Punishment**
Death penalty as cruel or unusual punishment

The punishment of death is not "cruel," within the meaning of that word as used in the Eighth Amendment, because cruelty implies something inhuman and barbarous, something more than the mere extinguishment of life. U.S. Const. Amend. 8.

Cases that cite this headnote

[5] **Sentencing and Punishment**
Mode of execution

The Eighth Amendment's prohibition of cruel and unusual punishments does not guarantee a death-row inmate a painless death, which is something that is not guaranteed to many people, including most victims of capital crimes. U.S. Const. Amend. 8.

Cases that cite this headnote

[6] **Sentencing and Punishment**
Mode of execution

What unites the punishments the Eighth Amendment was understood to forbid, and distinguishes them from those it was understood to allow, is that the former were long disused, or unusual, forms of punishment that intensified the sentence of death with a cruel superaddition of terror, pain, or disgrace. U.S. Const. Amend. 8.

Cases that cite this headnote

[7] **Sentencing and Punishment**
Mode of execution

Where the question in dispute is whether the State's chosen method of execution cruelly superadds pain to the death sentence, a prisoner must show a feasible and readily implemented alternative method of execution that would significantly reduce a substantial risk of severe pain, which the State has refused to adopt without a legitimate penological reason. U.S. Const. Amend. 8.

3 Cases that cite this headnote

[8] **Sentencing and Punishment**
Mode of execution

The Eighth Amendment does not demand the avoidance of all risk of pain in carrying out executions, and to the contrary, the Constitution affords a measure of deference to a State's choice of execution procedures and does not authorize courts to serve as boards of inquiry charged with determining best practices for executions. U.S. Const. Amend. 8.

Cases that cite this headnote

[9] **Sentencing and Punishment**
Mode of execution

The traditionally accepted methods of execution, such as hanging, the firing squad, electrocution, and lethal injection, are not necessarily rendered unconstitutional as soon as an arguably more humane method becomes available, because there are many legitimate reasons why a State might choose, consistent with the Eighth Amendment, not to adopt a prisoner's preferred method of execution. U.S. Const. Amend. 8.

Cases that cite this headnote

[10] **Sentencing and Punishment**
Mode of execution

A state death-row inmate asserting an as-applied constitutional challenge, under the Eighth Amendment's prohibition of cruel and unusual punishments, to a State's method of execution must meet the same standard that would apply to a facial challenge under *Baze v. Rees*, 128 S.Ct. 1520, and *Glossip v. Gross*, 135 S.Ct. 2726, by showing an alternative that is feasible and readily implemented and that in fact significantly reduces a substantial risk of severe pain, which the State has refused to adopt without a legitimate penological reason. U.S. Const. Amend. 8.

2 Cases that cite this headnote

[11] Sentencing and Punishment
Mode of execution

Distinguishing between constitutionally permissible and impermissible degrees of pain for an execution, under the Eighth Amendment's prohibition of cruel and unusual punishments, is a necessarily comparative exercise, and to decide whether the State has cruelly superadded pain to the punishment of death is not something that can be accomplished by examining the State's proposed method in a vacuum, but only by comparing that method with a viable alternative. U.S. Const. Amend. 8.

Cases that cite this headnote

[12] Sentencing and Punishment
Mode of execution

The Eighth Amendment standard for whether a method of execution is cruel and unusual punishment is not that executions must always be carried out painlessly if they can be carried out painlessly most of the time. U.S. Const. Amend. 8.

Cases that cite this headnote

[13] Constitutional Law
Facial invalidity

Constitutional Law
Invalidity as applied

A facial constitutional challenge is really just a claim that the law or policy at issue is unconstitutional in all its applications, and thus, classifying a lawsuit as facial or as-applied affects the extent to which the invalidity of the challenged law must be demonstrated and the corresponding breadth of the remedy, but it does not speak at all to the substantive rule of law necessary to establish a constitutional violation; surely it would be strange for the same words of the Constitution to bear entirely different meanings depending only on how broad a remedy the plaintiff chooses to seek.

1 Cases that cite this headnote

[14] Sentencing and Punishment
Mode of execution

An inmate seeking to identify an alternative method of execution, when alleging that a State's method of execution is cruel and unusual punishment in violation of the Eighth Amendment, is not limited to choosing among those presently authorized by a particular State's law, and so, for example, a prisoner may point to a well-established protocol in another State as a potentially viable option. U.S. Const. Amend. 8.

2 Cases that cite this headnote

[15] Sentencing and Punishment
Mode of execution

State death-row inmate failed to offer evidence that his proposed alternative method of execution, which would use nitrogen hypoxia as a lethal gas instead of Missouri's single-drug protocol for lethal injection using the sedative pentobarbital, was feasible and readily implemented, in § 1983 action asserting as-applied challenge under Eighth Amendment's prohibition of cruel and unusual punishments; inmate offered no evidence on essential questions like how nitrogen gas should be administered, in what concentration, how quickly and how long it should be introduced, or how the State

might ensure the safety of the execution team, including protecting them against the risk of gas leaks. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

Cases that cite this headnote

[16] Sentencing and Punishment
Mode of execution

For a state death-row inmate's proposed alternative method of execution to be readily implemented, the inmate's proposal must be sufficiently detailed to permit a finding that the State could carry it out relatively easily and reasonably quickly. U.S. Const. Amend. 8.

Cases that cite this headnote

[17] Sentencing and Punishment
Mode of execution

When a state death-row inmate proposes an alternative method of execution, in an Eighth Amendment challenge to a State's method of execution, the State's choice not to be the first to experiment with a new method of execution is a legitimate reason to reject the inmate's proposal. U.S. Const. Amend. 8.

2 Cases that cite this headnote

[18] Sentencing and Punishment
Mode of execution

The Eighth Amendment prohibits States from dredging up archaic cruel punishments or perhaps inventing new ones, but it does not compel a State to adopt untried and untested, and thus unusual in the constitutional sense, methods of execution. U.S. Const. Amend. 8.

Cases that cite this headnote

[19] Sentencing and Punishment
Mode of execution

State death-row inmate failed to offer evidence that his proposed alternative method of execution, which involved using nitrogen hypoxia as a lethal gas instead of Missouri's single-drug protocol for lethal injection using the sedative pentobarbital, would significantly reduce the allegedly substantial risk of severe pain, in § 1983 action asserting as-applied challenge under Eighth Amendment's prohibition of cruel and unusual punishments, alleging that inmate's medical condition from the disease cavernous hemangioma, which caused vascular tumors, i.e., clumps of blood vessels, to grow in his head, neck, and throat, could cause him to experience pain during a semiconscious twilight stage between the pentobarbital starting to take effect and the pentobarbital rendering him fully unconscious. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

Cases that cite this headnote

[20] Sentencing and Punishment
Mode of execution

For a state death-row inmate's proposed alternative method of execution to significantly reduce a substantial risk of severe pain, a minor reduction in risk is insufficient; the difference must be clear and considerable. U.S. Const. Amend. 8.

2 Cases that cite this headnote

[21] Federal Civil Procedure
Scope

Federal Civil Procedure
Identity and location of witnesses and others

Federal Civil Procedure
Persons Whose Depositions May Be Taken

Refusal to allow state death-row inmate to conduct discovery in order to learn the identities of members of the lethal injection execution team, to depose team members, or to inquire into their qualifications, training, and experience, was not an abuse of discretion, in prisoner's § 1983 action asserting Eighth Amendment challenge to state's lethal injection protocol; discovery into such granular matters was not relevant

because prisoner argued that there was no way he could be constitutionally executed by lethal injection, even with modifications to the State's lethal injection protocol. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

Cases that cite this headnote

[22] Sentencing and Punishment
Execution of Sentence

Both the State and the victims of crime have an important interest in the timely enforcement of a sentence.

Cases that cite this headnote

[23] Sentencing and Punishment
Mode of execution

Sentencing and Punishment
Stay of execution

The proper role of courts is to ensure that method-of-execution challenges to lawfully issued death sentences are resolved fairly and expeditiously, and courts should police carefully against attempts to use such challenges as tools to interpose unjustified delay; last-minute stays should be the extreme exception, not the norm, and the last-minute nature of a stay application that could have been brought earlier, or an applicant's attempt at manipulation, may be grounds for denial of a stay. U.S. Const. Amend. 8.

2 Cases that cite this headnote

[24] Sentencing and Punishment
Mode of execution

If method-of-execution litigation by a state death-row inmate is allowed to proceed, federal courts can and should protect settled state judgments from undue interference by invoking their equitable powers to dismiss or curtail suits that are pursued in a dilatory fashion or that are based on speculative theories.

Cases that cite this headnote

Syllabus [*]

**1 In *Baze v. Rees*, 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420, a plurality of this Court concluded that a State's refusal to alter its execution protocol could violate the Eighth Amendment only if an inmate first identified a "feasible, readily implemented" alternative procedure that would "significantly reduce a substantial risk of severe pain." *Id.*, at 52, 128 S.Ct. 1520. A majority of the Court subsequently held *Baze*'s plurality opinion to be controlling. See *Glossip* v. *Gross*, 576 U.S. ——, 135 S.Ct. 2726, 192 L.Ed.2d 761.

Petitioner Russell Bucklew was convicted of murder and sentenced to death. The State of Missouri plans to execute him by lethal injection using a single drug, pentobarbital. Mr. Bucklew presented an as-applied Eighth Amendment challenge to the State's lethal injection protocol, alleging that, regardless whether it would cause excruciating pain for *all* prisoners, it would cause *him* severe pain because of his particular medical condition.

The District Court dismissed his challenge. The Eighth Circuit, applying the *Baze*-*Glossip* test, remanded the case to allow Mr. Bucklew to identify a feasible, readily implemented alternative procedure that would significantly reduce his alleged risk of pain. Eventually, Mr. Bucklew identified nitrogen hypoxia, but the District Court found the proposal lacking and granted the State's motion for summary judgment. The Eighth Circuit affirmed.

Held:

1. *Baze* and *Glossip* govern all Eighth Amendment challenges, whether facial or as-applied, alleging that a method of execution ***1117** inflicts unconstitutionally cruel pain. Pp. 1122 – 1129.

(a) The Eighth Amendment forbids "cruel and unusual" methods of capital punishment but does not guarantee a prisoner a painless death. See *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2731–2732. As originally understood, the Eighth Amendment tolerated methods of execution, like hanging, that involved a significant risk of pain, while forbidding as cruel only those methods that intensified the death sentence by "superadding" terror, pain, or

disgrace. To establish that a State's chosen method cruelly "superadds" pain to the death sentence, a prisoner must show a feasible and readily implemented alternative method that would significantly reduce a substantial risk of severe pain and that the State has refused to adopt without a legitimate penological reason. *Baze*, 553 U.S. at 52, 128 S.Ct. 1520; *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2732–2738. And *Glossip* left no doubt that this standard governs "all Eighth Amendment method-of-execution claims." *Id.*, at ——, 135 S.Ct., at 2731. *Baze* and *Glossip* recognized that the Constitution affords a "measure of deference to a State's choice of execution procedures" and does not authorize courts to serve as "boards of inquiry charged with determining 'best practices' for executions." *Baze,* 553 U.S. at 51–52, 128 S.Ct. 1520. Nor do they suggest that traditionally accepted methods of execution are necessarily rendered unconstitutional as soon as an arguably more humane method becomes available. Pp. 1122 – 1126.

(b) Precedent forecloses Mr. Bucklew's argument that methods posing a "substantial and particular risk of grave suffering" when applied to a particular inmate due to his "unique medical condition" should be considered "categorically" cruel. Because distinguishing between constitutionally permissible and impermissible degrees of pain is a *necessarily* comparative exercise, the Court held in *Glossip*, identifying an available alternative is "a requirement of all Eighth Amendment method-of-execution claims" alleging cruel pain. 576 U.S., at ——, 135 S.Ct., at 2731. Mr. Bucklew's argument is also inconsistent with the original and historical understanding of the Eighth Amendment on which *Baze* and *Glossip* rest: When it comes to determining whether a punishment is unconstitutionally cruel because of the pain involved, the law has always asked whether the punishment superadds pain well beyond what's needed to effectuate a death sentence. And answering that question has always involved a comparison with available alternatives, not an abstract exercise in "categorical" classification. The substantive meaning of the Eighth Amendment does not change depending on how broad a remedy the plaintiff chooses to seek. Mr. Bucklew's solution also invites pleading games, and there is little likelihood that an inmate facing a serious risk of pain will be unable to identify an available alternative. Pp. 1125 – 1129.

**2 2. Mr. Bucklew has failed to satisfy the *Baze*-*Glossip* test. Pp. 1128 – 1133.

(a) He fails for two independent reasons to present a triable question on the viability of nitrogen hypoxia as an alternative to the State's lethal injection protocol. First, an inmate must show that his proposed alternative method is not just theoretically "feasible" but also " 'readily implemented,' " *Glossip*, 576 U.S., at —— – ——, 135 S.Ct., at 2737–2738. This means the inmate's proposal must be sufficiently detailed to permit a finding that the State could carry it out relatively easily and reasonably quickly. Mr. Bucklew's proposal falls well short of that standard. He presented no evidence on numerous questions essential to implementing his preferred method; instead, he merely pointed to reports from correctional authorities in ***1118** other States indicating the need for additional study to develop a nitrogen hypoxia protocol. Second, the State had a "legitimate" reason for declining to switch from its current method of execution as a matter of law, *Baze*, 553 U.S. at 52, 128 S.Ct. 1520, namely, choosing not to be the first to experiment with a new, "untried and untested" method of execution. *Id.*, at 41, 128 S.Ct. 1520. Pp. 1128 – 1130.

(b) Even if nitrogen hypoxia were a viable alternative, neither of Mr. Bucklew's theories shows that nitrogen hypoxia would significantly reduce a substantial risk of severe pain. First, his contention that the State may use painful procedures to administer the lethal injection, including forcing him to lie flat on his back (which he claims could impair his breathing even before the pentobarbital is administered), rests on speculation unsupported, if not affirmatively contradicted, by the record. And to the extent the record is unclear, he had ample opportunity to conduct discovery and develop a factual record concerning the State's planned procedures. Second, Mr. Bucklew contends that while either method will cause him to experience feelings of suffocation for some period of time before he is rendered fully unconscious, the duration of that period will be shorter with nitrogen than with pentobarbital. But nothing in the record suggests that he will be capable of experiencing pain for significantly more time after receiving pentobarbital than he would after receiving nitrogen. His claim to the contrary rested on his expert's testimony regarding a study of euthanasia in horses that everyone now agrees the expert misunderstood or misremembered. Pp. 1130 – 1133.

883 F.3d 1087, affirmed.

GORSUCH, J., delivered the opinion of the Court, in which ROBERTS, C.J., and THOMAS, ALITO, and KAVANAUGH, JJ., joined. THOMAS, J., and KAVANAUGH, J., filed concurring opinions. BREYER, J., filed a dissenting opinion, in which GINSBURG, SOTOMAYOR, and KAGAN, JJ., joined as to all but Part III. SOTOMAYOR, J., filed a dissenting opinion.

Attorneys and Law Firms

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Joshua D. Hawley, Attorney General, Office of the Missouri, Attorney General, Jefferson City, MO, D. John Sauer, State Solicitor, Joshua M. Divine, Julie Marie Blake, Peter T. Reed, Deputy Solicitors, Michael Joseph Spillane, Assistant Attorney General, for Respondents.

Opinion

Justice GORSUCH delivered the opinion of the Court.

Russell Bucklew concedes that the State of Missouri lawfully convicted him of murder and a variety of other crimes. He acknowledges that the U.S. Constitution permits a sentence of execution for his crimes. He accepts, too, that the State's lethal injection protocol is constitutional in most applications. But because of his unusual medical condition, he contends the protocol is unconstitutional as applied to him. Mr. Bucklew raised this claim for the first time less than two weeks before his scheduled execution. He received a stay of execution and five years to pursue the argument, but in the end neither the district court nor the Eighth Circuit found it ***1119** supported by the law or evidence. Now, Mr. Bucklew asks us to overturn those judgments. We can discern no lawful basis for doing so.

I

A

****3** In 1996, when Stephanie Ray announced that she wanted to end their relationship, Mr. Bucklew grew violent. He cut her jaw, punched her in the face, and threatened her with a knife. Frightened to remain in the home they had shared, Ms. Ray sought refuge with her children in Michael Sanders' nearby residence. But then one night Mr. Bucklew invaded that home. Bearing a pistol in each hand, he shot Mr. Sanders in the chest; fired at Mr. Sanders' 6-year-old son (thankfully, he missed); and pistol-whipped Ms. Ray, this time breaking her jaw. Then Mr. Bucklew handcuffed Ms. Ray, drove her to a secluded spot, and raped her at gunpoint. After a trooper spotted Mr. Bucklew, a shootout followed and he was finally arrested. While all this played out, Mr. Sanders bled to death. As a coda, Mr. Bucklew escaped from jail while awaiting trial and attacked Ms. Ray's mother with a hammer before he could be recaptured.

After a decade of litigation, Mr. Bucklew was seemingly out of legal options. A jury had convicted him of murder and other crimes and recommended a death sentence, which the court had imposed. His direct appeal had proved unsuccessful. *State v. Bucklew*, 973 S.W.2d 83 (Mo. 1998), cert. denied, 525 U.S. 1082, 119 S.Ct. 826, 142 L.Ed.2d 683 (1999). Separate rounds of state and federal post-conviction proceedings also had failed to yield relief. *Bucklew v. State*, 38 S.W.3d 395 (Mo.), cert. denied, 534 U.S. 964, 122 S.Ct. 374, 151 L.Ed.2d 284 (2001); *Bucklew v. Luebbers*, 436 F.3d 1010 (CA8), cert. denied, 549 U.S. 1079, 127 S.Ct. 725, 166 L.Ed.2d 565 (2006).

B

As it turned out, though, Mr. Bucklew's case soon became caught up in a wave of litigation over lethal injection procedures. Like many States, Missouri has periodically sought to improve its administration of the death penalty. Early in the 20th century, the State replaced hanging with the gas chamber. Later in the century, it authorized the use of lethal injection as an alternative to lethal gas. By the time Mr. Bucklew's post-conviction proceedings ended, Missouri's protocol called for lethal injections to be carried out using three drugs: sodium thiopental, pancuronium bromide, and potassium chloride. And by that time, too, various inmates were in the process of challenging the constitutionality of the State's protocol and others like it around the country. See *Taylor v. Crawford*, 457 F.3d 902 (CA8 2006); Note, A New

Test for Evaluating Eighth Amendment Challenges to Lethal Injections, 120 Harv. L. Rev. 1301, 1304 (2007) (describing flood of lethal injection lawsuits around 2006 that "severely constrained states' ability to carry out executions"); Denno, The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty, 76 Ford. L. Rev. 49, 102–116 (2007).

Ultimately, this Court answered these legal challenges in *Baze v. Rees*, 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008). Addressing Kentucky's similar three-drug protocol, THE CHIEF JUSTICE, joined by Justice ALITO and Justice Kennedy, concluded that a State's refusal to alter its lethal injection protocol could violate the Eighth Amendment only if an inmate first identified a "feasible, readily implemented" alternative procedure that would "significantly reduce a substantial risk of severe pain." *Id.*, at 52, 128 S.Ct. 1520. Justice ***1120** THOMAS, joined by Justice Scalia, thought the protocol passed muster because it was not intended "to add elements of terror, pain, or disgrace to the death penalty." *Id.*, at 107, 128 S.Ct. 1520. Justice BREYER reached the same result because he saw no evidence that the protocol created "a significant risk of unnecessary suffering." *Id.*, at 113, 128 S.Ct. 1520. And though Justice Stevens objected to the continued use of the death penalty, he agreed that petitioners' evidence was insufficient. *Id.*, at 87, 128 S.Ct. 1520. After this Court decided *Baze*, it denied review in a case seeking to challenge Missouri's similar lethal injection protocol. *Taylor v. Crawford*, 487 F.3d 1072 (CA8 2007), cert. denied, 553 U.S. 1004, 128 S.Ct. 2047, 170 L.Ed.2d 793 (2008).

But that still was not the end of it. Next, Mr. Bucklew and other inmates unsuccessfully challenged Missouri's protocol in state court, alleging that it had been adopted in contravention of Missouri's Administrative Procedure Act. *Middleton v. Missouri Dept. of Corrections*, 278 S.W.3d 193 (Mo.), cert. denied, 556 U.S. 1255, 129 S.Ct. 2430, 173 L.Ed.2d 1331 (2009). They also unsuccessfully challenged the protocol in federal court, this time alleging it was pre-empted by various federal statutes. *Ringo v. Lombardi*, 677 F.3d 793 (CA8 2012). And Mr. Bucklew sought to intervene in yet another lawsuit alleging that Missouri's protocol violated the Eighth Amendment because unqualified personnel might botch its administration. That lawsuit failed too. *Clemons v. Crawford*, 585 F.3d 1119 (CA8 2009), cert. denied, 561 U.S. 1026, 130 S.Ct. 3507, 177 L.Ed.2d 1092 (2010).

****4** While all this played out, pressure from anti-death-penalty advocates induced the company that manufactured sodium thiopental to stop supplying it for use in executions. As a result, the State was unable to proceed with executions until it could change its lethal injection protocol again. This it did in 2012, prescribing the use of a single drug, the sedative propofol. Soon after that, Mr. Bucklew and other inmates sued to invalidate this new protocol as well, alleging that it would produce excruciating pain and violate the Eighth Amendment on its face. After the State revised the protocol in 2013 to use the sedative pentobarbital instead of propofol, the inmates amended their complaint to allege that pentobarbital would likewise violate the Constitution.

C

Things came to a head in 2014. With its new protocol in place and the necessary drugs now available, the State scheduled Mr. Bucklew's execution for May 21. But 12 days before the execution Mr. Bucklew filed yet another lawsuit, the one now before us. In this case, he presented an as-applied Eighth Amendment challenge to the State's new protocol. Whether or not it would cause excruciating pain for *all* prisoners, as his previous lawsuit alleged, Mr. Bucklew now contended that the State's protocol would cause *him* severe pain because of his particular medical condition. Mr. Bucklew suffers from a disease called cavernous hemangioma, which causes vascular tumors—clumps of blood vessels—to grow in his head, neck, and throat. His complaint alleged that this condition could prevent the pentobarbital from circulating properly in his body; that the use of a chemical dye to flush the intravenous line could cause his blood pressure to spike and his tumors to rupture; and that pentobarbital could interact adversely with his other medications.

These latest protocol challenges yielded mixed results. The district court dismissed both the inmates' facial challenge and Mr. Bucklew's as-applied challenge. But, at Mr. ***1121** Bucklew's request, this Court agreed to stay his execution until the Eighth Circuit could hear his appeal. *Bucklew v. Lombardi*, 572 U.S. 1131, 134 S.Ct. 2333, 189 L.Ed.2d 206 (2014). Ultimately, the Eighth Circuit affirmed the dismissal of the facial challenge. *Zink v. Lombardi*, 783 F.3d 1089 (en banc) (*per curiam*), cert. denied, 576 U.S. ——, 135 S.Ct. 2941, 192 L.Ed.2d 976

(2015). Then, turning to the as-applied challenge and seeking to apply the test set forth by the *Baze* plurality, the court held that Mr. Bucklew's complaint failed as a matter of law to identify an alternative procedure that would significantly reduce the risks he alleged would flow from the State's lethal injection protocol. Yet, despite this dispositive shortcoming, the court of appeals decided to give Mr. Bucklew another chance to plead his case. The court stressed that, on remand before the district court, Mr. Bucklew had to identify "at the earliest possible time" a feasible, readily implemented alternative procedure that would address those risks. *Bucklew v. Lombardi*, 783 F.3d 1120, 1127–1128 (2015) (en banc).

Shortly after the Eighth Circuit issued its judgment, this Court decided *Glossip* v. *Gross*, 576 U.S. ——, 135 S.Ct. 2726, 192 L.Ed.2d 761 (2015), rejecting a challenge to Oklahoma's lethal injection protocol. There, the Court clarified that THE CHIEF JUSTICE's plurality opinion in *Baze* was controlling under *Marks v. United States*, 430 U.S. 188, 97 S.Ct. 990, 51 L.Ed.2d 260 (1977). In doing so, it reaffirmed that an inmate cannot successfully challenge a method of execution under the Eighth Amendment unless he identifies "an alternative that is 'feasible, readily implemented, and in fact significantly reduces a substantial risk of severe pain.' " 576 U.S., at ——– ——, 135 S.Ct., at 2737. Justice THOMAS, joined by Justice Scalia, reiterated his view that the Eighth Amendment "prohibits only those methods of execution that are deliberately designed to inflict pain," but he joined the Court's opinion because it correctly explained why petitioners' claim failed even under the controlling opinion in *Baze*. *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2750 (internal quotation marks and alterations omitted).

D

**5 Despite the Eighth Circuit's express instructions, when Mr. Bucklew returned to the district court in 2015 he still refused to identify an alternative procedure that would significantly reduce his alleged risk of pain. Instead, he insisted that inmates should have to carry this burden only in facial, not as-applied, challenges. Finally, after the district court gave him "one last opportunity," App. 30, Mr. Bucklew filed a fourth amended complaint in which he claimed that execution by "lethal gas" was a feasible and available alternative method that would significantly reduce his risk of pain. *Id.*, at 42. Mr. Bucklew later clarified that the lethal gas he had in mind was nitrogen, which neither Missouri nor any other State had ever used to carry out an execution.

The district court allowed Mr. Bucklew "extensive discovery" on his new proposal. 883 F.3d 1087, 1094 (CA8 2018). But even at the close of discovery in 2017, the district court still found the proposal lacking and granted the State's motion for summary judgment. By this point in the proceedings, Mr. Bucklew's contentions about the pain he might suffer had evolved considerably. He no longer complained about circulation of the drug, the use of dye, or adverse drug interactions. Instead, his main claim now was that he would experience pain during the period after the pentobarbital started to take effect but before it rendered him fully unconscious. According to his expert, Dr. Joel Zivot, while in this semiconscious "twilight stage" Mr. *1122 Bucklew would be unable to prevent his tumors from obstructing his breathing, which would make him feel like he was suffocating. Dr. Zivot declined to say how long this twilight stage would last. When pressed, however, he referenced a study on euthanasia in horses. He claimed that the horses in the study had displayed some amount of brain activity, as measured with an electroencephalogram (or EEG), for up to four minutes after they were given a large dose of pentobarbital. Based on Dr. Zivot's testimony, the district court found a triable issue as to whether there was a "substantial risk" that Mr. Bucklew would "experience choking and an inability to breathe for up to four minutes" if he were executed by lethal injection. App. 827. Even so, the court held, Mr. Bucklew's claim failed because he had produced no evidence that his proposed alternative, execution by nitrogen hypoxia, would significantly reduce that risk.

This time, a panel of the Eighth Circuit affirmed. The panel held that Mr. Bucklew had produced no evidence that the risk of pain he alleged "would be substantially reduced by use of nitrogen hypoxia instead of lethal injection as the method of execution." 883 F.3d at 1096. Judge Colloton dissented, arguing that the evidence raised a triable issue as to whether nitrogen gas would "render Bucklew insensate more quickly than pentobarbital." *Id.*, at 1099. The full court denied rehearing en banc over a dissent by Judge Kelly, who maintained that, while prisoners pursuing facial challenges to a state execution protocol must plead and prove an alternative method of execution under *Baze* and *Glossip*, prisoners like Mr.

Bucklew who pursue as-applied challenges should not have to bear that burden. 885 F.3d 527, 528 (2018).

On the same day Mr. Bucklew was scheduled to be executed, this Court granted him a second stay of execution. 583 U.S. ——, 138 S.Ct. 1323, 200 L.Ed.2d 510 (2018). We then agreed to hear his case to clarify the legal standards that govern an as-applied Eighth Amendment challenge to a State's method of carrying out a death sentence. 584 U.S. —— (2018).

II

We begin with Mr. Bucklew's suggestion that the test for lethal injection protocol challenges announced in *Baze* and *Glossip* should govern only facial challenges, not as-applied challenges like his. In evaluating this argument, we first examine the original and historical understanding of the Eighth Amendment and our precedent in *Baze* and *Glossip*. We then address whether, in light of those authorities, it would be appropriate to adopt a different constitutional test for as-applied claims.

A

****6** **[1]** **[2]** The Constitution allows capital punishment. See *Glossip*, 576 U.S., at —— – ——, 135 S.Ct., at 2731–2733; *Baze*, 553 U.S. at 47, 128 S.Ct. 1520. In fact, death was "the standard penalty for all serious crimes" at the time of the founding. S. Banner, The Death Penalty: An American History 23 (2002) (Banner). Nor did the later addition of the Eighth Amendment outlaw the practice. On the contrary—the Fifth Amendment, added to the Constitution at the same time as the Eighth, expressly contemplates that a defendant may be tried for a "capital" crime and "deprived of life" as a penalty, so long as proper procedures are followed. And the First Congress, which proposed both Amendments, made a number of crimes punishable by death. See Act of Apr. 30, 1790, 1 Stat. 112. Of course, that doesn't mean the American people must continue to use the death penalty. The same Constitution that permits States to authorize capital punishment also allows them to outlaw ***1123** it. But it does mean that the judiciary bears no license to end a debate reserved for the people and their representatives.

While the Eighth Amendment doesn't forbid capital punishment, it does speak to how States may carry out that punishment, prohibiting methods that are "cruel and unusual." What does this term mean? At the time of the framing, English law still formally tolerated certain punishments even though they had largely fallen into disuse—punishments in which "terror, pain, or disgrace [were] superadded" to the penalty of death. 4 W. Blackstone, Commentaries on the Laws of England 370 (1769). These included such "[d]isgusting" practices as dragging the prisoner to the place of execution, disemboweling, quartering, public dissection, and burning alive, all of which Blackstone observed "savor[ed] of torture or cruelty." *Ibid.*

[3] Methods of execution like these readily qualified as "cruel and unusual," as a reader at the time of the Eighth Amendment's adoption would have understood those words. They were undoubtedly "cruel," a term often defined to mean "[p]leased with hurting others; inhuman; hard-hearted; void of pity; wanting compassion; savage; barbarous; unrelenting," 1 S. Johnson, A Dictionary of the English Language (4th ed. 1773), or "[d]isposed to give pain to others, in body or mind; willing or pleased to torment, vex or afflict; inhuman; destitute of pity, compassion or kindness," 1 N. Webster, An American Dictionary of the English Language (1828). And by the time of the founding, these methods had long fallen out of use and so had become "unusual." 4 Blackstone, *supra,* at 370; Banner 76; *Baze*, 553 U.S. at 97, 128 S.Ct. 1520 (THOMAS, J., concurring in judgment); see also Stinneford, The Original Meaning of "Unusual": The Eighth Amendment as a Bar to Cruel Innovation, 102 Nw. U. L. Rev. 1739, 1770–1771, 1814 (2008) (observing that Americans in the late 18th and early 19th centuries described as "unusual" governmental actions that had "fall[en] completely out of usage for a long period of time").

Contemporary evidence confirms that the people who ratified the Eighth Amendment would have understood it in just this way. Patrick Henry, for one, warned that unless the Constitution was amended to prohibit "cruel and unusual punishments," Congress would be free to inflict "tortures" and "barbarous" punishments. 3 Debates on the Federal Constitution 447–448 (J. Elliot 2d ed. 1891). Many early commentators likewise described the Eighth Amendment as ruling out "the use of the rack or the stake, or any of those horrid modes of torture devised by

human ingenuity for the gratification of fiendish passion." J. Bayard, A Brief Exposition of the Constitution of the United States 140 (1833); see B. Oliver, The Rights of an American Citizen 186 (1832) (the Eighth Amendment prohibits such "barbarous and cruel punishments" as "[b]reaking on the wheel, flaying alive, rending asunder with horses, ... maiming, mutilating and scourging to death"). Justice Story even remarked that he thought the prohibition of cruel and unusual punishments likely "unnecessary" because no "free government" would ever authorize "atrocious" methods of execution like these. 3 J. Story, Commentaries on the Constitution of the United States § 1896, p. 750 (1833).

7 [4] Consistent with the Constitution's original understanding, this Court in *Wilkerson v. Utah*, 99 U.S. 130, 25 L.Ed. 345 (1879), permitted an execution by firing squad while observing that the Eighth Amendment forbade the gruesome methods of execution described by Blackstone "and all others in the same line of unnecessary cruelty." *Id.*, at 135–136. A few years later, the Court upheld a sentence of death ***1124 by electrocution while observing that, though electrocution was a new mode of punishment and therefore perhaps could be considered "unusual," it was not "cruel" in the constitutional sense: "[T]he punishment of death is not cruel, within the meaning of that word as used in the Constitution. [Cruelty] implies ... something inhuman and barbarous, something more than the mere extinguishment of life." *In re Kemmler*, 136 U.S. 436, 447, 10 S.Ct. 930, 34 L.Ed. 519 (1890).

It's instructive, too, to contrast the modes of execution the Eighth Amendment was understood to forbid with those it was understood to permit. At the time of the Amendment's adoption, the predominant method of execution in this country was hanging. *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2731–2732. While hanging was considered more humane than some of the punishments of the Old World, it was no guarantee of a quick and painless death. "Many and perhaps most hangings were evidently painful for the condemned person because they caused death slowly," and "[w]hether a hanging was painless or painful seems to have been largely a matter of chance." Banner 48, 170. The force of the drop could break the neck and sever the spinal cord, making death almost instantaneous. But that was hardly assured given the techniques that prevailed at the time. More often it seems the prisoner would die from loss of blood flow to the brain, which could produce unconsciousness usually within seconds, or suffocation, which could take several minutes. *Id.*, at 46–47; J. Laurence, The History of Capital Punishment 44–46 (1960); Gardner, Executions and Indignities: An Eighth Amendment Assessment of Methods of Inflicting Capital Punishment, 39 Ohio St. L.J. 96, 120 (1978). But while hanging could and often did result in significant pain, its use "was virtually never questioned." Banner 170. Presumably that was because, in contrast to punishments like burning and disemboweling, hanging wasn't "*intended* to be painful" and the risk of pain involved was considered "unfortunate but inevitable." *Ibid.*; see also *id.*, at 48.

[5] **[6]** What does all this tell us about how the Eighth Amendment applies to methods of execution? For one thing, it tells us that the Eighth Amendment does not guarantee a prisoner a painless death—something that, of course, isn't guaranteed to many people, including most victims of capital crimes. *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2732–2733 Instead, what unites the punishments the Eighth Amendment was understood to forbid, and distinguishes them from those it was understood to allow, is that the former were long disused (unusual) forms of punishment that intensified the sentence of death with a (cruel) " 'superadd[ition]' " of " 'terror, pain, or disgrace.' " *Baze*, 553 U.S. at 48, 128 S.Ct. 1520; accord, *id.*, at 96, 128 S.Ct. 1520 (THOMAS, J., concurring in judgment).

This Court has yet to hold that a State's method of execution qualifies as cruel and unusual, and perhaps understandably so. Far from seeking to superadd terror, pain, or disgrace to their executions, the States have often sought more nearly the opposite, exactly as Justice Story predicted. Through much of the 19th century, States experimented with technological innovations aimed at making hanging less painful. See Banner 170–177. In the 1880s, following the recommendation of a commission tasked with finding " 'the most humane and practical method known to modern science of carrying into effect the sentence of death,' " the State of New York replaced hanging with electrocution. *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2731. Several States followed suit in the " ' "belief that electrocution is less painful ***1125** and more humane than hanging." ' " *Ibid.* Other States adopted lethal gas after concluding it was " 'the most humane [method of execution] known to modern science.' " *Ibid.* And beginning in the 1970s, the search for less painful modes of execution led many States to switch to lethal injection. *Id.*, at ——, 135 S.Ct., at 2732; *Baze*, 553 U.S. at 42, 62,

128 S.Ct. 1520; see also Banner 178–181, 196–197, 297. Notably, all of these innovations occurred not through this Court's intervention, but through the initiative of the people and their representatives.

**8 [7] Still, accepting the possibility that a State might try to carry out an execution in an impermissibly cruel and unusual manner, how can a court determine when a State has crossed the line? THE CHIEF JUSTICE's opinion in *Baze*, which a majority of the Court held to be controlling in *Glossip*, supplies critical guidance. It teaches that where (as here) the question in dispute is whether the State's chosen method of execution cruelly superadds pain to the death sentence, a prisoner must show a feasible and readily implemented alternative method of execution that would significantly reduce a substantial risk of severe pain and that the State has refused to adopt without a legitimate penological reason. See *Glossip*, 576 U.S., at ——– ——, 135 S.Ct., 2732–2738; *Baze*, 553 U.S. at 52, 128 S.Ct. 1520. *Glossip* left no doubt that this standard governs "all Eighth Amendment method-of-execution claims." 576 U.S., at ——, 135 S.Ct., at 2731.

[8] [9] In reaching this conclusion, *Baze* and *Glossip* recognized that the Eighth Amendment "does not demand the avoidance of all risk of pain in carrying out executions." *Baze*, 553 U.S. at 47, 128 S.Ct. 1520. To the contrary, the Constitution affords a "measure of deference to a State's choice of execution procedures" and does not authorize courts to serve as "boards of inquiry charged with determining 'best practices' for executions." *Id.*, at 51–52, and nn. 2–3, 128 S.Ct. 1520. The Eighth Amendment does not come into play unless the risk of pain associated with the State's method is "substantial when compared to a known and available alternative." *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2738; see *Baze*, 553 U.S. at 61, 128 S.Ct. 1520. Nor do *Baze* and *Glossip* suggest that traditionally accepted methods of execution—such as hanging, the firing squad, electrocution, and lethal injection—are necessarily rendered unconstitutional as soon as an arguably more humane method like lethal injection becomes available. There are, the Court recognized, many legitimate reasons why a State might choose, consistent with the Eighth Amendment, not to adopt a prisoner's preferred method of execution. See, *e.g.*, *Glossip*, 576 U.S., at ——– ——, 135 S.Ct., at 2737–2738 (a State can't be faulted for failing to use lethal injection drugs that it's unable to procure through good-faith efforts); *Baze*, 553 U.S. at 57, 128 S.Ct. 1520 (a State has a legitimate interest in selecting a method it regards as "preserving the dignity of the procedure"); *id.*, at 66, 128 S.Ct. 1520 (ALITO, J., concurring) (a State isn't required to modify its protocol in ways that would require the involvement of "persons whose professional ethics rules or traditions impede their participation").

As we've seen, two Members of the Court whose votes were essential to the judgment in *Glossip* argued that establishing cruelty consistent with the Eighth Amendment's original meaning demands slightly more than the majority opinion there (or the *Baze* plurality opinion it followed) suggested. Instead of requiring an inmate to establish that a State has unreasonably refused to alter its method of execution to avoid a risk of unnecessary pain, ***1126** Justice THOMAS and Justice Scalia contended that an inmate must show that the State *intended* its method to inflict such pain. See *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2750 (THOMAS, J., concurring); *Baze*, 553 U.S. at 94–107, 128 S.Ct. 1520 (THOMAS, J., concurring in judgment). But revisiting that debate isn't necessary here because, as we'll see, the State was entitled to summary judgment in this case even under the more forgiving *Baze*-*Glossip* test. See Part III, *infra*.

B

[10] Before turning to the application of *Baze* and *Glossip*, however, we must confront Mr. Bucklew's argument that a different standard entirely should govern as-applied challenges like his. He admits that *Baze* and *Glossip* supply the controlling test in facial challenges to a State's chosen method of execution. But he suggests that he should not have to prove an alternative method of execution in his as-applied challenge because "certain categories" of punishment are "manifestly cruel ... without reference to any alternative methods." Brief for Petitioner 41–42 (internal quotation marks omitted). He points to " 'burning at the stake, crucifixion, [and] breaking on the wheel' " as examples of "categorically" cruel methods. *Ibid.* And, he says, we should use this case to add to the list of "categorically" cruel methods any method that, as applied to a particular inmate, will pose a "substantial and particular risk of grave suffering" due to the inmate's "unique medical condition." *Id.*, at 44.

9 **[11] The first problem with this argument is that it's foreclosed by precedent. *Glossip* expressly held that identifying an available alternative is "a requirement of *all* Eighth Amendment method-of-execution claims" alleging cruel pain. 576 U.S., at ——, 135 S.Ct., at 2731 (emphasis added). And just as binding as this holding is the reasoning underlying it. Distinguishing between constitutionally permissible and impermissible degrees of pain, *Baze* and *Glossip* explained, is a *necessarily* comparative exercise. To decide whether the State has cruelly "superadded" pain to the punishment of death isn't something that can be accomplished by examining the State's proposed method in a vacuum, but only by "compar[ing]" that method with a viable alternative. *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2737–2738; see *Baze*, 553 U.S. at 61, 128 S.Ct. 1520. As Mr. Bucklew acknowledges when speaking of facial challenges, this comparison "provides the needed metric" to measure whether the State is lawfully carrying out an execution or inflicting "gratuitous" pain. Brief for Petitioner 42–43. Yet it is that very comparison and needed metric Mr. Bucklew would now have us discard. Nor does he offer some persuasive reason for overturning our precedent. To the contrary, Mr. Bucklew simply repeats the same argument the principal dissent offered and the Court expressly and thoughtfully rejected in *Glossip*. Just as Mr. Bucklew argues here, the dissent there argued that "certain methods of execution" like "burning at the stake" should be declared "categorically off-limits." And just as Mr. Bucklew submits here, the dissent there argued that any other "intolerably painful" method of execution should be added to this list. 576 U.S., at —— – ——, 135 S.Ct., at 2792–2793 (SOTOMAYOR, J., dissenting). Mr. Bucklew's submission, thus, amounts to no more than a headlong attack on precedent.

Mr. Bucklew's argument fails for another independent reason: It is inconsistent with the original and historical understanding of the Eighth Amendment on which *Baze* and *Glossip* rest. As we've seen, when it comes to determining whether *1127 a punishment is unconstitutionally cruel because of the pain involved, the law has always asked whether the punishment "superadds" pain well beyond what's needed to effectuate a death sentence. And answering that question has always involved a comparison with available alternatives, not some abstract exercise in "categorical" classification. At common law, the ancient and barbaric methods of execution Mr. Bucklew cites were understood to be cruel precisely because—by comparison to other available methods—they went so far beyond what was needed to carry out a death sentence that they could only be explained as reflecting the infliction of pain for pain's sake. Meanwhile, hanging carried with it an acknowledged and substantial risk of pain but was not considered cruel because that risk was thought—by comparison to other known methods—to involve no more pain than was reasonably necessary to impose a lawful death sentence. See *supra*, at 1122 – 1125.

What does the principal dissent have to say about all this? It acknowledges that *Glossip*'s comparative requirement helps prevent facial method-of-execution claims from becoming a "backdoor means to abolish" the death penalty. *Post*, at 1140 (opinion of BREYER, J.). But, the dissent assures us, there's no reason to worry that as-applied method-of-execution challenges might be used that way. This assurance misses the point. As we've explained, the alternative-method requirement is compelled by our understanding of the Constitution, not by mere policy concerns.

12 With that, the dissent is left only to rehash the same argument that Mr. Bucklew offers. The dissent insists that some forms of execution are just categorically cruel. *Post*, at 1141 – 1142. At first and like others who have made this argument, the dissent offers little more than intuition to support its conclusion. Ultimately, though, even it bows to the necessity of something firmer. If a "comparator is needed" to assess whether an execution is cruel, the dissent tells us, we should compare the pain likely to follow from the use of a lethal injection in this case with the pain-free use of lethal injections in mine-run cases. *Post*, at 1141. But that's just another way of saying executions must always be carried out painlessly because they can be carried out painlessly most of the time, a standard the Constitution has never required and this Court has rejected time and time again. *Supra*, at 1124 – 1125. To determine whether the State is cruelly superadding pain, our precedents and history require asking whether the State had some other feasible and readily available method to carry out its lawful sentence that would have significantly reduced a substantial risk of pain.

**10 That Mr. Bucklew and the dissent fail to respect the force of our precedents—or to grapple with the understanding of the Constitution on which our precedents rest—is more than enough reason to reject their view that as-applied and facial challenges should

be treated differently. But it turns out their position on this score suffers from further problems too—problems that neither Mr. Bucklew nor the dissent even attempts to address.

[13] Take this one. A facial challenge is really just a claim that the law or policy at issue is unconstitutional in all its applications. So classifying a lawsuit as facial or as-applied affects the extent to which the invalidity of the challenged law must be demonstrated and the corresponding "breadth of the remedy," but it does not speak at all to the substantive rule of law necessary to establish a constitutional violation. *Citizens United v. Federal Election Comm'n*, 558 U.S. 310, 331, 130 S.Ct. 876, 175 L.Ed.2d 753 (2010). Surely it would be strange for the same words of the Constitution ***1128** to bear entirely different meanings depending only on how broad a remedy the plaintiff chooses to seek. See *Gross v. United States*, 771 F.3d 10, 14–15 (CADC 2014) (" '[T]he substantive rule of law is the same for both [facial and as-applied] challenges' "); *Brooklyn Legal Servs. Corp. v. Legal Servs. Corp.*, 462 F.3d 219, 228 (CA2 2006) (the facial/as-applied distinction affects "*the extent to which* the invalidity of a statute need be demonstrated," not "the *substantive rule of law* to be used"). And surely, too, it must count for something that we have found not a single court decision in over 200 years suggesting that the Eighth Amendment's meaning shifts in this way. To the contrary, our precedent suggests just the opposite. In the related context of an Eighth Amendment challenge to conditions of confinement, we have seen "no basis whatever" for applying a different legal standard to "deprivations inflicted upon all prisoners" and those "inflicted upon particular prisoners." *Wilson v. Seiter*, 501 U.S. 294, 299, n. 1, 111 S.Ct. 2321, 115 L.Ed.2d 271 (1991).

Here's yet another problem with Mr. Bucklew's argument: It invites pleading games. The line between facial and as-applied challenges can sometimes prove "amorphous," *Elgin v. Department of Treasury*, 567 U.S. 1, 15, 132 S.Ct. 2126, 183 L.Ed.2d 1 (2012), and "not so well defined," *Citizens United*, 558 U.S. at 331, 130 S.Ct. 876. Consider an example. Suppose an inmate claims that the State's lethal injection protocol violates the Eighth Amendment when used to execute anyone with a very common but not quite universal health condition. Should such a claim be regarded as facial or as-applied? In another context, we sidestepped a debate over how to categorize a comparable claim—one that neither sought "to strike [the challenged law] in all its applications" nor was "limited to plaintiff's particular case"—by concluding that "[t]he label is not what matters." *Doe v. Reed*, 561 U.S. 186, 194, 130 S.Ct. 2811, 177 L.Ed.2d 493 (2010). To hold now, for the first time, that choosing a label changes the meaning of the Constitution would only guarantee a good deal of litigation over labels, with lawyers on each side seeking to classify cases to maximize their tactical advantage. Unless increasing the delay and cost involved in carrying out executions is the point of the exercise, it's hard to see the benefit in placing so much weight on what can be an abstruse exercise.

[14] Finally, the burden Mr. Bucklew must shoulder under the *Baze*-*Glossip* test can be overstated. An inmate seeking to identify an alternative method of execution is not limited to choosing among those presently authorized by a particular State's law. Missouri itself seemed to acknowledge as much at oral argument. Tr. of Oral Arg. 65. So, for example, a prisoner may point to a well-established protocol in another State as a potentially viable option. Of course, in a case like that a court would have to inquire into the possibility that one State possessed a legitimate reason for declining to adopt the protocol of another. See *supra*, at 1125 – 1126. And existing state law might be relevant to determining the proper procedural vehicle for the inmate's claim. See *Hill v. McDonough*, 547 U.S. 573, 582–583, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006) (if the relief sought in a 42 U.S.C. § 1983 action would "foreclose the State from implementing the [inmate's] sentence under present law," then "recharacterizing a complaint as an action for habeas corpus might be proper"). But the Eighth Amendment is the supreme law of the land, and the comparative assessment it requires can't be controlled by the State's choice of which methods to authorize in its statutes. In light of this, we see little likelihood that an inmate facing a serious risk of pain will be unable ***1129** to identify an available alternative—assuming, of course, that the inmate is more interested in avoiding unnecessary pain than in delaying his execution.

III

****11** Having (re)confirmed that anyone bringing a method of execution claim alleging the infliction of unconstitutionally cruel pain must meet the *Baze*-*Glossip* test, we can now turn to the question whether Mr. Bucklew

is able to satisfy that test. Has he identified a feasible and readily implemented alternative method of execution the State refused to adopt without a legitimate reason, even though it would significantly reduce a substantial risk of severe pain? Because the case comes to us after the entry of summary judgment, this appeal turns on whether Mr. Bucklew has shown a genuine issue of material fact warranting a trial.

A

[15] We begin with the question of a proposed alternative method. Through much of this case and despite many opportunities, Mr. Bucklew refused to identify *any* alternative method of execution, choosing instead to stand on his argument that *Baze* and *Glossip*'s legal standard doesn't govern as-applied challenges like his (even after the Eighth Circuit rejected that argument). Only when the district court warned that his continued refusal to abide this Court's precedents would result in immediate dismissal did Mr. Bucklew finally point to nitrogen hypoxia. The district court then afforded Mr. Bucklew "extensive discovery" to explore the viability of that alternative. 883 F.3d at 1094. But even after all that, we conclude Mr. Bucklew has failed for two independent reasons to present a triable question on the viability of nitrogen hypoxia as an alternative to the State's lethal injection protocol.

[16] *First*, an inmate must show that his proposed alternative method is not just theoretically " 'feasible' " but also " 'readily implemented.' " *Glossip*, 576 U.S., at —— – ——, 135 S.Ct., at 2737–2738. This means the inmate's proposal must be sufficiently detailed to permit a finding that the State could carry it out "relatively easily and reasonably quickly." *McGehee v. Hutchinson*, 854 F.3d 488, 493 (CA8 2017); *Arthur v. Commissioner, Ala. Dept. of Corrections*, 840 F.3d 1268, 1300 (CA11 2016). Mr. Bucklew's bare-bones proposal falls well short of that standard. He has presented no evidence on essential questions like how nitrogen gas should be administered (using a gas chamber, a tent, a hood, a mask, or some other delivery device); in what concentration (pure nitrogen or some mixture of gases); how quickly and for how long it should be introduced; or how the State might ensure the safety of the execution team, including protecting them against the risk of gas leaks. Instead of presenting the State with a readily implemented alternative method, Mr. Bucklew (and the principal dissent) point to reports from correctional authorities in other States indicating that additional study is needed to develop a protocol for execution by nitrogen hypoxia. See App. 697 (Oklahoma grand jury report recommending that the State "retain experts" and conduct "further research" to "determine how to carry out the sentence of death by this method"); *id.*, at 736 (report of Louisiana Dept. of Public Safety & Corrections stating that "[r]esearch ... is ongoing" to develop a nitrogen hypoxia protocol). That is a proposal for more research, not the readily implemented alternative that *Baze* and *Glossip* require.

[17] **[18]** *Second*, and relatedly, the State had a "legitimate" reason for declining to switch from its current method of ***1130** execution as a matter of law. *Baze*, 553 U.S. at 52, 128 S.Ct. 1520. Rather than point to a proven alternative method, Mr. Bucklew sought the adoption of an entirely new method—one that had "never been used to carry out an execution" and had "no track record of successful use." *McGehee*, 854 F.3d at 493. But choosing not to be the first to experiment with a new method of execution is a legitimate reason to reject it. In *Baze* we observed that "no other State ha[d] adopted" the one-drug protocol the inmates sought and they had "proffered no study showing" their one-drug protocol would be as effective and humane as the State's existing three-drug protocol. 553 U.S. at 57, 128 S.Ct. 1520. Under those circumstances, we held as a matter of law that Kentucky's refusal to adopt the inmates' proffered protocol could not "constitute a violation of the Eighth Amendment." *Ibid.* The Eighth Amendment prohibits States from dredging up archaic cruel punishments or perhaps inventing new ones, but it does not compel a State to adopt "untried and untested" (and thus unusual in the constitutional sense) methods of execution. *Id.*, at 41, 128 S.Ct. 1520. [1]

B

****12** **[19]** **[20]** Even if a prisoner can carry his burden of showing a readily available alternative, he must still show that it would significantly reduce a substantial risk of severe pain. *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2737–2738; *Baze*, 553 U.S. at 52, 128 S.Ct. 1520. A minor reduction in risk is insufficient; the difference must be clear and considerable. Over the course of this litigation, Mr. Bucklew's explanation why nitrogen hypoxia meets this standard has evolved significantly. But neither of the two

theories he has advanced in this Court turns out to be supported by record evidence.

First, Mr. Bucklew points to several risks that he alleges could result from use of the State's lethal injection protocol that would not be present if the State used nitrogen gas. For example, he says the execution team might try to insert an IV into one of his peripheral veins, which could cause the vein to rupture; or the team might instead use an allegedly painful "cut-down" procedure to access his femoral vein. He also says that he might be forced to lie flat on his back during the execution, which could impair his breathing even before the pentobarbital is administered. And he says the stress from all this could cause his tumors to bleed, further impairing his breathing. These risks, we may assume, would not exist if Mr. Bucklew were executed by his preferred method of nitrogen hypoxia.

The problem with all of these contentions is that they rest on speculation unsupported, if not affirmatively contradicted, by the evidence in this case. Nor does the principal dissent contend otherwise. ***1131** So, for example, uncontroverted record evidence indicates that the execution team will have discretion to adjust the gurney to whatever position is in Mr. Bucklew's best medical interests. 883 F.3d at 1092, n. 3; App. 531. Moreover, the State agreed in the district court that it would not try to place an IV in Mr. Bucklew's compromised peripheral veins. *Id.*, at 820; see Brief for Appellant in No. 17–3052 (CA8), p. 7. And, assuming without granting that using a cut-down would raise issues under the Eighth Amendment—but see *Nooner v. Norris*, 594 F.3d 592, 604 (CA8 2010) (holding otherwise)—the State's expert, Dr. Michael Antognini, testified without contradiction that it should be possible to place an IV in Mr. Bucklew's femoral vein without using a cut-down procedure, App. 350. Mr. Bucklew responds by pointing to the warden's testimony that he once saw medical staff perform a cut-down as part of an execution; but there's no evidence that what the warden saw was an attempt to access a femoral vein, as opposed to some other vein.

[21] Moreover, to the extent the record is unclear on any of these issues, Mr. Bucklew had ample opportunity to conduct discovery and develop a factual record concerning exactly what procedures the State planned to use. He failed to do so—presumably because the thrust of his constitutional claim was that *any* attempt to execute him via lethal injection would be unconstitutional, regardless of the specific procedures the State might use. As the court of appeals explained: "Having taken the position that *any* lethal injection procedure would violate the Eighth Amendment," Mr. Bucklew "made no effort to determine what changes, if any, the [State] would make in applying its lethal injection protocol" to him, and he "never urged the district court to establish a suitable fact-finding procedure ... to define the as-applied lethal injection protocol [the State] intends to use." 883 F.3d at 1095–1096. [2]

****13** *Second*, Mr. Bucklew contends that the lethal injection itself will expose him to a substantial risk of severe pain that could be eliminated by adopting his preferred method. He claims that once the sedative pentobarbital is injected he will "lose the ability to manage" the tumors in his airway and, as a result, will experience a "sense of suffocation" for some period of time before the State's sedative renders him fully unconscious. Brief for Petitioner 12–13. "It is during this in-between twilight stage," according to his expert, Dr. Zivot, "that Mr. Bucklew is likely to experience prolonged feelings of suffocation and excruciating pain." App. 234. Mr. Bucklew admits that similar feelings of suffocation could occur with nitrogen, the only difference being the potential duration of the so-called "twilight stage." He contends that with nitrogen the stage would last at most 20 to 30 seconds, while with pentobarbital it could last up to several minutes.

But here again the record contains insufficient evidence to permit Mr. Bucklew to avoid summary judgment. For starters, in the courts below Mr. Bucklew maintained he would have trouble managing his airway only if he were forced to lie supine, ***1132** which (as we've explained) the evidence shows he won't be. (The dissenters don't address this point.) But even indulging his new claim that he will have this difficulty regardless of position, he still has failed to present colorable evidence that nitrogen would significantly reduce his risk of pain. We can assume for argument's sake that Mr. Bucklew is correct that with nitrogen the twilight stage would last 20 to 30 seconds. The critical question, then, is how long that period might last with pentobarbital. The State's expert, Dr. Antognini, testified that pentobarbital, too, would render Mr. Bucklew fully unconscious and incapable of experiencing pain within 20 to 30 seconds. *Id.*, at 299–301, 432–433. Dr. Zivot disagreed; but when

he was asked how long he thought the twilight stage would last with pentobarbital, his testimony was evasive. Eventually, he said his "number would be longer than" 20 to 30 seconds, but he declined to say how much longer. *Id.*, at 195. Instead, he referenced a 2015 study on euthanasia in horses. He said the study found that when horses were given a large dose of pentobarbital (along with other drugs), they exhibited "isoelectric EEG"—a complete absence of detectable brain activity—after 52 to 240 seconds. *Id.*, at 194–196. The district court assumed Dr. Zivot meant that "pain might be felt until measurable brain activity ceases" and that, extrapolating from the horse study, it might take up to four minutes for pentobarbital to "induc[e] a state in which [Mr. Bucklew] could no longer sense that he is choking or unable to breathe." The district court acknowledged, however, that this might be "a generous interpretation of Dr. Zivot's testimony." *Id.*, at 822, and n. 5.

In fact, there's nothing in the record to suggest that Mr. Bucklew will be capable of experiencing pain for significantly more than 20 to 30 seconds after being injected with pentobarbital. For one thing, Mr. Bucklew's lawyer now admits that Dr. Zivot "crossed up the numbers" from the horse study. Tr. of Oral Arg. 7–8, 11–12. The study actually reported that the horses displayed isoelectric EEG between 2 and 52 seconds after infusion of pentobarbital was completed, with an average time of less than 24 seconds. App. 267. So if anything, the horse study appears to bolster Dr. Antognini's time estimate. For another thing, everyone now also seems to acknowledge that isoelectric EEG is the wrong measure. Dr. Zivot never claimed the horses were capable of experiencing pain until they reached isoelectric EEG. And Mr. Bucklew's lawyer now concedes that doctors perform major surgery on human patients with measurable EEG readings, which strongly suggests that Mr. Bucklew will be insensible to pain *before* reaching isoelectric EEG. Tr. of Oral Arg. 9. Finally, the record evidence even allows the possibility that nitrogen could *increase* the risk of pain. Because Dr. Zivot declined to testify about the likely effects of nitrogen gas, Mr. Bucklew must rely on Dr. Antognini's testimony. And while Dr. Antognini did say he thought nitrogen's "onset of action" could be "relatively fast," App. 458, he added that the effects of nitrogen could vary depending on exactly how it would be administered—information Mr. Bucklew hadn't provided. Indeed, he stated that "depending on ... how it's used, you might get more suffering from nitrogen gas than you would have" from the State's current protocol. *Id.*, at 460–461.

****14** Of course, the principal dissent maintains that Dr. Zivot's testimony supports an inference that pentobarbital might cause Mr. Bucklew to suffer for a prolonged period. But its argument rests on a number of mistakes about the record. For example, the dissent points to Dr. Zivot's remark that, with pentobarbital, ***1133** " 'the period of time between receiving the injection and death could range over a few minutes to many minutes.' " *Post*, at 1138, —— (quoting App. 222). From this, the dissent concludes that Mr. Bucklew may suffer for "up to several minutes." *Post*, at 1136, 1139, 1140 – 1141. But everyone agrees that the relevant question isn't how long it will take for Mr. Bucklew to die, but how long he will be capable of feeling pain. Seeking to address the problem, the dissent next points to *another* part of Dr. Zivot's testimony and says it means Mr. Bucklew could experience pain during the entire time between injection and death. *Post*, at 1139, 1142 – 1143 (quoting App. 222). But the dissent clips the relevant quotation. As the full quotation makes clear, Dr. Zivot claimed that Mr. Bucklew might be unable to "maintain the integrity of his airway" until he died—but he carefully avoided claiming that Mr. Bucklew would be capable of feeling pain until he died. [3] To avoid *this* problem, the dissent quotes Dr. Zivot's assertions that pentobarbital might not produce " 'rapid unconsciousness' " and that Mr. Bucklew's suffering with pentobarbital could be " 'prolonged.' " *Post*, at 1138 – 1139, 1142 – 1143 (quoting App. 233–234). But Dr. Zivot's statements here, too, fail to specify how long Mr. Bucklew is likely to be able to feel pain. The hard fact is that, when Dr. Zivot was *finally* compelled to offer a view on this question, his only response was to refer to the horse study. *Id.*, at 195–196. The dissent's effort to suggest that Dr. Zivot "did not rely exclusively or even heavily on that study," *post*, at 1139 – 1140, is belied by (among other things) Mr. Bucklew's own brief in this Court, which asserted that the twilight stage during which he might feel pain could last "between 52 and 240 seconds," based entirely on a citation of Dr. Zivot's incorrect testimony about the horse study. Brief for Petitioner 13.

In sum, even if execution by nitrogen hypoxia were a feasible and readily implemented alternative to the State's chosen method, Mr. Bucklew has still failed to present any evidence suggesting that it would significantly reduce his risk of pain. For that reason as well, the State was

entitled to summary judgment on Mr. Bucklew's Eighth Amendment claim. [4]

IV

[22] "Both the State and the victims of crime have an important interest in the timely enforcement of a sentence." *Hill*, 547 U.S. at 584, 126 S.Ct. 2096. Those interests have been frustrated in this case. Mr. Bucklew committed his crimes more than two decades ago. He exhausted his appeal and separate state and federal habeas challenges more than a decade ago. Yet since then he has managed to secure ***1134** delay through lawsuit after lawsuit. He filed his current challenge just days before his scheduled execution. That suit has now carried on for five years and yielded two appeals to the Eighth Circuit, two 11th-hour stays of execution, and plenary consideration in this Court. And despite all this, his suit in the end amounts to little more than an attack on settled precedent, lacking enough evidence even to survive summary judgment—and on not just one but many essential legal elements set forth in our case law and required by the Constitution's original meaning.

[23] **[24]** The people of Missouri, the surviving victims of Mr. Bucklew's crimes, and others like them deserve better. Even the principal dissent acknowledges that "the long delays that now typically occur between the time an offender is sentenced to death and his execution" are "excessive." *Post*, at 1144. The answer is not, as the dissent incongruously suggests, to reward those who interpose delay with a decree ending capital punishment by judicial fiat. *Post*, at 1145. Under our Constitution, the question of capital punishment belongs to the people and their representatives, not the courts, to resolve. The proper role of courts is to ensure that method-of-execution challenges to lawfully issued sentences are resolved fairly and expeditiously. Courts should police carefully against attempts to use such challenges as tools to interpose unjustified delay. Last-minute stays should be the extreme exception, not the norm, and "the last-minute nature of an application" that "could have been brought" earlier, or "an applicant's attempt at manipulation," "may be grounds for denial of a stay." *Hill*, 547 U.S. at 584, 126 S.Ct. 2096 (internal quotation marks omitted). So, for example, we have vacated a stay entered by a lower court as an abuse of discretion where the inmate waited to bring an available claim until just 10 days before his scheduled execution for a murder he had committed 24 years earlier. See *Dunn* v. *Ray*, 586 U.S. ——, 139 S.Ct. 661, —— L.Ed.2d —— (2019). [5] If litigation is allowed to proceed, federal courts "can and should" protect settled state judgments from "undue interference" by invoking their "equitable powers" to dismiss or curtail suits that are pursued in a "dilatory" fashion or based on "speculative" theories. *Id.*, at 584–585, 126 S.Ct. 2096.

*

****15** The judgment of the court of appeals is

Affirmed.

Justice THOMAS, concurring.

***1135** I adhere to my view that "a method of execution violates the Eighth Amendment only if it is deliberately designed to inflict pain." *Baze v. Rees*, 553 U.S. 35, 94, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (opinion concurring in judgment); *ante*, at 1125 – 1126. Because there is no evidence that Missouri designed its protocol to inflict pain on anyone, let alone Russell Bucklew, I would end the inquiry there. Nonetheless, I join the Court's opinion in full because it correctly explains why Bucklew's claim fails even under the Court's precedents.

I write separately to explain why Justice BREYER's dissenting opinion does not cast doubt on this standard. *Post*, at 1143 – 1144. As I explained in *Baze*, "the evil the Eighth Amendment targets is intentional infliction of gratuitous pain." 553 U.S. at 102, 128 S.Ct. 1520 (opinion concurring in judgment). The historical evidence shows that the Framers sought to disable Congress from imposing various kinds of torturous punishments, such as " 'gibbeting,' " "burning at the stake," and " 'embowelling alive, beheading, and quartering.' " *Id.*, at 95–98, 128 S.Ct. 1520 (quoting 4 W. Blackstone, Commentaries *376 (Blackstone), and S. Banner, The Death Penalty: An American History 71–72 (2002)). In England, these aggravated forms of capital punishment were " 'superadded' " to increase terror and disgrace for " 'very atrocious crimes,' " such as treason and murder. See *Baze*, *supra*, at 96–97, 128 S.Ct. 1520 (quoting 4 Blackstone *376). The founding generation ratified the Eighth Amendment to reject that practice, contemplating that capital punishment would continue, but without those punishments deliberately designed to superadd pain.

See *Baze*, 553 U.S. at 97–98, 128 S.Ct. 1520. Under this view, the constitutionality of a particular execution thus turns on whether the Government "deliberately designed" the method of execution "to inflict pain," *id.*, at 94, 128 S.Ct. 1520, without regard to the subjective intent of the executioner.

Contrary to Justice BREYER's suggestion, my view does not render the Eighth Amendment "a static prohibition" proscribing only "the same things that it proscribed in the 18th century." *Post,* at 1143 – 1144. A method of execution not specifically contemplated at the founding could today be imposed to "superad[d]" "terror, pain, or disgrace." 4 Blackstone *376. Thankfully—and consistent with Justice Story's view that the Eighth Amendment is "wholly unnecessary in a free government," 3 J. Story, Commentaries on the Constitution of the United States 750 (1833)—States do not attempt to devise such diabolical punishments. *E.g.*, *Baze*, *supra*, at 107, 128 S.Ct. 1520 ("Kentucky adopted its lethal injection protocol in an effort to make capital punishment more humane"). It is therefore unsurprising that, despite Justice BREYER's qualms about the death penalty, *e.g.*, *post*, at 1145, this Court has never held a method of execution unconstitutional. Because the Court correctly declines to do so again today, I join in full.

Justice KAVANAUGH, concurring.

When an inmate raises an *as-applied* constitutional challenge to a particular method of execution—that is, a challenge to a method of execution that is constitutional in general but that the inmate says is very likely to cause him severe pain—one question is whether the inmate must identify an available alternative method of execution that would significantly reduce the risk of severe pain. Applying our recent decisions in *Glossip* v. *Gross*, 576 U.S. ——, 135 S.Ct. 2726, 192 L.Ed.2d 761 (2015), and *Baze v. Rees*, 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality ***1136** opinion), the Court's answer to that question is yes. Under those precedents, I agree with the Court's holding and join the Court's opinion.

****16** I write to underscore the Court's additional holding that the alternative method of execution need not be authorized under current state law—a legal issue that had been uncertain before today's decision. See *Arthur* v. *Dunn*, 580 U.S. ——, —— – ——, 137 S.Ct. 725, 729–731, 197 L.Ed.2d 225 (2017) (SOTOMAYOR, J., dissenting from denial of certiorari). Importantly, all nine Justices today agree on that point. *Ante*, at 1143; *post*, at 1128 (BREYER, J., dissenting).

As the Court notes, it follows from that additional holding that the burden of the alternative-method requirement "can be overstated." *Ante*, at 1128. Indeed, the Court states: "[W]e see little likelihood that an inmate facing a serious risk of pain will be unable to identify an available alternative." *Ante*, at 1128 – 1129.

In other words, an inmate who contends that a particular method of execution is very likely to cause him severe pain should ordinarily be able to plead some alternative method of execution that would significantly reduce the risk of severe pain. At oral argument in this Court, the State suggested that the firing squad would be such an available alternative, if adequately pleaded. Tr. of Oral Arg. 63–64 ("He can plead firing squad.... Of course, if he had ... pleaded firing squad, it's possible that Missouri could have executed him by firing squad"). Justice SOTOMAYOR has likewise explained that the firing squad is an alternative method of execution that generally causes an immediate and certain death, with close to zero risk of a botched execution. See *Arthur*, 580 U.S., at —— – ——, 137 S.Ct., at 733–734. I do not here prejudge the question whether the firing squad, or any other alternative method of execution, would be a feasible and readily implemented alternative for every State. See *McGehee v. Hutchinson*, 854 F.3d 488, 493–494 (CA8 2017). Rather, I simply emphasize the Court's statement that "we see little likelihood that an inmate facing a serious risk of pain will be unable to identify an available alternative." *Ante*, at 1128 – 1129.

Justice BREYER, with whom Justice GINSBURG, Justice SOTOMAYOR, and Justice KAGAN join as to all but Part III, dissenting.

The Court's decision in this case raises three questions. The first is primarily a factual question, namely, whether Bucklew has established genuine issues of material fact concerning whether executing him by lethal injection would cause him excessive suffering. The second is primarily a legal question, namely, whether a prisoner like Bucklew with a rare medical condition must identify an alternative method by which the State may execute him. And the third is a more general question, namely, how to minimize delays in executing offenders who have been condemned to death.

I disagree with the majority's answers to all three questions. Bucklew cites evidence that executing him by lethal injection will cause the tumors that grow in his throat to rupture during his execution, causing him to sputter, choke, and suffocate on his own blood for up to several minutes before he dies. That evidence establishes at this stage of the proceedings that executing Bucklew by lethal injection risks subjecting him to constitutionally impermissible suffering. The majority holds that the State may execute him anyway. In my view, that holding violates the clear command of the Eighth Amendment.

***1137** I

I begin with a factual question: whether Bucklew has established that, because of his rare medical condition, the State's current method of execution risks subjecting him to excessive suffering. See *Glossip* v. *Gross*, 576 U.S. ——, ——, 135 S.Ct. 2726, 2737, 192 L.Ed.2d 761 (2015) (requiring "a demonstrated risk of severe pain"); see also *Baze v. Rees*, 553 U.S. 35, 50, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality opinion) (requiring "a substantial risk of serious harm" (internal quotation marks omitted)).

****17** There is no dispute as to the applicable summary judgment standard. Because the State moved for summary judgment, it can prevail if, but only if, it "shows that there is no genuine dispute as to any material fact." Fed. Rule Civ. Proc. 56(a); see also *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). On review, we examine the record as a whole, which includes "depositions, documents, [and] affidavits or declarations." Rule 56(c). And we must construe the evidence in the light most favorable to Bucklew and draw every justifiable inference in his favor. See *Tolan v. Cotton*, 572 U.S. 650, 651, 134 S.Ct. 1861, 188 L.Ed.2d 895 (2014) (*per curiam*).

A

Bucklew has easily established a genuine issue of material fact regarding whether an execution by lethal injection would subject him to impermissible suffering.

The record indicates that Bucklew suffers from a congenital condition known as cavernous hemangioma that causes tumors filled with blood vessels to grow throughout his body, including in his head, face, neck, and oral cavity. The condition is rare. One study estimates that hemangiomas in the oral cavity occur in less than one percent of the population, and that hemangiomas like Bucklew's have been identified in five cases. See Wang, Chen, Mojica, & Chen, Cavernous Hemangioma of the Uvula, 8 N. Am. J. Med. & Sci. 56, 56–59 (2015).

Tumors grow out of Bucklew's lip and over his mouth, as well as on his hard and soft palates. One tumor also grows directly on Bucklew's uvula, which has become "grossly enlarged" as a result. App. 225. (The uvula is the "pendent fleshy lobe" that hangs from the back of the throat. Merriam-Webster's Collegiate Dictionary 1379 (11th ed. 2003).) Bucklew's tumors obstruct his airway and make it difficult for him to breathe. His difficulty breathing is chronic, but is particularly acute when he lies flat and gravity pulls his engorged uvula into his airway. He often has to adjust the positioning of his head to prevent his uvula from obstructing his breathing. He sleeps at a 45-degree angle to facilitate breathing, and he often wakes up in the middle of the night gasping for air.

Due to the sensitivity of his tumors, even minimal contact may cause them to hemorrhage. He has described past hemorrhages as " 'squirting' " or "leaking" blood, and he states that the first thing he does each morning is to wipe the blood off his face that leaked from his nose and mouth as he slept. Bucklew's condition is progressive and, due to the risk of significant blood loss caused by the sensitivity of his tumors, cannot be treated by surgery.

Bucklew maintains that, as a result of this medical condition, executing him by lethal injection would prove excruciatingly painful. In support of this claim, Bucklew submitted sworn declarations and deposition testimony from an expert witness, Dr. Joel Zivot, an anesthesiologist. Dr. Zivot provided extensive testimony regarding the pain that Bucklew would likely endure in an execution by lethal injection:

***1138** • Dr. Zivot testified that in light of "the degree to which Mr. Bucklew's airway is compromised by the hemangiomas" and "the particular psychological and physical effects of lethal injection, it is highly likely that Mr. Bucklew would be unable to maintain the integrity of his airway during the time after receiving the lethal injection and before death." App. 221.

• Dr. Zivot explained that, as a result of "the highly friable and fragile state of the tissue of Mr. Bucklew's mouth and airway," Bucklew "will likely experience hemorrhaging and/or the possible rupture of the tumor" on his uvula during his execution. *Id.*, at 222.

****18** • Dr. Zivot added that the "hemorrhaging will further impede Mr. Bucklew's airway by filling his mouth and airway with blood, causing him to choke and cough on his own blood." *Ibid.*

• Dr. Zivot concluded that "it is highly likely that Mr. Bucklew, given his specific congenital medical condition, cannot undergo lethal injection without experiencing the excruciating pain and suffering" of "suffocation, convulsions, and visible hemorrhaging." *Id.*, at 223.

Dr. Zivot also testified about the duration of pain to which an execution by lethal injection would subject Bucklew, describing it as "prolonged." *Id.*, at 234.

• Dr. Zivot stated that the effects of a pentobarbital injection "are highly unlikely to be instantaneous and the period of time between receiving the injection and death could range *over a few minutes to many minutes*." *Id.*, at 222 (emphasis added).

• Dr. Zivot "strongly disagree[d] with [the State's expert's] repeated claim that the pentobarbital injection would result in 'rapid unconsciousness.' " *Id.*, at 233.

• Dr. Zivot explained that Bucklew "would likely experience unconsciousness that sets in progressively as the chemical circulates through his system" and that it was during this period that Bucklew was "likely to experience prolonged feelings of suffocation and excruciating pain." *Id.*, at 233–234.

The State asked the District Court to grant summary judgment in its favor on the theory that Bucklew failed to identify a genuine factual issue regarding whether an execution by lethal injection would be impermissibly painful. The District Court refused. The court believed that Bucklew had adequately shown that for up to several minutes he "could be aware that he is choking or unable to breathe but be unable to 'adjust' his breathing to remedy the situation." *Id.*, at 827. Recognizing that the State's evidence suggested that Bucklew would experience this choking sensation for a shorter period, the District Court concluded that the dispute between the experts was "a factual dispute that the Court cannot resolve on summary judgment, and would have to be resolved at trial." *Ibid.*

The District Court was right. The evidence, taken in the light most favorable to Bucklew, creates a genuine factual issue as to whether Missouri's lethal injection protocol would subject him to several minutes of "severe pain and suffering," *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2738, during which he would choke and suffocate on his own blood. In my view, executing Bucklew by forcing him to choke on his grossly enlarged uvula and suffocate on his blood would exceed "the limits of civilized standards." *Kennedy v. Louisiana*, 554 U.S. 407, 435, 128 S.Ct. 2641, 171 L.Ed.2d 525 (2008) (internal quotation marks omitted); see also *Trop v. Dulles*, 356 U.S. 86, 100–101, 78 S.Ct. 590, 2 L.Ed.2d 630 (1958) (plurality opinion). The experts dispute whether Bucklew's execution will prove as ***1139** unusually painful as he claims, but resolution of that dispute is a matter for trial.

B

The majority, while characterizing the matter as "critical," says that there is "nothing in the record to suggest that Mr. Bucklew will be capable of experiencing pain for significantly more than 20 to 30 seconds after being injected with pentobarbital." *Ante*, at 1133. But what about Dr. Zivot's testimony that the time between injection and death "could range over a few minutes to many minutes"? App. 222. What about Dr. Zivot's characterization of the pain involved as "prolonged"? *Id.*, at 234. What about Dr. Zivot's "stron[g] disagree[ment] with [the State's expert's] repeated claim that the pentobarbital injection would result in 'rapid unconsciousness' "? *Id.*, at 233.

****19** The majority construes Dr. Zivot's testimony to show only that Bucklew might remain alive for several minutes after the injection, not that he will be capable of feeling pain for several minutes after the injection. *Ante*, at 1132 – 1133. But immediately following his prediction that the time between injection and death could range up to many minutes, Dr. Zivot stated that "beginning with the injection of the Pentobarbital solution and ending with Mr. Bucklew's death *several minutes to as long as many minutes* later, Mr. Bucklew would be highly likely to experience feelings of 'air hunger' *and the excruciating pain*

of prolonged suffocation." App. 222 (emphasis added). Dr. Zivot thus testified both that lethal injection would take up to several minutes to kill Bucklew and that Bucklew would experience excruciating pain during this period. And it is not the case, as the majority believes, that Dr. Zivot "carefully avoided claiming that Mr. Bucklew would be capable of feeling pain until he died," *ante*, at 1133, particularly given that the record must be construed in the light most favorable to Bucklew.

The majority also justifies its refusal to credit Dr. Zivot's testimony on the ground that Dr. Zivot gave a response during his deposition suggesting that he misinterpreted a study of euthanasia in horses. *Ante*, at 1132 – 1133. Bucklew's expert, however, did not rely exclusively or even heavily upon that study; he mentioned it only in response to a question posed in his deposition. To the contrary, Dr. Zivot explained that his testimony regarding the pain to which Bucklew would be subjected was "supported both by [his] own professional knowledge of how chemicals of this type are likely to exert their effects in the body as well as by the terms of Missouri's Execution Procedure." App. 222.

Whether any mistake about the importance of a single study makes all the difference to Bucklew's case is a matter not for this Court to decide at summary judgment, but for the factfinder to resolve at trial. As Judge Colloton pointed out in dissent below, attacks on the "reliability and credibility of Dr. Zivot's opinion," including "his possible misreading of the horse study on which he partially relied," give rise to factual disputes. See 883 F.3d 1087, 1099 (CA8 2018). Judge Colloton therefore concluded that "[t]he district court did not err in concluding that it could not resolve the dispute between the experts on summary judgment." *Ibid.* I agree.

II

This case next presents a legal question. The Court in *Glossip* held in the context of a facial challenge to a State's execution protocol that the plaintiffs were required not only to establish that the execution method gave rise to a "demonstrated risk of severe pain," but also to identify a "known and available" alternative method. ***1140** 576 U.S., at ——, 135 S.Ct., at 2737–2738. The Court added that the alternative must be "feasible, readily implemented, and in fact significantly reduc[e] a substantial risk of severe pain." *Id.*, at —— – ——, 135 S.Ct., at 2737 (internal quotation marks omitted).

I joined the dissent in *Glossip,* but for present purposes I accept the *Glossip* majority opinion as governing. I nonetheless do not believe its "alternative method" requirement applies in this case. We "often read general language in judicial opinion[s] as referring in context to circumstances similar to the circumstances then before the Court and not referring to quite different circumstances that the Court was not then considering." *Illinois v. Lidster*, 540 U.S. 419, 424, 124 S.Ct. 885, 157 L.Ed.2d 843 (2004). And while I acknowledge that the Court in *Glossip* spoke in unqualified terms, the circumstances in *Glossip* were indeed "different" in relevant respects from the circumstances presented here.

A

The plaintiffs in *Glossip* undertook an across-the-board attack against the use of a particular execution method, which they maintained violated the Eighth Amendment categorically. In this case, by contrast, Bucklew does not attack Missouri's lethal injection protocol categorically, or even in respect to any execution other than his own. Instead, he maintains that he is special; that he suffers from a nearly unique illness; and that, by virtue of that illness, Missouri's execution method will be excruciatingly painful for him even though it would not affect others in the same way. These differences make a difference.

****20** *First*, these differences show that the reasons that underlie *Glossip*'s "alternative method" requirement do not apply here.

The *Glossip* Court stressed the importance of preventing method-of-execution challenges from becoming a backdoor means to abolish capital punishment in general. The Court wrote that "because it is settled that capital punishment is constitutional, it necessarily follows that there must be a constitutional means of carrying it out." *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2732–2733 (alterations omitted). The Court added that "we have time and again reaffirmed that capital punishment is not *per se* unconstitutional." *Id.*, at ——, 135 S.Ct., at 2739. And the Court feared that allowing prisoners to invalidate a State's method of execution without identifying an alternative would "effectively overrule these decisions."

Ibid. But there is no such risk here. Holding Missouri's lethal injection protocol unconstitutional as applied to Bucklew—who has a condition that has been identified in only five people, see *supra,* at 1137 – 1138—would not risk invalidating the death penalty in Missouri. And, because the State would remain free to execute prisoners by other permissible means, declining to extend *Glossip*'s "alternative method" requirement in this context would be unlikely to exempt Bucklew or any other prisoner from the death penalty. Even in the unlikely event that the State could not identify a permissible alternative in a particular case, it would be perverse to treat that as a reason to execute a prisoner by the method he has shown to involve excessive suffering.

The *Glossip* Court, in adopting the "alternative method" requirement, relied on THE CHIEF JUSTICE's plurality opinion in *Baze*, which discussed the need to avoid "intrud[ing] on the role of state legislatures in implementing their execution procedures." 553 U.S. at 51, 128 S.Ct. 1520; see also *ante*, at 1125 (we owe "a measure of deference to a State's choice of execution procedures" (internal quotation marks omitted)). But no such intrusion problem exists in a case like this one. ***1141** When adopting a method of execution, a state legislature will rarely consider the method's application to an individual who, like Bucklew, suffers from a rare disease. It is impossible to believe that Missouri's legislature, when adopting lethal injection, considered the possibility that it would cause prisoners to choke on their own blood for up to several minutes before they die. Exempting a prisoner from the State's chosen method of execution in these circumstances does not interfere with any legislative judgment.

The Court in *Glossip* may have also believed that the identification of a permissible alternative method of execution would provide a reference point to assist in determining how much pain in an execution is too much pain. See 576 U.S., at ——–——, 135 S.Ct., at 2737–2738; *Baze*, 553 U.S. at 47, 51, 128 S.Ct. 1520 (plurality opinion); see also *ante*, at 1126 (arguing that determining the constitutionality of a method of execution "is a *necessarily* comparative exercise"). But there is no need for any such reference point in a case like this. Bucklew accepts the constitutionality of Missouri's chosen execution method as to prisoners who do not share his medical condition. See Brief for Petitioner 36. We are informed that this method has been used in 20 executions, apparently without subjecting prisoners to undue pain. See Brief for Respondents 5. To the extent that any comparator is needed, those executions provide a readymade, built-in comparator against which a court can measure the degree of excessive pain Bucklew will suffer.

****21** *Second*, precedent counsels against extending *Glossip*. Neither this Court's oldest method-of-execution case, *Wilkerson v. Utah*, 99 U.S. 130, 25 L.Ed. 345 (1879), nor any subsequent decision of this Court until *Glossip*, held that prisoners who challenge a State's method of execution must identify an alternative means by which the State may execute them. To the contrary, in *Hill v. McDonough*, 547 U.S. 573, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006), the Court squarely and unanimously rejected the argument that a prisoner must "identif[y] an alternative, authorized method of execution." *Id.*, at 582, 126 S.Ct. 2096. The Court noted that any such requirement would "change the traditional pleading requirements for § 1983 actions," which we were not at liberty to do. *Ibid.* It is thus difficult to see how the "alternative-method" requirement could be "compelled by our understanding of the Constitution," *ante*, at 1127, even though the Constitution itself never hints at such a requirement, even though we did not apply such a requirement in more than a century of method-of-execution cases, and even though we unanimously rejected such a requirement in *Hill*. And while the Court in *Glossip* did not understand itself to be bound by *Hill*, see *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2738–2739 (distinguishing *Hill* on the theory that *Hill* merely rejected a heightened pleading requirement for § 1983 suits), the two decisions remain in considerable tension. Confining *Glossip*'s "alternative method" requirement to facial challenges would help to reconcile them.

Third, the troubling implications of today's ruling provide the best reason for declining to extend *Glossip*'s "alternative method" requirement. The majority acknowledges that the Eighth Amendment prohibits States from executing prisoners by " 'horrid modes of torture' " such as burning at the stake. *Ante*, at 1123 – 1124. But the majority's decision permits a State to execute a prisoner who suffers from a medical condition that would render his execution no less painful. Bucklew has provided evidence of a serious risk that his execution will be excruciating and grotesque. The majority holds that the State may execute him anyway. That decision ***1142** confirms the warning leveled by the *Glossip* dissent

—that the Court has converted the Eighth Amendment's "categorical prohibition into a conditional one." 576 U.S., at ——, 135 S.Ct., at 2739 (opinion of SOTOMAYOR, J.).

B

Even assuming for argument's sake that Bucklew must bear the burden of showing the existence of a "known and available" alternative method of execution that "significantly reduces a substantial risk of severe pain," *id.*, at ——, 135 S.Ct., at 2737 (majority opinion) (alteration and internal quotation marks omitted), Bucklew has satisfied that burden. The record contains more than enough evidence on the point to raise genuine and material factual issues that preclude summary judgment.

Bucklew identified as an alternative method of execution the use of nitrogen hypoxia, which is a form of execution by lethal gas. Missouri law permits the use of this method of execution. See Mo. Rev. Stat. § 546.720 (2002). Three other States—Alabama, Mississippi, and Oklahoma—have specifically authorized nitrogen hypoxia as a method of execution. See *ante,* at 1130, n. 1. And Bucklew introduced into the record reports from Oklahoma and Louisiana indicating that nitrogen hypoxia would be simple and painless. These reports summarized the scientific literature as indicating that there is "no reported physical discom[fort] associated with inhaling pure nitrogen," App. 742, that the "onset of hypoxia is typically so subtle that it is unnoticeable to the subject," *id.*, at 745, and that nitrogen hypoxia would take an estimated "seventeen-to-twenty seconds" to render a subject unconscious, *id.,* at 746–747. The Oklahoma study concluded that nitrogen hypoxia is "the most humane method" of execution available. *Id.,* at 736. And the Louisiana study stated that the "[u]se of nitrogen as a method of execution can assure a quick and painless death of the offender." *Id.*, at 746.

How then can the majority conclude that Bucklew has failed to identify an alternative method of execution? The majority finds Bucklew's evidence inadequate in part because, in the majority's view, it does not show that nitrogen hypoxia will "significantly reduce" Bucklew's risk of pain as compared with lethal injection. *Ante*, at 1130 – 1131. But the majority does not dispute the evidence suggesting that nitrogen hypoxia would be "quick and painless" and would take effect in 20 to 30 seconds. The majority instead believes that "nothing in the record" suggests that lethal injection would take longer than nitrogen gas to take effect. *Ante*, at 1132. As I have already explained, the majority reaches this conclusion by overlooking considerable evidence to the contrary—such as Dr. Zivot's testimony that Bucklew's pain would likely prove "prolonged," App. 234, that lethal injection would not "result in 'rapid unconsciousness,' " *id.*, at 233, and that from the time of injection to "Mr. Bucklew's death several minutes to as long as many minutes later, Mr. Bucklew would be highly likely to experience ... the excruciating pain of prolonged suffocation," *id.*, at 222. In discounting this evidence, the majority simply fails "to adhere to the axiom that in ruling on a motion for summary judgment, the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Tolan*, 572 U.S. at 651, 134 S.Ct. 1861 (internal quotation marks and alteration omitted).

****22** The majority additionally believes that Bucklew's evidence fails to show that nitrogen hypoxia would be easy to implement. *Ante*, at 1129. But the reports from Oklahoma and Louisiana tell a different story. The Louisiana report states that ***1143** nitrogen hypoxia would be "simple to administer." App. 737. The Oklahoma report similarly concludes that "[d]eath sentences carried out by nitrogen inhalation would be simple to administer." *Id.*, at 746; see also *id.,* at 696. The reports explain that nitrogen hypoxia would "not require the use of a complex medical procedure or pharmaceutical products," *id.*, at 747, would "not require the assistance of licensed medical professionals," *id.*, 736, and would require only materials that are "readily available for purchase," *id.*, at 739. Further, "[b]ecause the protocol involved in nitrogen induced hypoxia is so simple, mistakes are unlikely to occur." *Id.*, at 748. And both studies recommend the development of protocols for actual implementation. See *id.*, at 697 (Oklahoma report recommending development of "a nitrogen hypoxia protocol"); *id.*, at 736 (Louisiana report noting that although "the exact protocol" has not been finalized, the report recommends "that hypoxia induced by the inhalation of nitrogen be considered for adoption"); see also Murphy, Oklahoma Says It Plans To Use Nitrogen for Executions, USA Today, Mar. 15, 2018 (quoting the Oklahoma attorney general's statement that nitrogen "will be effective, simple to administer, easy to obtain and

requires no complex medical procedures"); but cf. *ante*, at 1129.

Presented with evidence such as Bucklew's, I believe a State should take at least minimal steps to determine the feasibility of the proposed alternative. The responsible state official in this case, however, acknowledged that he "did not conduct research concerning the feasibility of lethal gas as a method of execution in Missouri." *Id.*, at 713; see also Record in No. 14–800 (WD Mo.), Doc. 182–6, p. 16 (different official acknowledging that, "to be candid, no, I did not go out and try to find answers to those questions").

The majority sensibly recognizes that an inmate seeking to identify an alternative method of execution "is not limited to choosing among those presently authorized by a particular State's law." *Ante*, at 1128. But the majority faults Bucklew for failing to provide guidance about the administration of nitrogen hypoxia down to the last detail. The majority believes that Bucklew failed to present evidence "on essential questions" such as whether the nitrogen should be administered "using a gas chamber, a tent, a hood, [or] a mask"; or "in what concentration (pure nitrogen or some mixture of gases)" it should be administered; or even how the State might "protec[t the execution team] against the risk of gas leaks." *Ante,* at 1129.

Perhaps Bucklew did not provide these details. But *Glossip* did not refer to any of these requirements; today's majority invents them. And to insist upon them is to create what, in a case like this one, would amount to an insurmountable hurdle for prisoners like Bucklew. That hurdle, I fear, could permit States to execute even those who will endure the most serious pain and suffering, irrespective of how exceptional their case and irrespective of how thoroughly they prove it. I cannot reconcile the majority's decision with a constitutional Amendment that forbids all "cruel and unusual punishments." Amdt. 8.

C

Justice THOMAS concurs in the majority's imposition of an "alternative method" requirement, but would also permit Bucklew's execution on the theory that a method of execution violates the Eighth Amendment " 'only if it is deliberately designed to inflict pain.' " *Ante*, at 1135 (concurring opinion) (quoting *Baze*, 553 U.S. at 94, 128 S.Ct. 1520 (THOMAS, J., concurring in judgment)). But that is not the proper standard.

***1144** For one thing, Justice THOMAS' view would make the constitutionality of a particular execution turn on the intent of the person inflicting it. But it is not correct that concededly torturous methods of execution such as burning alive are impermissible when imposed to inflict pain but not when imposed for a subjectively different purpose. To the prisoner who faces the prospect of a torturous execution, the intent of the person inflicting the punishment makes no difference.

For another thing, we have repeatedly held that the Eighth Amendment is not a static prohibition that proscribes the same things that it proscribed in the 18th century. Rather, it forbids punishments that would be considered cruel and unusual today. The Amendment prohibits "unnecessary suffering" in the infliction of punishment, which this Court has understood to prohibit punishments that are "grossly disproportionate to the severity of the crime" as well as punishments that do not serve any "penological purpose." *Estelle v. Gamble*, 429 U.S. 97, 103, and n. 7, 97 S.Ct. 285, 50 L.Ed.2d 251 (1976). The Constitution prohibits gruesome punishments even though they may have been common at the time of the founding. Few would dispute, for example, the unconstitutionality of "a new law providing public lashing, or branding of the right hand, as punishment ... [e]ven if it could be demonstrated unequivocally that these were not cruel and unusual measures in 1791." Scalia, Originalism: The Lesser Evil, 57 U. Cin. L. Rev. 849, 861 (1989). The question is not, as Justice THOMAS maintains, whether a punishment is deliberately inflicted to cause unnecessary pain, but rather whether we would today consider the punishment to cause excessive suffering.

III

****23** Implicitly at the beginning of its opinion and explicitly at the end, the majority invokes the long delays that now typically occur between the time an offender is sentenced to death and his execution. Bucklew was arrested for the crime that led to his death sentence more than 20 years ago. And Bucklew's case is not an anomaly. The average time between sentencing and execution approaches 18 years and in some instances rises

to more than 40 years. See *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2764 (BREYER, J., dissenting); *Reynolds* v. *Florida*, 586 U.S. ——, ——, 139 S.Ct. 27, 28, 202 L.Ed.2d 389 (2018) (BREYER, J., statement respecting denial of certiorari).

I agree with the majority that these delays are excessive. Undue delays in death penalty cases frustrate the interests of the State and of surviving victims, who have "an important interest" in seeing justice done quickly. *Hill*, 547 U.S. at 584, 126 S.Ct. 2096. Delays also exacerbate the suffering that accompanies an execution itself. *Glossip*, 576 U.S., at —— – ——, 135 S.Ct., at 2764–2767 (BREYER, J., dissenting). Delays can "aggravate the cruelty of capital punishment" by subjecting the offender to years in solitary confinement, and delays also "undermine [capital punishment's] jurisprudential rationale" by reducing its deterrent effect and retributive value. *Id.*, at ——, ——, 135 S.Ct., at 2769, 2772.

The majority responds to these delays by curtailing the constitutional guarantees afforded to prisoners like Bucklew who have been sentenced to death. By adopting elaborate new rules regarding the need to show an alternative method of execution, the majority places unwarranted obstacles in the path of prisoners who assert that an execution would subject them to cruel and unusual punishment. These obstacles in turn give rise to an unacceptable risk that Bucklew, or others in yet more difficult ***1145** circumstances, may be executed in violation of the Eighth Amendment. Given the rarity with which cases like this one will arise, an unfortunate irony of today's decision is that the majority's new rules are not even likely to improve the problems of delay at which they are directed.

In support of the need to end delays in capital cases, the majority refers to *Dunn* v. *Ray*, 586 U.S. ——, 139 S.Ct. 661, —— L.Ed.2d —— (2019). In that case, the Court vacated a stay of execution on the ground that the prisoner brought his claim too late. The prisoner in that case, however, brought his claim only five days after he was notified of the policy he sought to challenge. See *id.*, at ——, 139 S.Ct., at 662 (KAGAN, J., dissenting). And in the view of some of us, the prisoner's claim—that prisoners of some faiths were entitled to have a minister present at their executions while prisoners of other faiths were not—raised a serious constitutional question. See *id.*, at ——, 139 S.Ct., at 661 (characterizing the Court's decision as "profoundly wrong"). And therein lies the problem. It might be possible to end delays by limiting constitutional protections for prisoners on death row. But to do so would require us to pay too high a constitutional price.

Today's majority appears to believe that because "[t]he Constitution allows capital punishment," *ante*, at 1122, the Constitution must allow capital punishment to occur quickly. In reaching that conclusion the majority echoes an argument expressed by the Court in *Glossip*, namely, that "because it is settled that capital punishment is constitutional, it *necessarily follows* that there must be a constitutional means of carrying it out." 576 U.S., at ——, 135 S.Ct., at 2732–2733 (emphasis added; alterations and internal quotation marks omitted).

****24** These conclusions do not follow. It may be that there is no way to execute a prisoner quickly while affording him the protections that our Constitution guarantees to those who have been singled out for our law's most severe sanction. And it may be that, as our Nation comes to place ever greater importance upon ensuring that we accurately identify, through procedurally fair methods, those who may lawfully be put to death, there simply is no constitutional way to implement the death penalty.

I have elsewhere written about these problems. See *id.*, at —— – ——, 135 S.Ct., at 2770–2773 (BREYER, J., dissenting). And I simply conclude here that the law entitles Bucklew to an opportunity to prove his claim at trial. I note, however, that this case adds to the mounting evidence that we can either have a death penalty that avoids excessive delays and "arguably serves legitimate penological purposes," or we can have a death penalty that "seeks reliability and fairness in the death penalty's application" and avoids the infliction of cruel and unusual punishments. *Id.*, at ——, 135 S.Ct., at 2772. It may well be that we "cannot have both." *Ibid.*

* * *

I respectfully dissent.

Justice SOTOMAYOR, dissenting.

As I have maintained ever since the Court started down this wayward path in *Glossip* v. *Gross*, 576 U.S. ——, 135 S.Ct. 2726, 192 L.Ed.2d 761 (2015), there is no

sound basis in the Constitution for requiring condemned inmates to identify an available means for their own executions. Justice BREYER ably explains why today's extension of *Glossip*'s alternative-method requirement is misguided (even on that precedent's own terms), and why (with or without that requirement) a trial is needed to determine whether Missouri's ***1146** planned means of executing Russell Bucklew creates an intolerable risk of suffering in light of his rare medical condition. I join Justice BREYER's dissent, except for Part III. I write separately to address the troubling dicta with which the Court concludes its opinion.

I

Given the majority's ominous words about late-arising death penalty litigation, *ante,* at 1133 – 1134, one might assume there is some legal question before us concerning delay. Make no mistake: There is not. The majority's commentary on once and future stay applications is not only inessential but also wholly irrelevant to its resolution of any issue before us.

The majority seems to imply that this litigation has been no more than manipulation of the judicial process for the purpose of delaying Bucklew's execution. *Ante,* at 1133 – 1134. When Bucklew commenced this case, however, there was nothing "settled," *ibid.*, about whether the interaction of Missouri's lethal-injection protocol and his rare medical condition would be tolerable under the Eighth Amendment. At that time, *Glossip* had not yet been decided, much less extended to any as-applied challenge like Bucklew's. In granting prior stay requests in this case, we acted as necessary to ensure sufficient time for sober review of Bucklew's claims. The majority laments those decisions, but there is nothing unusual—and certainly nothing untoward—about parties pressing, and courts giving full consideration to, potentially meritorious constitutional claims, even when those claims do not ultimately succeed.

II

I am especially troubled by the majority's statement that "[l]ast-minute stays should be the extreme exception," which could be read to intimate that late-occurring stay requests from capital prisoners should be reviewed with an especially jaundiced eye. See *ante,* at 1134. Were those comments to be mistaken for a new governing standard, they would effect a radical reinvention of established law and the judicial role.

****25** Courts' equitable discretion in handling stay requests is governed by well-established principles. See *Nken v. Holder*, 556 U.S. 418, 434, 129 S.Ct. 1749, 173 L.Ed.2d 550 (2009). Courts examine the stay applicant's likelihood of success on the merits, whether the applicant will suffer irreparable injury without a stay, whether other parties will suffer substantial injury from a stay, and public interest considerations. *Ibid.*

It is equally well established that "[d]eath is a punishment different from all other sanctions in kind rather than degree." *Woodson v. North Carolina*, 428 U.S. 280, 303–304, 96 S.Ct. 2978, 49 L.Ed.2d 944 (1976). For that reason, the equities in a death penalty case will almost always favor the prisoner so long as he or she can show a reasonable probability of success on the merits. See *Nken*, 556 U.S. at 434, 129 S.Ct. 1749 (noting that success on the merits and irreparable injury "are the most critical" factors); cf. *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2737 (observing, in a preliminary-injunction posture, that "[t]he parties agree that this case turns on whether petitioners are able to establish a likelihood of success on the merits" and analyzing the case accordingly); accord, *id.*, at ——, 135 S.Ct., at 2792 (SOTOMAYOR, J., dissenting). This accords with each court's " 'duty to search for constitutional error with painstaking care' " in capital cases. *Kyles v. Whitley*, 514 U.S. 419, 422, 115 S.Ct. 1555, 131 L.Ed.2d 490 (1995).

***1147** It is of course true that a court may deny relief when a party has "unnecessarily" delayed seeking it, *Nelson v. Campbell*, 541 U.S. 637, 649–650, 124 S.Ct. 2117, 158 L.Ed.2d 924 (2004), and that courts should not grant equitable relief on clearly " 'dilatory,' " " 'speculative,' " or meritless grounds, *ante*, at 1134 (quoting *Hill v. McDonough*, 547 U.S. 573, 584–585, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006)); see also *Gomez v. United States Dist. Court for Northern Dist. of Cal.*, 503 U.S. 653, 654, 112 S.Ct. 1652, 118 L.Ed.2d 293 (1992) (*per curiam*) (vacating a stay where an inmate's unjustified 10-year delay in bringing a claim was an "obvious attempt at manipulation"). That is hardly the same thing as treating late-arising claims as presumptively suspect. [1]

The principles of federalism and finality that the majority invokes are already amply served by other constraints on our review of state judgments—most notably the Antiterrorism and Effective Death Penalty Act of 1996, but also statutes of limitations and other standard filters for dilatory claims. We should not impose further constraints on judicial discretion in this area based on little more than our own policy impulses. Finality and federalism need no extra thumb on the scale from this Court, least of all with a human life at stake.

****26** The only sound approach is for courts to continue to afford each request for equitable relief a careful hearing on its own merits. That responsibility is never graver than when the litigation concerns an impending execution. See, *e.g.*, *Kyles*, 514 U.S. at 422, 115 S.Ct. 1555; *Woodson*, 428 U.S. at 303–304, 96 S.Ct. 2978. Meritorious claims can and do come to light even at the eleventh hour, and the cost of cursory review in such cases would be unacceptably high. See *Glossip*, 576 U.S., at —— – ——, 135 S.Ct., at 2766 (BREYER, J., dissenting) (collecting examples of inmates who came "within hours or days of execution before later being exonerated"). A delay, moreover, may be entirely beyond a prisoner's control. Execution methods, for example, have been moving targets subject to considerable secrecy in recent years, which means that constitutional concerns may surface only once a State settles on a procedure and communicates its choice to the prisoner. [2] In other contexts, too, fortuity or the imminence of an execution may ***1148** shake loose constitutionally significant information when time is short. [3]

There are higher values than ensuring that executions run on time. If a death sentence or the manner in which it is carried out violates the Constitution, that stain can never come out. Our jurisprudence must remain one of vigilance and care, not one of dismissiveness.

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139 S.Ct. 1112, 2019 WL 1428884, 19 Cal. Daily Op. Serv. 2926, 2019 Daily Journal D.A.R. 2733

Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

1 While this case has been pending, a few States have authorized nitrogen hypoxia as a method of execution. See 2018 Ala. Acts no. 2018–353 (allowing condemned inmates to elect execution by nitrogen hypoxia); 2017 Miss. Laws ch. 406, p. 905 (authorizing execution by nitrogen hypoxia only if lethal injection is held unconstitutional or is otherwise unavailable); 2015 Okla. Sess. Laws ch. 75, p. 244 (same). In March 2018, officials in Oklahoma announced that, due to the unavailability of lethal injection drugs, the State would use nitrogen gas for its executions going forward. See Williams, Oklahoma Proposes To Use Nitrogen Gas for Executions by Asphyxiation, N. Y. Times, Mar. 15, 2018, p. A22. But Oklahoma has so far been unable to find a manufacturer willing to sell it a gas delivery device for use in executions. See Clay, State Not Ready for Executions, The Oklahoman, Jan. 27, 2019, p. A1. To date, no one in this case has pointed us to an execution in this country using nitrogen gas.

2 While the district court allowed discovery on many other matters, Mr. Bucklew protests that it did not permit him to learn the identities of the lethal injection execution team members, to depose them, or to inquire into their qualifications, training, and experience. Like the Eighth Circuit, we see no abuse of discretion in the district court's discovery rulings. As the district court explained, Mr. Bucklew argues that there is no way he may be constitutionally executed by lethal injection, even with modifications to the State's lethal injection protocol. And in a case like that, discovery into such granular matters as who administers the protocol simply is not relevant.

3 Here's the full quotation, with the portion quoted by the dissent underlined:
"As a result of his inability to maintain the integrity of his airway for the period of time beginning with the injection of the Pentobarbital solution and ending with Mr. Bucklew's death several minutes to as long as many minutes later, Mr. Bucklew would be highly likely to experience feelings of 'air hunger' and the excruciating pain of prolonged suffocation resulting from the complete obstruction of his airway by the large vascular tumor." App. 222.

4 The State contends that Mr. Bucklew's claim should fail for yet another reason: because, in the State's view, the evidence does not show that he is very likely to suffer " '*severe* pain' " cognizable under the Eighth Amendment. *Glossip* v. *Gross*, 576 U.S. ——, ——, 135 S.Ct. 2726, 2737–2738, 192 L.Ed.2d 761 (2015) (quoting *Baze v. Rees*, 553 U.S. 35, 52, 128

S.Ct. 1520, 170 L.Ed.2d 420 (2008); emphasis added). We have no need, however, to address that argument because (as explained above) Mr. Bucklew fails even to show that a feasible and readily available alternative could significantly reduce the pain he alleges.

5 Seeking to relitigate *Dunn* v. *Ray*, the principal dissent asserts that that case involved no undue delay because the inmate "brought his claim only five days after he was notified" that the State would not allow his spiritual adviser to be present with him in the execution chamber itself, although it *would* allow the adviser to be present on the other side of a glass partition. *Post*, at 1144 – 1145. But a state statute listed "[t]he spiritual adviser of the condemned" as one of numerous individuals who would be allowed to "be present at an execution," many of whom—such as "newspaper reporters," "relatives or friends of the condemned person," and "the victim's immediate family members"—obviously would not be allowed into the chamber itself. Ala. Code § 15–18–83 (2018). The inmate thus had long been on notice that there was a question whether his adviser would be allowed into the chamber or required to remain on the other side of the glass. Yet although he had been on death row since 1999, and the State had set a date for his execution on November 6, 2018, he waited until January 23, 2019—just 15 days before the execution—to ask for clarification. He then brought a claim 10 days before the execution and sought an indefinite stay. This delay implicated the "strong equitable presumption" that no stay should be granted "where a claim could have been brought at such a time as to allow consideration of the merits without requiring entry of a stay." *Hill v. McDonough*, 547 U.S. 573, 584, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006).

1 A skewed view of the facts caused the majority to misapply these principles and misuse its "equitable powers," see *ante,* at 1134, and n. 5, in vacating the Court of Appeals' unanimous stay in *Dunn* v. *Ray*, 586 U.S. ——, 139 S.Ct. 661, —— L.Ed.2d —— (2019). Even today's belated explanation from the majority rests on the mistaken premise that Domineque Ray could have figured out sooner that Alabama planned to deny his imam access to the execution chamber. But see *id.,* at ——, 139 S.Ct., at 662 (KAGAN, J., dissenting) (noting that the governing statute authorized both the inmate's imam and the prison's Christian chaplain to attend the execution, and that "the prison refused to give Ray a copy of its own practices and procedures" that would have clarified the two clergymen's degrees of access); *Ray v. Commissioner, Ala. Dept. of Corrections*, 915 F.3d 689, 701–703 (CA11 2019).

2 See *Zagorski* v. *Parker*, 586 U.S. ——, —— – ——, 139 S.Ct. 11, 202 L.Ed.2d 258 (2018) (SOTOMAYOR, J., dissenting from denial of application for stay and denial of certiorari) (describing Tennessee's recent equivocation about the availability of its preferred lethal injection protocol); *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2796 (SOTOMAYOR, J., dissenting) (noting States' "scramble" to formulate "new and untested" execution methods); *Sepulvado v. Jindal*, 739 F.3d 716, 717–718 (CA5 2013) (Dennis, J., dissenting from denial of rehearing en banc) (describing Louisiana's refusal to inform a prisoner of the drugs that would be used to execute him); Denno, Lethal Injection Chaos Post-*Baze*, 102 Geo. L.J. 1331, 1376–1380 (2014) (describing increased secrecy around execution procedures).

3 See *Connick v. Thompson*, 563 U.S. 51, 55–56, and n. 1, 131 S.Ct. 1350, 179 L.Ed.2d 417 (2011) (intentionally suppressed exculpatory crime lab report discovered a month before a scheduled execution); *Ex parte Braziel*, No. WR–72,186–01 (Tex. Crim. App., Dec. 11, 2018), pp. 1–2 (Alcala, J., dissenting) (disclosure by the State of "new information about possible prosecutorial misconduct" the same day as an execution).

139 S.Ct. 11
Supreme Court of the United States

Edmund ZAGORSKI
v.
Tony PARKER, Commissioner, Tennessee Department of Corrections, et al.

No. 18–6238 (18A376).
|
Oct. 11, 2018.

Opinion

The application for stay of **execution** of sentence of death presented to Justice KAGAN and by her referred to the Court is denied. The petition for a writ of certiorari is denied.

Justice SOTOMAYOR, with whom Justice BREYER joins, dissenting from denial of application for stay and denial of certiorari.

Once again, a State hastens to kill a prisoner despite mounting evidence that the sedative to be used, midazolam, will not prevent the prisoner from feeling as if he is "drowning, suffocating, and being burned alive from the inside out" during a process that could last as long as 18 minutes. *Irick v. Tennessee*, 585 U.S. ——, ——, 139 S.Ct. 1, ——, —— L.Ed.2d ——, 2018 WL 3767151 (2018) (SOTOMAYOR, J., dissenting from denial of application for stay); see also *Arthur v. Dunn*, 580 U.S. ——, ——, 137 S.Ct. 725, 725, 197 L.Ed.2d 225 (2017) (SOTOMAYOR, J., dissenting from denial of certiorari). And once again the State claims the right to do so under the Eighth Amendment not because a court has concluded that these risks are overblown, but rather because of the "perverse requirement that inmates offer alternative methods for their own **executions**." *McGehee v. Hutchinson*, 581 U.S. ——, ——, 137 S.Ct. 1275, 1276, 197 L.Ed.2d 746 (2017) (SOTOMAYOR, J., dissenting from denial of application for stay and denial of certiorari); see also *Glossip v. Gross*, 576 U.S. ——, —— – ——, 135 S.Ct. 2726, 2737–2739, 192 L.Ed.2d 761 (2015). This requirement was legally and morally wrong when it was promulgated, and it has been proved even crueler in light of the obstacles that have prevented capital prisoners from satisfying this precondition. I would therefore grant a stay of **execution** and grant petitioner Edmund Zagorski's petition for certiorari to consider what suffices for a prisoner to prove "a known and available alternative method of **execution**." See *Glossip*, 576 U.S., at ——, 135 S.Ct., at 2737–2738. [1]

For several years, Tennessee has provided for the **execution** of capital prisoners via a single drug called **pentobarbital**. See *Abdur'Rahman v. Parker*, No. M2018–01385–SC–RDO–CV, —— S.W.3d ——, —— – ——, 2018 WL 4858002 (Sup. Ct. Tenn., Oct. 8, 2018), pp. 3–4. **Pentobarbital**, a barbiturate, does not carry the risks described above; unlike midazolam (a benzodiazepine), **pentobarbital** is widely conceded to be able to render a person fully ***12** insensate. See, *e.g., Glossip,* 576 U.S., at ——, 135 S.Ct., at 2733.

In January 2018, Tennessee Department of Corrections (TDOC) adopted an alternative to **pentobarbital**: Protocol B, a three-drug sequence beginning with midazolam (the drug whose sedative properties are dubious), to be followed by vecuronium bromide (to paralyze the prisoner) and then potassium chloride (to stop the prisoner's heart). [2] No. M2018–01385–SC–RDO–CV, at 4, —— S.W.3d at ——. The **pentobarbital** option—Protocol A—remained, meanwhile, in effect. *Ibid.* In February 2018, the State set **execution** dates for several prisoners, including Zagorski, and Zagorski and others soon thereafter filed suit challenging Protocol B and pointing to Protocol A, **pentobarbital**, as the available, significantly less risky alternative. See *id.,* at 4–5, —— S.W.3d, at —— – ——. The State, however, was noncommittal about **pentobarbital's** availability. At a pretrial hearing in April 2018, as Justice Lee explained in dissent below, the trial court "zeroed in on the problem and repeatedly questioned counsel about the availability of **pentobarbital**," emphasizing that an answer to this question was " 'essential.' " *Id.,* at 4, —— S.W.3d, at ——. "The State's response to the trial court's direct question—'will [Protocol A] be available for the August 9th **execution**?'—was 'I can't answer that question, Your Honor.' " *Id.,* at 5, —— S.W.3d, at ——.

Then, "[j]ust a few hours before the parties filed their trial briefs on July 5, 2018, [TDOC] adopted a revised **execution** protocol that abandoned [**pentobarbital**], leaving only Protocol B"—the midazolam option. *Id.,* at 4, —— S.W.3d, at ——. Trial commenced a few days later. Working on a highly expedited timeline, the trial court ruled against the prisoners later that month, concluding that they had

failed to prove the availability of **pentobarbital**—the very method that TDOC had retained as Protocol A until just before trial started.[3] See *Abdur'Rahman v. Parker*, No. 18–183–II(III) (Ch. Ct. Davidson Cty., Tenn., July 26, 2018), pp. 2, 34. The Tennessee Supreme Court affirmed on that ground, while declining to "address the Plaintiffs' claim that the three-drug protocol creates a demonstrated risk of severe pain." No. M2018–01385–SC–RDO–CV, at 22, —— S.W.3d, at ——.

The circumstances surrounding Zagorski and his fellow prisoners' attempts to ***13** prove that **pentobarbital** was "available" demonstrate how unfairly this already perverse requirement is being applied. For one, the prisoners' ability to prove the drug's availability was severely constrained by rules of secrecy surrounding individuals involved in the **execution** process. See *id.*, at 3, —— S.W.3d, at —— (Lee, J., dissenting); see also Tenn. Code Ann. § 10–7–504(h) (2018). The prisoners were unable to depose individuals with direct knowledge of the State's efforts to obtain **pentobarbital**. Nor were the prisoners allowed to learn which potential sellers the State ostensibly approached to try to obtain **pentobarbital**. Short of cold-calling every pharmacy in the country and asking for **pentobarbital**, it is anyone's guess how the prisoners were supposed to challenge meaningfully the State's claim that it could not obtain the drug. Yet they were faulted below for failing to offer "direct proof." No. M2018–01385–SC–RDO–CV, at 21, —— S.W.3d, at ——.

Moreover, it is not as if **pentobarbital** has vanished from the Earth, for purposes of **execution** or otherwise. As Justice Lee noted in dissent, Texas and Georgia have each used it multiple times in **executions** this year alone. See No. M2018–01385–SC–RDO–CV, at 5, —— S.W.3d, at ——. Missouri also appears to be prepared to use it in upcoming **executions**. See, *e.g.*, Brief for Respondent in *Bucklew v. Precythe*, O.T. 2018, No. 17–8151, p. 1. Moreover, what discovery the prisoners did obtain below indicates that roughly 10 of the 100 suppliers that TDOC reached out to in 2017 did have **pentobarbital** for sale—just not the number of doses that the State had requested. No. 18–183–II(III), at 13. And at least one supplier around this time evidently quoted a price and discussed a "bulk $ option." App. to Pet. for Cert. 197a.

The trial court found credible the senior TDOC officials who testified to having delegated a search for **pentobarbital** to their subordinates, see No. 18–183–II(III), at 11–12, and the Tennessee Supreme Court based its affirmance in significant part on these "credibility determinations," see No. M2018–01385–SC–RDO–CV, at 21–22, —— S.W.3d, at —— – ——. But these senior officials were not the individuals who actually undertook the search for **pentobarbital**, see *id.*, at 12, —— S.W.3d, at ——; the actual procurers, by contrast, were unavailable to the prisoners because of the State's secrecy laws. When the prisoners tasked with asking the State to kill them another way are denied by the State information crucial to establishing the availability of that other means of killing, a grotesque requirement has become Kafkaesque as well.

Such barriers are not the only ways in which prisoners proposing a more humane means of **execution** may be thwarted. In other instances, courts have rejected claims by petitioners proposing means of **execution** that are unavailable under state law. See, *e.g.*, *Arthur*, 580 U.S., at ——, 137 S.Ct., at 725 (SOTOMAYOR, J., dissenting from denial of certiorari). Such rejections are likewise troubling, because they suggest that "all a State has to do to **execute** [a person] through an unconstitutional method is to pass a statute declining to authorize any alternative method," *id.*, at 729, and they likewise show the need for us to address in more detail what *Glossip* actually requires. In any event, the prisoners here sought only the State's own Protocol A, which the State itself had held out as a seemingly available method before eliminating it "on the eve of trial." No. M2018–01385–SC–RDO–CV, at 5, —— S.W.3d, at —— (Lee, J., dissenting). That is hardly an extravagant request, particularly when the State's own evidence discloses that there had been opportunities to ***14** purchase **pentobarbital** both in smaller quantities and in bulk.

I accordingly would grant Zagorski's request for a stay and grant certiorari to address what renders a method of **execution** "available" under *Glossip*. Capital prisoners are not entitled to pleasant deaths under the Eighth Amendment, but they are entitled to humane deaths. The longer we stand silent amid growing evidence of inhumanity in **execution** methods like Tennessee's, the longer we extend our own complicity in state-sponsored brutality. I dissent.

All Citations

139 S.Ct. 11 (Mem), 202 L.Ed.2d 258

Footnotes

1 The State's refusal to allow Zagorski's attorneys to access a telephone during Zagorski's scheduled **execution** is also troubling. For reasons expressed before, I would grant review of this question as well. See *Arthur v. Dunn*, 581 U.S. ——, —— – ——, 137 S.Ct. 725, 725–726, 197 L.Ed.2d 225 (2017) (SOTOMAYOR, J., dissenting from denial of application for stay and denial of certiorari).

2 "The first drug [midazolam] is critical; without it, the prisoner faces the unadulterated agony of the second and third drugs." *Arthur v. Dunn*, 580 U.S. ——, ——, 137 S.Ct. 725, 726, 197 L.Ed.2d 225 (2017) (SOTOMAYOR, J., dissenting from denial of certiorari). This Court in *Glossip* concluded that a district court did not clearly err in finding that midazolam could render a prisoner sufficiently insensate to the excruciating effects of the second and third drugs. See 576 U.S., at ——, 135 S.Ct., at 2740–2741. Any confidence in that conclusion has since eroded in the face of growing contrary medical evidence and worrisome results from **executions** themselves. See, *e.g., Abdur'Rahman v. Parker*, No. 18–183–II(III) (Ch. Ct. Davidson Cty., Tenn., July 26, 2018), pp. 21–22, 27–28. Because the opinions below do not defend the use of midazolam on the merits, midazolam's inadequacy is not the focus here.

3 The trial court also concluded that the prisoners' experts "established that midazolam does not elicit strong analgesic effects and the inmate being **executed** may be able to feel pain from the administration of the second and third drugs." *Abdur'Rahman v. Parker*, No. 18-183-II(III), at 21. But it nevertheless concluded, without expressing any countervailing confidence in midazolam's anesthetic properties, that this Court "would not find the facts established in this case to violate the Constitution." *Id.,* at 22; see also *Irick v. Tennessee*, 585 U.S. ——, —— – ——, 139 S.Ct. 1, —— – ——, —— L.Ed.2d ——, 2018 WL 3767151 (2018) (SOTOMAYOR, J., dissenting from denial of certiorari).

137 S.Ct. 725
Supreme Court of the United States

Thomas D. ARTHUR
v.
Jefferson S. DUNN, Commissioner,
Alabama Department of Corrections, et al.

No. 16–602.
|
Feb. 21, 2017.

Opinion

The motion of Certain Medical Professionals and Medical Ethicists for leave to file a brief as *amici curiae* is granted. The petition for a writ of certiorari is denied.

Justice SOTOMAYOR, with whom Justice BREYER joins, dissenting from the denial of certiorari.

Nearly two years ago in *Glossip v. Gross,* 576 U.S. ——, 135 S.Ct. 2726, 192 L.Ed.2d 761 (2015), the Court issued a macabre challenge. In order to successfully attack a State's method of **execution** as cruel and unusual under the Eighth Amendment, a condemned prisoner must not only prove that the State's chosen method risks severe pain, but must also propose a "known and available" alternative method for his own **execution**. *Id.*, at ——, ——, 135 S.Ct., at 2737, 2739.

Petitioner Thomas Arthur, a prisoner on Alabama's death row, has met this challenge. He has amassed significant evidence that Alabama's current lethal-injection protocol will result in intolerable and needless agony, and he has proposed an alternative—death by firing squad. The Court of Appeals, without considering any of the evidence regarding the risk posed by the current protocol, denied Arthur's claim because Alabama law does not expressly permit **execution** by firing squad, and so it cannot be a "known and available" alternative under *Glossip*. Because this decision permits States to immunize their methods of **execution**—no matter how cruel or how unusual—from judicial review and thus permits state law to subvert the Federal Constitution, I would grant certiorari and reverse. I dissent from my colleagues' decision not to do so.

I

A

Execution by lethal injection is generally accomplished through serial administration of three drugs. First, a fast-acting sedative such as sodium thiopental induces "a deep, comalike unconsciousness." *Baze v. Rees,* 553 U.S. 35, 44, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality opinion). Second, a paralytic agent—most often pancuronium bromide—"inhibits all muscular-skeletal movements and, by paralyzing the diaphragm, stops respiration." *Ibid.* Third, potassium chloride induces fatal cardiac arrest. *Ibid.*

The first drug is critical; without it, the prisoner faces the unadulterated agony of the second and third drugs. The second drug causes "an extremely painful sensation of crushing and suffocation," see Denno, When Legislatures Delegate Death: The Troubling Paradox Behind State Uses of Electrocution and Lethal Injection and What It Says About Us, 63 Ohio St. L.J. 63, 109, n. 321 (2002); but paralyzes the prisoner so as to "mas[k] any outward sign of distress," thus serving States' interest " 'in preserving the dignity of the procedure,' " *Baze,* 553 U.S., at 71, 73, 128 S.Ct. 1520 (Stevens, J., concurring in judgment). And the third drug causes an "excruciating burning sensation" that is "equivalent to the sensation of a hot poker being inserted into the arm" and traveling "with the chemical up the prisoner's arm and ... across his chest until it reaches his heart." Denno, *supra,* at 109, n. 321.

***726** **Execution** absent an adequate sedative thus produces a nightmarish death: The condemned prisoner is conscious but entirely paralyzed, unable to move or scream his agony, as he suffers "what may well be the chemical equivalent of being burned at the stake." *Glossip,* 576 U.S., at ——, 135 S.Ct., at 2781 (SOTOMAYOR, J., dissenting).

B

For many years, the barbiturate sodium thiopental seemed up to this task.[1] In 2009, however, the sole American manufacturer of sodium thiopental suspended domestic production and later left the market altogether.

Id., at ——– – ——–, 135 S.Ct., at 2732–2733 (majority opinion). States then began to use another barbiturate, **pentobarbital**. *Id.,* at ——–, 135 S.Ct., at 2733. But in 2013, it also became unavailable. *Id.,* at ——– – ——–, 135 S.Ct., at 2733–2734. Only then did States turn to midazolam, the drug at the center of this case.

Midazolam, like Valium and Xanax, belongs to a class of medicines known as benzodiazepines and has some anesthetic effect. *Id.,* at ——–, 135 S.Ct., at 2782–2783 (SOTOMAYOR, J., dissenting). Generally, anesthetics can cause a level of sedation and depression of electrical brain activity sufficient to block *all* sensation, including pain. App. to Pet. for Cert. 283a–290a. But it is not clear that midazolam adequately serves this purpose. This is because midazolam, unlike barbiturates such as **pentobarbital**, has no analgesic—pain-relieving—effects. *Id.,* at 307a; see also *Glossip,* 576 U.S., at ——–, 135 S.Ct., at 2782–2783 (SOTOMAYOR, J., dissenting). Thus, "for midazolam to maintain unconsciousness through application of a particular stimulus, it would need to depress electrical activity *to a deeper level* than would be required of, for example, **pentobarbital**." App. to Pet. for Cert. 307a.[2] Although it can be used to render individuals unconscious, midazolam is not used on its own to *maintain* anesthesia—complete obliviousness to physical sensation—in surgical procedures, and indeed, the Food and Drug Administration has not approved the drug for this purpose. *Glossip,* 576 U.S., at ——–, 135 S.Ct., at 2782–2783 (SOTOMAYOR, J., dissenting).

Like the experts in *Glossip,* the experts in this case agree that midazolam is subject to a ceiling effect, which means that ***727** there is a point at which increasing the dose of the drug does not result in any greater effect. *Ibid.* The main dispute with respect to midazolam relates to how this ceiling effect operates—if the ceiling on midazolam's sedative effect is reached before complete unconsciousness can be achieved, it may be incapable of keeping individuals insensate to the extreme pain and discomfort associated with administration of the second and third drugs in lethal-injection protocols. *Ibid.*

After the horrific **execution** of Clayton Lockett, who, notwithstanding administration of midazolam, awoke during his **execution** and appeared to be in great pain, we agreed to hear the case of death row inmates seeking to avoid the same fate. In *Glossip,* these inmates alleged that because midazolam is incapable of rendering prisoners unconscious and insensate to pain during lethal injection, Oklahoma's intended use of the drug in their **executions** would violate the Eighth Amendment. The Court rejected this claim for two reasons.

First, the Court found that the District Court had not clearly erred in determining that "midazolam is highly likely to render a person unable to feel pain during an **execution**." *Id.,* at ——–, 135 S.Ct., at 2739. Second, the Court held that the petitioners had failed to satisfy the novel requirement of pleading and proving a "known and available alternative" method of **execution**. *Id.*, at ——–, 135 S.Ct., at 2739.

Post-*Glossip,* in order to prevail in an Eighth Amendment challenge to a State's method of **execution**, prisoners first must prove the State's current method "entails a substantial risk of severe pain," *id.*, at ——–, 135 S.Ct., at 2731, and second, must "identify a known and available alternative method of **execution** that entails a lesser risk of pain," *id.*, at ——–, 135 S.Ct., at 2731.

II

This case centers on whether Thomas Arthur has met these requirements with respect to Alabama's lethal-injection protocol.

A

Alabama adopted lethal injection as its default method of **execution** in 2002. Ala.Code § 15–18–82.1(a) (2011); see also *Ex parte Borden,* 60 So.3d 940, 941 (Ala.2007). The State's capital punishment statute delegates the task of prescribing the drugs necessary to compound a lethal injection to the Department of Corrections. § 15–18–82.1(f). Consistent with the practice in other States following the national shortage of sodium thiopental and **pentobarbital**, the department has adopted a protocol involving the same three drugs considered in *Glossip*. See *Brooks v. Warden,* 810 F.3d 812, 823 (C.A.11 2016).

Perhaps anticipating constitutional challenges, Alabama's legislature enacted a contingency plan: The statute provides that "[i]f electrocution or lethal injection is held to be unconstitutional ... all persons sentenced to death

for a capital crime shall be **executed** by any constitutional method of **execution**." § 15–18–82.1(c).

B

Thomas Douglas Arthur killed his paramour's husband in 1982. 840 F.3d 1268, 1272–1273 (C.A.11 2016). Over the next decade, two juries found Arthur guilty of murder, and each time, Arthur's conviction was overturned on appeal. *Ibid.* After a third trial in 1992, Arthur was convicted and sentenced to death. *Ibid.* Since then, Arthur has been scheduled to die on six separate occasions, and each time, his **execution** was stayed. *Id.,* at 1275, n. 2. After 34 years of legal challenges, Arthur has ***728** accepted that he will die for his crimes. He now challenges only *how* the State will be permitted to kill him.

Arthur asserted two distinct claims in the District Court. First, Arthur asserted a *facial* challenge, arguing that midazolam is generally incapable of performing as intended during Alabama's three-drug lethal-injection procedure. Second, Arthur asserted an *as-applied* challenge, arguing that because of his individual health attributes, midazolam creates a substantial risk of severe pain for him during the procedure.

The District Court considered these two claims separately. With respect to the facial challenge, the District Court ordered bifurcated proceedings, with the first hearing limited to the availability of a feasible alternative method of **execution**. App. to Pet. for Cert. 189a, and n. 2. Arthur's initial complaint proposed a single dose either of **pentobarbital** or sodium thiopental rather than a three-drug protocol, but the District Court found that those methods were unavailable given the elimination of both drugs from the domestic market. *Id.,* at 203a–205a.

Arthur then moved to amend his complaint to allege the firing squad as an alternative method of **execution**. The District Court denied the motion, holding that "**execution** by firing squad is not permitted by statute and, therefore, is not a method of **execution** that could be considered either feasible or readily implemented by Alabama at this time." *Id.,* at 241a. Because Arthur's claim failed on this ground, the court never considered Arthur's evidence with respect to midazolam, despite later observing that it was "impressive." *Id.,* at 166a.

In a separate order, the District Court considered Arthur's as-applied challenge. Arthur alleged, based on the expert opinion of Dr. Jack Strader, that "his cardiovascular issues, combined with his age and emotional makeup, create a constitutionally unacceptable risk of pain that will result in a violation of the Eighth Amendment if he is **executed** under the [midazolam] protocol." *Id.,* at 151a. Echoing its rationale with respect to Arthur's facial challenge, the District Court found that Arthur failed to prove the existence of a feasible, readily available alternative.

The court then turned to the question it had avoided in the facial challenge: whether Alabama's lethal-injection protocol created a risk of serious illness or needless suffering. But because the District Court considered the question as part of Arthur's as-applied challenge, it focused on the protocol as applied to Arthur's personal physical condition. The court rejected Dr. Strader's opinion that the dose of midazolam required by Alabama's protocol "will likely induce a rapid and dangerous reduction in blood pressure more quickly than it results in sedation," and that during this time gap, Arthur—whom he believed to suffer from heart disease—would suffer a painful heart attack. *Id.,* at 169a. Because Dr. Strader's experience was limited to *clinical* doses of midazolam, which typically range from 2 to 5 mg, the court concluded that he had no basis to extrapolate his experience to non-clinical, *lethal* doses, such as the 500–mg bolus required by Alabama's lethal-injection protocol. *Id.,* at 177a.

The District Court expressly refused to consider the expert opinions that Arthur proffered as part of his facial challenge, noting that they "are untested in court, due to Arthur's inability to provide a[n alternative] remedy in his facial, and now as-applied, challenges." *Id.,* at 167a, n. 16.

The District Court therefore concluded that Arthur failed to meet the *Glossip* standard and entered judgment in favor of the State. App. to Pet. for Cert. 238a.

***729** C

The Eleventh Circuit affirmed. In a 111–page slip opinion issued the day before Arthur's scheduled **execution**, the court first found that "Arthur never showed Alabama's current lethal injection protocol, *per se* or as applied to

him, violates the Constitution." 840 F.3d, at 1315. The court based this finding on Arthur's failure to "satisfy the first [*Glossip*] prong as to midazolam" as part of his as-applied challenge, *ibid.,* and the fact that this Court "upheld the midazolam-based **execution** protocol" in *Arthur,* 840 F.3d, at 1315. Like the District Court, the Eleventh Circuit *never* considered the evidence Arthur introduced in support of his facial challenge to the protocol. Then, "[a]s an alternative and independent ground," *ibid.,* the Court of Appeals found that the firing squad is not an available alternative because that method is "beyond [the Department of Corrections'] statutory authority," *id.*, at 1320. Finally, and as yet another independent ground for denying relief, the court held Arthur's motion regarding the firing squad barred by the doctrine of laches. *Ibid.,* n. 35. According to the Eleventh Circuit, the "known and available" alternative requirement was made clear in *Baze*—not *Glossip*—and because Arthur failed to amend his complaint in 2008 when *Baze* was decided, his claim was barred by laches.

On the day of his scheduled **execution**, Arthur filed a petition for certiorari and an application to stay his **execution**. The Court granted the stay, 580 U.S. ——, 137 S.Ct. 14, 196 L.Ed.2d 326 (2016), but now denies certiorari.

III

A

The decision below permits a State, by statute, to bar a death-row inmate from vindicating a right guaranteed by the Eighth Amendment. Under this view, even if a prisoner can prove that the State plans to kill him in an intolerably cruel manner, and even if he can prove that there is a feasible alternative, all a State has to do to **execute** him through an unconstitutional method is to pass a statute declining to authorize any alternative method. This cannot be right.

To begin with, it contradicts the very decisions it purports to follow—*Baze* and *Glossip*. *Glossip* based its "known and available alternative" requirement on the plurality opinion in *Baze*. *Baze,* in turn, states that "[t]o qualify, the alternative procedure must be feasible, readily implemented, and in fact significantly reduce a substantial risk of severe pain." 553 U.S., at 52, 128 S.Ct. 1520 (plurality opinion). The Court did not mention—or even imply—that a State must authorize the alternative by statute. To the contrary, *Baze* held that "[i]f a State refuses to adopt such an alternative in the face of these documented advantages," its "*refusal* to change its method can be viewed as 'cruel and unusual' under the Eighth Amendment." *Ibid.* (emphasis added). The decision below turns this language on its head, holding that if the State *refuses* to adopt the alternative legislatively, the inquiry ends. That is an alarming misreading of *Baze*.

Even more troubling, by conditioning federal constitutional rights on the operation of state statutes, the decision below contravenes basic constitutional principles. The Constitution is the "supreme law of the land"—irrespective of contrary state laws. Art. VI, cl. 2. And for more than two centuries it has been axiomatic that this Court—not state courts or legislatures—is the final arbiter of the Federal Constitution. See ***730** *Marbury v. Madison,* 1 Cranch 137, 177, 2 L.Ed. 60 (1803). Acting within our exclusive "province and duty" to "say what the law is," *ibid.*, we have interpreted the Eighth Amendment to entitle prisoners to relief when they succeed in proving that a State's chosen method of **execution** poses a substantial risk of severe pain and that a constitutional alternative is "known and available," *Glossip,* 576 U.S., at —— – ——, 135 S.Ct., at 2731–2732. The States have no power to override this constitutional guarantee. While States are free to define and punish crimes, "state laws respecting crimes, punishments, and criminal procedure are ... subject to the overriding provisions of the United States Constitution." *Payne v. Tennessee,* 501 U.S. 808, 824, 111 S.Ct. 2597, 115 L.Ed.2d 720 (1991).

Equally untenable are the differing interpretations of the Eighth Amendment that would result from the Eleventh Circuit's rule. Under the Eleventh Circuit's view, whether an inmate who will die in an intolerably cruel manner can obtain relief under *Glossip* depends not on the Constitution but on vagaries of state law. The outcome of this case, for instance, would turn on whether Arthur had been sentenced in Oklahoma, where state law expressly permits the firing squad, see Okla. Stat., Tit. 22, § 1014 (Supp.2016), rather than in Alabama, which—according to the Eleventh Circuit [3]—does not, see Ala.Code § 15–18–82.1. But since the very beginning of our Nation, we have emphasized the "necessity of uniformity" in constitutional interpretation "throughout

the whole United States, upon all subjects within the purview of the constitution." *Martin v. Hunter's Lessee,* 1 Wheat. 304, 347–348, 4 L.Ed. 97 (1816) (emphasis deleted). Nowhere is the need for uniformity more pressing than the rules governing States' imposition of death.

B

The Eleventh Circuit's alternative holdings are unavailing.

First, the court erroneously concluded that Arthur failed to carry his burden on the first *Glossip* requirement —proving that Alabama's midazolam-centered protocol poses a substantial risk of severe pain. The court used the District Court's finding that Arthur failed to meet this prong with respect to his *as-applied* challenge to hold that Arthur's *facial* challenge likewise failed. But it is undisputed that Arthur put forth "impressive" evidence to support his facial challenge that neither the District Court nor the Court of Appeals considered. This evidence included the expert testimony of Dr. Alan Kaye, chairman of the Department of Anesthesiology at Louisiana State University's Health Sciences Center, who found the dose of midazolam prescribed in Alabama's protocol insufficient to "cure ... the *fundamental unsuitability* of midazolam as the first drug in [Alabama's lethal-injection] protocol." ***731** App. to Pet. for Cert. 302a (emphasis added). Dr. Kaye concluded that "the chemical properties of midazolam limit its ability to depress electrical activity in the brain. The lack of another chemical property—analgesia—renders midazolam incapable of maintaining even that limited level of depressed electrical activity under the undiminished pain of the second and third lethal injection drugs." *Id.*, at 311a.

The court next read *Glossip* as categorically "uph[olding] the midazolam-based **execution** protocol." 840 F.3d, at 1315. *Glossip* did no such thing. The majority opinion in *Glossip* concluded that, based on the facts presented in that case, "[t]he District Court did not commit clear error when it found that midazolam is highly likely to render a person unable to feel pain during an **execution**." 576 U.S., at ——, 135 S.Ct., at 2739. The opinion made no determination whether midazolam-centered lethal injection represents a constitutional method of **execution**.

Finally, the court's laches finding faults Arthur for failing to act immediately after *Baze,* which, according to the panel, "made clear in 2008 ... that a petitioner-inmate had the burden to show that a proffered alternative was 'feasible, readily implemented, and in fact significantly reduced a substantial risk of pain.' " 840 F.3d, at 1320, n. 35 (quoting *Baze,* 553 U.S., at 41, 128 S.Ct. 1520). But the District Court in this case—not to mention at least four Justices of this Court, see *Glossip,* 576 U.S., at —— – ——, 135 S.Ct., at 2793–2795 (SOTOMAYOR, J., dissenting)—did not read *Baze* as requiring an alternative. See Record in *Arthur v. Myers,* No. 2:11–cv–438 (MD Ala.), Doc. 195, p. 11 ("[T]he court does not accept the State's argument that [a known and available alternative method of **execution**] is a specific pleading requirement set forth by *Baze* that must be properly alleged before a case can survive a motion to dismiss"). Arthur filed a statement within 14 days of our decision in *Glossip* informing the District Court of his belief that our decision would impact his case, see *id.,* Doc. 245, and moved to amend his complaint a few weeks later, see *id.,* Doc. 256.

In sum, the Eleventh Circuit's opinion rests on quicksand foundations and flouts the Constitution, as well as the Court's decisions in *Baze* and *Glossip*. These errors alone counsel in favor of certiorari.

IV

The decision below is all the more troubling because it would put an end to an ongoing national conversation —between the legislatures and the courts—around the methods of **execution** the Constitution tolerates. The meaning of the Eighth Amendment's prohibition on cruel and unusual punishments "is determined not by the standards that prevailed when the Eighth Amendment was adopted in 1791" but instead derives from " 'the evolving standards of decency that mark the progress of a maturing society.' " *Kennedy v. Louisiana,* 554 U.S. 407, 419, 128 S.Ct. 2641, 171 L.Ed.2d 525 (2008) (quoting *Trop v. Dulles,* 356 U.S. 86, 101, 78 S.Ct. 590, 2 L.Ed.2d 630 (1958) (plurality opinion)). Evolving standards have yielded a familiar cycle: States develop a method of **execution**, which is generally accepted for a time. Science then reveals that—unknown to the previous generation—the States' chosen method of **execution** causes unconstitutional levels of suffering. A new method of **execution** is devised, and the dialogue continues. The Eighth Amendment requires this

conversation. States should not be permitted to silence it by statute.

A

From the time of the founding until the early 20th century, hanging was the preferred ***732** practice. Gardner, **Executions** and Indignities—An Eighth Amendment Assessment of Methods of Inflicting Capital Punishment, 39 Ohio St. L.J. 96, 119 (1978). After several grotesque failures at the gallows—including slow asphyxiation and violent decapitation—revealed the "crude and imprecise" nature of the practice, *Campbell v. Wood,* 511 U.S. 1119, 1122, 114 S.Ct. 2125, 128 L.Ed.2d 682 (1994) (Blackmun, J., dissenting from denial of certiorari), States sought to **execute** condemned prisoners " 'in a less barbarous manner' " and settled on electrocution. See *In re Kemmler,* 136 U.S. 436, 444, 10 S.Ct. 930, 34 L.Ed. 519 (1890).

New York carried out the world's first electrocution in ghastly fashion,[4] leading the New York Times to declare it "a disgrace to civilization." See Far Worse Than Hanging, N.Y. Times, Aug. 7, 1890, p. 1. Electrocution nonetheless remained the dominant mode of **execution** for more than a century, until the specter of charred and grossly disfigured bodies proved too much for the public, and the courts, to bear.[5] See, *e.g., Dawson v. State,* 274 Ga. 327, 335, 554 S.E.2d 137, 144 (2001) ("[W]e hold that death by electrocution, with its specter of excruciating pain and its certainty of cooked brains and blistered bodies, violates the prohibition against cruel and unusual punishment").

The States then tried lethal gas. Although the gas chamber was initially believed to produce relatively painless death, it ultimately became clear that it exacted "exquisitely painful" sensations of "anxiety, panic, [and] terror," leading courts to declare it unconstitutional. See, *e.g., Fierro v. Gomez,* 77 F.3d 301, 308 (C.A.9 1996) (internal quotation marks omitted).[6]

Finally, States turned to a "more humane and palatable" method of **execution**: ***733** lethal injection. Denno, 63 Ohio St. L. J., at 92. Texas performed the first lethal injection in 1982 and, impressed with the apparent ease of the process, other States quickly followed suit. S. Banner, The Death Penalty: An American History 297 (2002). One prison chaplain marveled: " 'It's extremely sanitary.... The guy just goes to sleep. That's all there is to it.' " *Ibid.* What cruel irony that the method that appears most humane may turn out to be our most cruel experiment yet.

B

Science and experience are now revealing that, at least with respect to midazolam-centered protocols, prisoners **executed** by lethal injection are suffering horrifying deaths beneath a "medically sterile aura of peace." Denno, *supra,* at 66. Even if we sweep aside the scientific evidence, we should not blind ourselves to the mounting firsthand evidence that midazolam is simply unable to render prisoners insensate to the pain of **execution**. The examples abound.

After Ohio administered midazolam during the **execution** of Dennis McGuire in January 2014, he "strained against the restraints around his body, and ... repeatedly gasped for air, making snorting and choking sounds for about 10 minutes." Johnson, Inmate's Death Called 'Horrific', Columbus Dispatch, Jan. 17, 2014, pp. A1, A10.

The scene was much the same during Oklahoma's **execution** of Clayton Lockett in April 2014. After executioners administered midazolam and declared him unconscious, Lockett began to writhe against his restraints, saying, "[t]his s* * * is f* * *ing with my mind," "something is wrong," and "[t]he drugs aren't working." *Glossip,* 576 U.S., at ——, 135 S.Ct., at 2781–2782 (SOTOMAYOR, J., dissenting).

When Arizona **executed** Joseph Rudolph Wood in July 2014 using a midazolam-based protocol, he "gulped like a fish on land." Kiefer, Botched **Execution**, Arizona Dispatch, July 24, 2014, pp. A1, A9. A witness reported more than 640 gasps as Woods convulsed on the gurney for more than an hour and a half before being declared dead. *Ibid.*

Finally, and just over a month after this Court stayed Thomas Arthur's **execution**, Alabama **executed** Ronald Bert Smith. Following the dose of midazolam, Smith "clenched his fist" and was "apparently struggling for breath as he heaved and coughed for about 13 minutes." Berman & Barnes, Alabama Inmate was

Heaving, Coughing During Lethal–Injection **Execution**, Washington Post, Dec. 10, 2016, p. A3.

It may well be that as originally designed, lethal injection can be carried out in a humane fashion that comports with the Eighth Amendment. But our lived experience belies any suggestion that midazolam reliably renders prisoners entirely unconscious to the searing pain of the latter two drugs. These accounts are especially terrifying considering that each of these men received doses of powerful paralytic agents, which likely masked the full extent of their pain. Like a hangman's poorly tied noose or a malfunctioning electric chair, midazolam might render our latest method of **execution** too much for our conscience—and the Constitution—to bear.

C

As an alternative to death by midazolam, Thomas Arthur has proposed death by firing squad. Some might find this choice regressive, but the available evidence suggests "that a competently performed shooting may cause nearly instant death." Denno, Is Electrocution An Unconstitutional ***734** Method of **Execution**? The Engineering of Death Over the Century, 35 Wm. & Mary L.Rev. 551, 688 (1994). In addition to being near instant, death by shooting may also be comparatively painless. See Banner, *supra,* at 203. And historically, the firing squad has yielded significantly fewer botched **executions**. See A. Sarat, Gruesome Spectacles: Botched **Executions** and America's Death Penalty, App. A, p. 177 (2014) (calculating that while 7.12% of the 1,054 **executions** by lethal injection between 1900 and 2010 were "botched," none of the 34 **executions** by firing squad had been).

Chief Justice Warren famously wrote that "[t]he basic concept underlying the Eighth Amendment is nothing less than the dignity of man." *Trop,* 356 U.S., at 100, 78 S.Ct. 590 (plurality opinion). States have designed lethal-injection protocols with a view toward protecting their own dignity, but they should not be permitted to shield the true horror of **executions** from official and public view. Condemned prisoners, like Arthur, might find more dignity in an instantaneous death rather than prolonged torture on a medical gurney.

To be clear, this is not a matter of permitting inmates to choose the manner of death that best suits their desires. It is a matter of permitting a death row inmate to make the showing *Glossip* requires in order to prove that the Constitution demands something less cruel and less unusual than what the State has offered. Having met the challenge set forth in *Glossip,* Arthur deserves the opportunity to have his claim fairly reviewed in court. The Eleventh Circuit denied him this opportunity, and in doing so, thwarted the Court's decision in *Glossip,* as well as basic constitutional principles.

* * *

Twice in recent years, this Court has observed that it "has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment." *Baze,* 553 U.S., at 48, 128 S.Ct. 1520 (plurality opinion); *Glossip,* 576 U.S., at ——, 135 S.Ct., at 2732 (same). In *Glossip,* the majority opinion remarked that the Court "did not retreat" from this nonintervention strategy even after Louisiana strapped a 17–year–old boy to its electric chair and, having failed to kill him the first time, argued for a second try—which this Court permitted. *Id.*, at —— – ——, 135 S.Ct., at 2732–2733. We should not be proud of this history. Nor should we rely on it to excuse our current inaction.

I dissent.

All Citations

137 S.Ct. 725 (Mem), 197 L.Ed.2d 225, 85 USLW 3385, 85 USLW 3392, 85 USLW 3393, 17 Cal. Daily Op. Serv. 1542

Footnotes

1 We examined the constitutionality of lethal injection in *Baze v. Rees,* 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008). There, the parties did not dispute that "proper administration of ... sodium thiopental ... eliminates any meaningful risk that a prisoner would experience pain" and results in a humane death. *Id.*, at 49, 128 S.Ct. 1520 (plurality opinion). The petitioners nonetheless challenged Kentucky's three-drug protocol on the ground that, if prison executioners failed to follow the mandated procedures, an unconstitutional risk of significant pain would result. *Ibid.* A plurality of the Court concluded that "petitioners ha[d] not carried their burden of showing that the risk of pain from maladministration of a

concededly humane lethal injection protocol" would violate the prohibition on cruel and unusual punishments. *Id*., at 41, 128 S.Ct. 1520.

2 Because "midazolam is not an analgesic drug, any painful stimulus applied to an inmate will generate and transmit full intensity pain signals to the brain without interference." App. to Pet. for Cert. 309a. Arthur's expert witness provides "a rough analogy":

"[I]f being sedated is like being asleep, analgesia is like wearing earplugs. If two people are sleeping equally deeply, but only one is wearing earplugs, it will be much easier to shout and wake the person who is not wearing earplugs. If two people are sedated to equivalent levels of electrical brain activity, but only one has analgesia, the person sedated without analgesia will be much more easily aroused to consciousness by the application of pain." *Ibid*.

3 I question the Eleventh Circuit's conclusion that the statute does not authorize the firing squad as an available means of **execution**. In my view, the Alabama statute unambiguously reads as a codification of *Glossip*. If *either* of the specified methods—lethal injection *or* electrocution—is declared unconstitutional, the statute authorizes the State to **execute** prisoners by "*any* constitutional method of **execution**." Ala.Code § 15–18–82.1(c) (2016) (emphasis added). The state statute thus permits exactly what the Court required in *Glossip*—if a condemned prisoner can prove that the lethal-injection protocol presents an unconstitutional risk of needless suffering, he may propose an alternative, constitutional means of **execution**, which may include the firing squad. Even assuming, however, that the Eleventh Circuit properly interpreted Alabama's statute, the question remains whether States may legislatively determine what the Eighth Amendment requires or prohibits. That question is worthy of our review.

4 New York **executed** William Kemmler on August 6, 1890. According to the New York Times, "[p]robably no convicted murderer of modern times has been made to suffer as Kemmler suffered." Far Worse Than Hanging, N.Y. Times, Aug. 7, 1890, p. 1. Witnesses recounted the **execution**:

"After the first convulsion there was not the slightest movement of Kemmler's body.... Then the eyes that had been momentarily turned from Kemmler's body returned to it and gazed with horror on what they saw. The men rose from their chairs impulsively and groaned at the agony they felt. 'Great God! [H]e is alive!' [S]omeone said[.] 'Turn on the current,' said another....

"Again came that click as before, and again the body of the unconscious wretch in the chair became as rigid as one of bronze. It was awful, and the witnesses were so horrified by the ghastly sight that they could not take their eyes off it. The dynamo did not seem to run smoothly. The current could be heard sharply snapping. Blood began to appear on the face of the wretch in the chair. It stood on the face like sweat....

"An awful odor began to permeate the death chamber, and then, as though to cap the climax of this fearful sight, it was seen that the hair under and around the electrode on the head and the flesh under and around the electrode at the base of the spine was singeing. The stench was unbearable." *Ibid.* (paragraph break omitted).

5 After a particularly gruesome electrocution in Florida, this Court granted certiorari on the question whether electrocution creates a constitutionally unacceptable risk of physical suffering in violation of the Eighth Amendment, see *Bryan v. Moore,* 528 U.S. 960, 120 S.Ct. 394, 145 L.Ed.2d 306 (1999), but later dismissed the writ as improvidently granted in light of an amendment to the State's **execution** statute that permitted prisoners to choose lethal injection rather than electrocution, see *Bryan v. Moore,* 528 U.S. 1133, 120 S.Ct. 1003, 145 L.Ed.2d 927 (2000). See also Fla. Stat. Ann. § 922.10 (West 2001).

6 This Court granted certiorari in *Fierro,* vacated the judgment, and remanded for consideration in light of the California Legislature's adoption of lethal injection as the State's primary method of **execution**. See *Gomez v. Fierro,* 519 U.S. 918, 117 S.Ct. 285, 136 L.Ed.2d 204 (1996).

KeyCite Yellow Flag - Negative Treatment
Distinguished by Adams v. Bradshaw, 6th Cir.(Ohio), March 15, 2016

135 S.Ct. 2726
Supreme Court of the United States

Richard E. GLOSSIP, et al., Petitioners
v.
Kevin J. GROSS, et al.

No. 14–7955.
|
Argued April 29, 2015.
|
Decided June 29, 2015.

Synopsis
Background: State death-row inmates brought § 1983 action alleging that Oklahoma's three-drug lethal injection protocol created an unacceptable risk of severe pain in violation of Eighth Amendment. The United States District Court for the Western District of Oklahoma, Stephen P. Friot, J., 2014 WL 7671680, entered an order denying inmates' motion for a preliminary injunction, and they appealed. The United States Court of Appeals for the Tenth Circuit, Briscoe, Chief Judge, 776 F.3d 721, affirmed. Certiorari was granted.

Holdings: The Supreme Court, Justice Alito, held that:

[1] inmates failed to establish that any risk of harm was substantial when compared to a known and available method of execution, and

[2] district court did not commit clear error in finding that midazolam was likely to render an inmate unable to feel pain.

Affirmed.

Justice Scalia filed a concurring opinion in which Justice Thomas joined.

Justice Thomas filed a concurring opinion in which Justice Scalia joined.

Justice Breyer filed a dissenting opinion in which Justice Ginsburg joined.

Justice Sotomayor filed a dissenting opinion in which Justices Ginsburg, Breyer, and Kagan joined.

West Headnotes (11)

[1] Injunction
Grounds in general;multiple factors

A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.

48 Cases that cite this headnote

[2] Sentencing and Punishment
Mode of execution

Prisoners cannot successfully challenge a method of execution under the Eighth Amendment's prohibition of cruel and unusual punishment unless they establish that the method presents a risk that is sure or very likely to cause serious illness and needless suffering and give rise to sufficiently imminent dangers. U.S.C.A. Const.Amend. 8.

68 Cases that cite this headnote

[3] Sentencing and Punishment
Mode of execution

To prevail on a method-of-execution claim under the Eighth Amendment's prohibition of cruel and unusual punishment, there must be a substantial risk of serious harm, that is, an objectively intolerable risk of harm that prevents prison officials from pleading that they were subjectively blameless for purposes of the Eighth Amendment. U.S.C.A. Const.Amend. 8.

67 Cases that cite this headnote

[4] **Sentencing and Punishment**
Mode of execution

Prisoners cannot successfully challenge a state's method of execution under the Eighth Amendment's prohibition of cruel and unusual punishment merely by showing a slightly or marginally safer alternative; instead, the prisoners must identify an alternative that is feasible and readily implemented, and that in fact significantly reduces a substantial risk of severe pain. U.S.C.A. Const.Amend. 8.

81 Cases that cite this headnote

[5] **Sentencing and Punishment**
Mode of execution

State death-row inmates failed to establish that any risk of harm from Oklahoma's three-drug lethal injection protocol, which used midazolam to induce a coma-like state and render inmate insensate to pain, was substantial when compared to a known and available method of execution, as required to prevail on their claim that protocol amounted to cruel and unusual punishment in violation of Eighth Amendment, where inmates did not identify any drugs that could be used in place of midazolam and were available to Oklahoma Department of Corrections, and they did not show a risk of pain so great that other available methods of execution were required to be used. U.S.C.A. Const.Amend. 8.

91 Cases that cite this headnote

[6] **Federal Courts**
Review of federal district courts

The Supreme Court reviews a district court's factual findings under the deferential clear error standard.

10 Cases that cite this headnote

[7] **Federal Courts**
Review of federal district courts

The clear error standard for reviewing a district court's factual findings does not entitle the Supreme Court to overturn a finding simply because the Court is convinced that it would have decided the case differently.

6 Cases that cite this headnote

[8] **Federal Courts**
Scope and Extent of Review

Where an intermediate court reviews, and affirms, a trial court's factual findings, the Supreme Court will not lightly overturn the concurrent findings of the two lower courts, and the Court's review is even more deferential where multiple trial courts have reached the same finding, and multiple appellate courts have affirmed those findings.

1 Cases that cite this headnote

[9] **Civil Rights**
Criminal law enforcement;prisons

Evidence
Nature of Subject

In § 1983 action alleging that Oklahoma's three-drug lethal injection protocol created an unacceptable risk of severe pain in violation of Eighth Amendment, district court did not commit clear error in finding that midazolam was likely to render an inmate unable to feel pain associated with administration of second and third drugs, where State's expert testified that a 500-milligram dose of midazolam would make it a virtual certainty that an inmate would not feel pain associated with other drugs, inmates' experts acknowledged that they had no contrary scientific proof, and there was no probative evidence as to whether midazolam's ceiling effect occurred below 500-milligram dosage level. U.S.C.A. Const.Amend. 8; 42 U.S.C.A. § 1983.

14 Cases that cite this headnote

[10] **Sentencing and Punishment**
Mode of execution

The mere fact that a method of execution might result in some unintended side effects does not amount to an Eighth Amendment violation, since the Constitution does not demand the avoidance of all risk of pain. U.S.C.A. Const.Amend. 8.

5 Cases that cite this headnote

[11] Evidence

Medical testimony

In § 1983 action alleging that Oklahoma's three-drug lethal injection protocol created an unacceptable risk of severe pain in violation of Eighth Amendment, expert's testimony as to effectiveness of midazolam in inducing a coma-like state and rendering an inmate insensate to pain could not be disqualified simply because one source on which he relied warned that it was not intended for medical advice and another source stated that its information was provided without any warranty regarding its correctness, where expert relied on multiple sources and his own expertise, and both parties' experts relied on sources containing similar disclaimers. U.S.C.A. Const.Amend. 8; 42 U.S.C.A. § 1983.

1 Cases that cite this headnote

***2728** *Syllabus* [*]

Because capital punishment is constitutional, there must be a constitutional means of carrying it out. After Oklahoma adopted lethal injection as its method of execution, it settled on a three-drug protocol of (1) sodium thiopental (a barbiturate) to induce a state of unconsciousness, (2) a paralytic agent to inhibit all muscular-skeletal movements, and (3) potassium chloride to induce cardiac arrest. In *Baze v. Rees,* 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420, the Court held that this protocol ***2729** does not violate the Eighth Amendment's prohibition against cruel and unusual punishments. Anti-death-penalty advocates then pressured pharmaceutical companies to prevent sodium thiopental (and, later, another barbiturate called pentobarbital) from being used in executions. Unable to obtain either sodium thiopental or pentobarbital, Oklahoma decided to use a 500–milligram dose of midazolam, a sedative, as the first drug in its three-drug protocol.

Oklahoma death-row inmates filed a 42 U.S.C. § 1983 action claiming that the use of midazolam violates the Eighth Amendment. Four of those inmates filed a motion for a preliminary injunction and argued that a 500–milligram dose of midazolam will not render them unable to feel pain associated with administration of the second and third drugs. After a three-day evidentiary hearing, the District Court denied the motion. It held that the prisoners failed to identify a known and available alternative method of execution that presented a substantially less severe risk of pain. It also held that the prisoners failed to establish a likelihood of showing that the use of midazolam created a demonstrated risk of severe pain. The Tenth Circuit affirmed.

Held : Petitioners have failed to establish a likelihood of success on the merits of their claim that the use of midazolam violates the Eighth Amendment. Pp. 2736 – 2746.

(a) To obtain a preliminary injunction, petitioners must establish, among other things, a likelihood of success on the merits of their claim. See *Winter v. Natural Resources Defense Council, Inc.,* 555 U.S. 7, 20, 129 S.Ct. 365, 172 L.Ed.2d 249. To succeed on an Eighth Amendment method-of-execution claim, a prisoner must establish that the method creates a demonstrated risk of severe pain and that the risk is substantial when compared to the known and available alternatives. *Baze, supra,* at 61, 128 S.Ct. 1520 (plurality opinion). Pp. 2736 – 2738.

(b) Petitioners failed to establish that any risk of harm was substantial when compared to a known and available alternative method of execution. Petitioners have suggested that Oklahoma could execute them using sodium thiopental or pentobarbital, but the District Court did not commit a clear error when it found that those drugs are unavailable to the State. Petitioners argue that the Eighth Amendment does not require them to identify such an alternative, but their argument is inconsistent with the controlling opinion in *Baze,* which imposed a requirement that the Court now follows. Petitioners also argue that the requirement to identify

an alternative is inconsistent with the Court's pre-*Baze* decision in *Hill v. McDonough,* 547 U.S. 573, 126 S.Ct. 2096, 165 L.Ed.2d 44, but they misread that decision. *Hill* concerned a question of civil procedure, not a substantive Eighth Amendment question. That case held that § 1983 alone does not require an inmate asserting a method-of-execution claim to plead an acceptable alternative. *Baze,* on the other hand, made clear that the Eighth Amendment requires a prisoner to plead and prove a known and available alternative. Pp. 2738 – 2739.

(c) The District Court did not commit clear error when it found that midazolam is likely to render a person unable to feel pain associated with administration of the paralytic agent and potassium chloride. Pp. 2739 – 2746.

(1) Several initial considerations bear emphasis. First, the District Court's factual findings are reviewed under the deferential "clear error" standard. Second, petitioners have the burden of persuasion on the question whether midazolam is effective. ***2730** Third, the fact that numerous courts have concluded that midazolam is likely to render an inmate insensate to pain during execution heightens the deference owed to the District Court's findings. Finally, challenges to lethal injection protocols test the boundaries of the authority and competency of federal courts, which should not embroil themselves in ongoing scientific controversies beyond their expertise. *Baze, supra,* at 51, 128 S.Ct. 1520. Pp. 2739 – 2740.

(2) The State's expert presented persuasive testimony that a 500–milligram dose of midazolam would make it a virtual certainty that an inmate will not feel pain associated with the second and third drugs, and petitioners' experts acknowledged that they had no contrary scientific proof. Expert testimony presented by both sides lends support to the District Court's conclusion. Evidence suggested that a 500–milligram dose of midazolam will induce a coma, and even one of petitioners' experts agreed that as the dose of midazolam increases, it is expected to produce a lack of response to pain. It is not dispositive that midazolam is not recommended or approved for use as the sole anesthetic during painful surgery. First, the 500–milligram dose at issue here is many times higher than a normal therapeutic dose. Second, the fact that a low dose of midazolam is not the best drug for maintaining unconsciousness says little about whether a 500–milligram dose is constitutionally adequate to conduct an execution. Finally, the District Court did not err in concluding that the safeguards adopted by Oklahoma to ensure proper administration of midazolam serve to minimize any risk that the drug will not operate as intended. Pp. 2740 – 2743.

(3) Petitioners' speculative evidence regarding midazolam's "ceiling effect" does not establish that the District Court's findings were clearly erroneous. The mere fact that midazolam has a ceiling above which an increase in dosage produces no effect cannot be dispositive, and petitioners provided little probative evidence on the relevant question, *i.e.,* whether midazolam's ceiling effect occurs below the level of a 500–milligram dose and at a point at which the drug does not have the effect of rendering a person insensate to pain caused by the second and third drugs. Petitioners attempt to deflect attention from their failure of proof on this point by criticizing the testimony of the State's expert. They emphasize an apparent conflict between the State's expert and their own expert regarding the biological process that produces midazolam's ceiling effect. But even if petitioners' expert is correct regarding that biological process, it is largely beside the point. What matters for present purposes is the dosage at which the ceiling effect kicks in, not the biological process that produces the effect. Pp. 2742 – 2744.

(4) Petitioners' remaining arguments—that an expert report presented in the District Court should have been rejected because it referenced unreliable sources and contained an alleged mathematical error, that only four States have used midazolam in an execution, and that difficulties during two recent executions suggest that midazolam is ineffective—all lack merit. Pp. 2744 – 2746.

776 F.3d 721, affirmed.

ALITO, J., delivered the opinion of the Court, in which ROBERTS, C.J., and SCALIA, KENNEDY, and THOMAS, JJ., joined. SCALIA, J., filed a concurring opinion, in which THOMAS, J., joined. THOMAS, J., filed a concurring opinion, in which SCALIA, J., joined. BREYER, J., filed a dissenting opinion, in which GINSBURG, J., joined. SOTOMAYOR, J., filed a dissenting opinion, in which ***2731** GINSBURG, BREYER, and KAGAN, JJ., joined.

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Opinion

Justice ALITO delivered the opinion of the Court.

Prisoners sentenced to death in the State of Oklahoma filed an action in federal court under Rev. Stat. § 1979, 42 U.S.C. § 1983, contending that the method of execution now used by the State violates the Eighth Amendment because it creates an unacceptable risk of severe pain. They argue that midazolam, the first drug employed in the State's current three-drug protocol, fails to render a person insensate to pain. After holding an evidentiary hearing, the District Court denied four prisoners' application for a preliminary injunction, finding that they had failed to prove that midazolam is ineffective. The Court of Appeals for the Tenth Circuit affirmed and accepted the District Court's finding of fact regarding midazolam's efficacy.

For two independent reasons, we also affirm. First, the prisoners failed to identify a known and available alternative method of execution that entails a lesser risk of pain, a requirement of all Eighth Amendment method-of-execution claims. See *Baze v. Rees,* 553 U.S. 35, 61, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality opinion). Second, the District Court did not commit clear error when it found that the prisoners failed to establish that Oklahoma's use of a massive dose of midazolam in its execution protocol entails a substantial risk of severe pain.

I

A

The death penalty was an accepted punishment at the time of the adoption of the Constitution and the Bill of Rights. In that era, death sentences were usually carried out by hanging. The Death Penalty in America: Current Controversies 4 (H. Bedau ed. 1997). Hanging remained the standard method of execution through much of the 19th century, but that began to change in the century's later years. See *Baze, supra,* at 41–42, 128 S.Ct. 1520. In the 1880's, the Legislature of the State of New York appointed a commission to find " 'the most humane and practical method known to modern science of carrying into effect the sentence of death in capital cases.' " *In re Kemmler,* 136 U.S. 436, 444, 10 S.Ct. 930, 34 L.Ed. 519 (1890). ***2732** The commission recommended electrocution, and in 1888, the Legislature enacted a law providing for this method of execution. *Id.,* at 444–445, 10 S.Ct. 930. In subsequent years, other States followed New York's lead in the " 'belief that electrocution is less painful and more humane than hanging.' " *Baze,* 553 U.S., at 42, 128 S.Ct. 1520 (quoting *Malloy v. South Carolina,* 237 U.S. 180, 185, 35 S.Ct. 507, 59 L.Ed. 905 (1915)).

In 1921, the Nevada Legislature adopted another new method of execution, lethal gas, after concluding that this was "the most humane manner known to modern science." *State v. Jon,* 46 Nev. 418, 437, 211 P. 676, 682 (1923). The Nevada Supreme Court rejected the argument that the use of lethal gas was unconstitutional, *id.,* at 435–437, 211 P., at 681–682, and other States followed Nevada's lead, see, *e.g.,* Ariz. Const., Art. XXII, § 22 (1933); 1937 Cal. Stats. ch. 172, § 1; 1933 Colo. Sess. Laws ch. 61, § 1; 1955 Md. Laws ch. 625, § 1, p. 1017; 1937 Mo. Laws p. 222, § 1. Nevertheless, hanging and the firing squad were retained in some States, see, *e.g.,* 1961 Del. Laws ch. 309, § 2 (hanging); 1935 Kan. Sess. Laws ch. 155, § 1 (hanging); Utah Code Crim. Proc. § 105–37–16 (1933) (hanging or firing squad), and electrocution remained the predominant method of execution until the 9–year hiatus in executions that ended with our judgment in *Gregg v. Georgia,* 428 U.S. 153, 96 S.Ct. 2909, 49 L.Ed.2d 859 (1976). See *Baze, supra,* at 42, 128 S.Ct. 1520.

After *Gregg* reaffirmed that the death penalty does not violate the Constitution, some States once again sought a more humane way to carry out death sentences. They eventually adopted lethal injection, which today is "by far the most prevalent method of execution in the United States." *Baze, supra,* at 42, 128 S.Ct. 1520. Oklahoma adopted lethal injection in 1977, see 1977 Okla. Sess. Laws p. 89, and it eventually settled on a protocol that called for the use of three drugs: (1) sodium thiopental, "a fast-acting barbiturate sedative that induces a deep, comalike unconsciousness when given in the amounts used for lethal injection," (2) a paralytic agent, which "inhibits all muscular-skeletal movements and, by paralyzing the diaphragm, stops respiration," and (3) potassium chloride, which "interferes with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest." *Baze, supra,* at 44, 128 S.Ct. 1520; see also Brief for Respondents 9. By 2008, at least 30 of the 36 States that used lethal injection employed that particular three-drug protocol. 553 U.S., at 44, 128 S.Ct. 1520.

While methods of execution have changed over the years, "[t]his Court has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment." *Id.,* at 48, 128 S.Ct. 1520. In *Wilkerson v. Utah,* 99 U.S. 130, 134–135, 25 L.Ed. 345 (1879), the Court upheld a sentence of death by firing squad. In *In re Kemmler, supra,* at 447–449, 10 S.Ct. 930, the Court rejected a challenge to the use of the electric chair. And the Court did not retreat from that holding even when presented with a case in which a State's initial attempt to execute a prisoner by electrocution was unsuccessful. *Louisiana ex rel. Francis v. Resweber,* 329 U.S. 459, 463–464, 67 S.Ct. 374, 91 L.Ed. 422 (1947) (plurality opinion). Most recently, in *Baze, supra,* seven Justices agreed that the three-drug protocol just discussed does not violate the Eighth Amendment.

Our decisions in this area have been animated in part by the recognition that because it is settled that capital punishment is constitutional, "[i]t necessarily follows that there must be a [constitutional] ***2733** means of carrying it out." *Id.,* at 47, 128 S.Ct. 1520. And because some risk of pain is inherent in any method of execution, we have held that the Constitution does not require the avoidance of all risk of pain. *Ibid.* After all, while most humans wish to die a painless death, many do not have that good fortune. Holding that the Eighth Amendment demands the elimination of essentially all risk of pain would effectively outlaw the death penalty altogether.

B

Baze cleared any legal obstacle to use of the most common three-drug protocol that had enabled States to carry out the death penalty in a quick and painless fashion. But a practical obstacle soon emerged, as anti-death-penalty advocates pressured pharmaceutical companies to refuse to supply the drugs used to carry out death sentences. The sole American manufacturer of sodium thiopental, the first drug used in the standard three-drug protocol, was persuaded to cease production of the drug. After suspending domestic production in 2009, the company planned to resume production in Italy. Koppel, Execution Drug Halt Raises Ire of Doctors, Wall Street Journal, Jan. 25, 2011, p. A6. Activists then pressured both the company and the Italian Government to stop the sale of sodium thiopental for use in lethal injections in this country. Bonner, Letter from Europe: Drug Company in Cross Hairs of Death Penalty Opponents, N.Y. Times, Mar. 30, 2011; Koppel, Drug Halt Hinders Executions in the U.S., Wall Street Journal, Jan. 22, 2011, p. A1. That effort proved successful, and in January 2011, the company announced that it would exit the sodium thiopental market entirely. See Hospira, Press Release, Hospira Statement Regarding Pentothal ™ (sodium thiopental) Market Exit (Jan. 21, 2011).

After other efforts to procure sodium thiopental proved unsuccessful, States sought an alternative, and they eventually replaced sodium thiopental with pentobarbital, another barbiturate. In December 2010, Oklahoma became the first State to execute an inmate using pentobarbital. See Reuters, Chicago Tribune, New Drug Mix Used in Oklahoma Execution, Dec. 17 2010, p. 41. That execution occurred without incident, and States gradually shifted to pentobarbital as their supplies of sodium thiopental ran out. It is reported that pentobarbital was used in all of the 43 executions carried out in 2012. The Death Penalty Institute, Execution List 2012, online at www.deathpenalty info.org/execution–list–2012 (all Internet materials as visited June 26, 2015, and available in Clerk of Court's case file). Petitioners concede that pentobarbital, like sodium thiopental, can "reliably induce and maintain a comalike state

that renders a person insensate to pain" caused by administration of the second and third drugs in the protocol. Brief for Petitioners 2. And courts across the country have held that the use of pentobarbital in executions does not violate the Eighth Amendment. See, *e.g., Jackson v. Danberg,* 656 F.3d 157 (C.A.3 2011); *Beaty v. Brewer,* 649 F.3d 1071 (C.A.9 2011); *De Young v. Owens,* 646 F.3d 1319 (C.A.11 2011); *Pavatt v. Jones,* 627 F.3d 1336 (C.A.10 2010).

Before long, however, pentobarbital also became unavailable. Anti-death-penalty advocates lobbied the Danish manufacturer of the drug to stop selling it for use in executions. See Bonner, *supra*. That manufacturer opposed the death penalty and took steps to block the shipment of pentobarbital for use in executions in the United States. Stein, New Obstacle to Death Penalty in U.S., Washington Post, July 3, 2011, p. A4. Oklahoma eventually became unable to acquire the drug through any means. The District Court ***2734** below found that both sodium thiopental and pentobarbital are now unavailable to Oklahoma. App. 67–68.

C

Unable to acquire either sodium thiopental or pentobarbital, some States have turned to midazolam, a sedative in the benzodiazepine family of drugs. In October 2013, Florida became the first State to substitute midazolam for pentobarbital as part of a three-drug lethal injection protocol. Fernandez, Executions Stall As States Seek Different Drugs, N.Y. Times, Nov. 9, 2013, p. A1. To date, Florida has conducted 11 executions using that protocol, which calls for midazolam followed by a paralytic agent and potassium chloride. See Brief for State of Florida as *Amicus Curiae* 2–3; *Chavez v. Florida SP Warden,* 742 F.3d 1267, 1269 (C.A.11 2014). In 2014, Oklahoma also substituted midazolam for pentobarbital as part of its three-drug protocol. Oklahoma has already used this three-drug protocol twice: to execute Clayton Lockett in April 2014 and Charles Warner in January 2015. (Warner was one of the four inmates who moved for a preliminary injunction in this case.)

The Lockett execution caused Oklahoma to implement new safety precautions as part of its lethal injection protocol. When Oklahoma executed Lockett, its protocol called for the administration of 100 milligrams of midazolam, as compared to the 500 milligrams that are currently required. On the morning of his execution, Lockett cut himself twice at " 'the bend of the elbow.' " App. 50. That evening, the execution team spent nearly an hour making at least one dozen attempts to establish intravenous (IV) access to Lockett's cardiovascular system, including at his arms and elsewhere on his body. The team eventually believed that it had established intravenous access through Lockett's right femoral vein, and it covered the injection access point with a sheet, in part to preserve Lockett's dignity during the execution. After the team administered the midazolam and a physician determined that Lockett was unconscious, the team next administered the paralytic agent (vecuronium bromide) and most of the potassium chloride. Lockett began to move and speak, at which point the physician lifted the sheet and determined that the IV had "infiltrated," which means that "the IV fluid, rather than entering Lockett's blood stream, had leaked into the tissue surrounding the IV access point." *Warner v. Gross,* 776 F.3d 721, 725 (C.A.10 2015) (case below). The execution team stopped administering the remaining potassium chloride and terminated the execution about 33 minutes after the midazolam was first injected. About 10 minutes later, Lockett was pronounced dead.

An investigation into the Lockett execution concluded that "the viability of the IV access point was the single greatest factor that contributed to the difficulty in administering the execution drugs." App. 398. The investigation, which took five months to complete, recommended several changes to Oklahoma's execution protocol, and Oklahoma adopted a new protocol with an effective date of September 30, 2014. That protocol allows the Oklahoma Department of Corrections to choose among four different drug combinations. The option that Oklahoma plans to use to execute petitioners calls for the administration of 500 milligrams of midazolam followed by a paralytic agent and potassium chloride.[1] ***2735** The paralytic agent may be pancuronium bromide, vecuronium bromide, or rocuronium bromide, three drugs that, all agree, are functionally equivalent for purposes of this case. The protocol also includes procedural safeguards to help ensure that an inmate remains insensate to any pain caused by the administration of the paralytic agent and potassium chloride. Those safeguards include: (1) the insertion of both a primary and backup IV catheter, (2) procedures to confirm the viability of the IV site, (3) the option to postpone an execution if viable IV sites cannot

be established within an hour, (4) a mandatory pause between administration of the first and second drugs, (5) numerous procedures for monitoring the offender's consciousness, including the use of an electrocardiograph and direct observation, and (6) detailed provisions with respect to the training and preparation of the execution team. In January of this year, Oklahoma executed Warner using these revised procedures and the combination of midazolam, a paralytic agent, and potassium chloride.

II

A

In June 2014, after Oklahoma switched from pentobarbital to midazolam and executed Lockett, 21 Oklahoma death row inmates filed an action under 42 U.S.C. § 1983 challenging the State's new lethal injection protocol. The complaint alleged that Oklahoma's use of midazolam violates the Eighth Amendment's prohibition of cruel and unusual punishment.

In November 2014, four of those plaintiffs—Richard Glossip, Benjamin Cole, John Grant, and Warner—filed a motion for a preliminary injunction. All four men had been convicted of murder and sentenced to death by Oklahoma juries. Glossip hired Justin Sneed to kill his employer, Barry Van Treese. Sneed entered a room where Van Treese was sleeping and beat him to death with a baseball bat. See *Glossip v. State,* 2007 OK CR 12, 157 P.3d 143, 147–149. Cole murdered his 9–month–old daughter after she would not stop crying. Cole bent her body backwards until he snapped her spine in half. After the child died, Cole played video games. See *Cole v. State,* 2007 OK CR 27, 164 P.3d 1089, 1092–1093. Grant, while serving terms of imprisonment totaling 130 years, killed Gay Carter, a prison food service supervisor, by pulling her into a mop closet and stabbing her numerous times with a shank. See *Grant v. State,* 2002 OK CR 36, 58 P.3d 783, 789. Warner anally raped and murdered an 11–month–old girl. The child's injuries included two skull fractures, internal brain injuries, two fractures to her jaw, a lacerated liver, and a bruised spleen and lungs. See *Warner v. State,* 2006 OK CR 40, 144 P.3d 838, 856–857.

The Oklahoma Court of Criminal Appeals affirmed the murder conviction and death sentence of each offender. Each of the men then unsuccessfully sought both state postconviction and federal habeas corpus relief. Having exhausted the avenues for challenging their convictions and sentences, they moved for a preliminary injunction against Oklahoma's lethal injection protocol.

B

In December 2014, after discovery, the District Court held a 3–day evidentiary hearing on the preliminary injunction motion. The District Court heard testimony from 17 witnesses and reviewed numerous exhibits. Dr. David Lubarsky, an anesthesiologist, and Dr. Larry Sasich, a doctor of pharmacy, provided expert testimony about midazolam for petitioners, and Dr. Roswell Evans, a doctor of pharmacy, provided expert testimony for respondents.

***2736** After reviewing the evidence, the District Court issued an oral ruling denying the motion for a preliminary injunction. The District Court first rejected petitioners' challenge under *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), to the testimony of Dr. Evans. It concluded that Dr. Evans, the Dean of Auburn University's School of Pharmacy, was well qualified to testify about midazolam's properties and that he offered reliable testimony. The District Court then held that petitioners failed to establish a likelihood of success on the merits of their claim that the use of midazolam violates the Eighth Amendment. The court provided two independent reasons for this conclusion. First, the court held that petitioners failed to identify a known and available method of execution that presented a substantially less severe risk of pain than the method that the State proposed to use. Second, the court found that petitioners failed to prove that Oklahoma's protocol "presents a risk that is 'sure or very likely to cause serious illness and needless suffering,' amounting to 'an objectively intolerable risk of harm.' " App. 96 (quoting *Baze,* 553 U.S., at 50, 128 S.Ct. 1520). The court emphasized that the Oklahoma protocol featured numerous safeguards, including the establishment of two IV access sites, confirmation of the viability of those sites, and monitoring of the offender's level of consciousness throughout the procedure.

The District Court supported its decision with findings of fact about midazolam. It found that a 500–milligram dose of midazolam "would make it a virtual certainty that any

individual will be at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from the application of the second and third drugs." App. 77. Indeed, it found that a 500–milligram dose alone would likely cause death by respiratory arrest within 30 minutes or an hour.

The Court of Appeals for the Tenth Circuit affirmed. 776 F.3d 721. The Court of Appeals explained that our decision in *Baze* requires a plaintiff challenging a lethal injection protocol to demonstrate that the risk of severe pain presented by an execution protocol is substantial " 'when compared to the known and available alternatives.' " *Id.,* at 732 (quoting *Baze, supra,* at 61, 128 S.Ct. 1520). And it agreed with the District Court that petitioners had not identified any such alternative. The Court of Appeals added, however, that this holding was "not outcome-determinative in this case" because petitioners additionally failed to establish that the use of midazolam creates a demonstrated risk of severe pain. 776 F.3d, at 732. The Court of Appeals found that the District Court did not abuse its discretion by relying on Dr. Evans' testimony, and it concluded that the District Court's factual findings about midazolam were not clearly erroneous. It also held that alleged errors in Dr. Evans' testimony did not render his testimony unreliable or the District Court's findings clearly erroneous.

Oklahoma executed Warner on January 15, 2015, but we subsequently voted to grant review and then stayed the executions of Glossip, Cole, and Grant pending the resolution of this case. 574 U.S. ——, 135 S.Ct. 1173, 190 L.Ed.2d 929 (2015).

III

[1] "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter* ***2737** *v. Natural Resources Defense Council, Inc.,* 555 U.S. 7, 20, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008). The parties agree that this case turns on whether petitioners are able to establish a likelihood of success on the merits.

The Eighth Amendment, made applicable to the States through the Fourteenth Amendment, prohibits the infliction of "cruel and unusual punishments." The controlling opinion in *Baze* outlined what a prisoner must establish to succeed on an Eighth Amendment method-of-execution claim. *Baze* involved a challenge by Kentucky death row inmates to that State's three-drug lethal injection protocol of sodium thiopental, pancuronium bromide, and potassium chloride. The inmates conceded that the protocol, if properly administered, would result in a humane and constitutional execution because sodium thiopental would render an inmate oblivious to any pain caused by the second and third drugs. 553 U.S., at 49, 128 S.Ct. 1520. But they argued that there was an unacceptable risk that sodium thiopental would not be properly administered. *Ibid.* The inmates also maintained that a significant risk of harm could be eliminated if Kentucky adopted a one-drug protocol and additional monitoring by trained personnel. *Id.,* at 51, 128 S.Ct. 1520.

[2] **[3]** **[4]** The controlling opinion in *Baze* first concluded that prisoners cannot successfully challenge a method of execution unless they establish that the method presents a risk that is " '*sure or very likely* to cause serious illness and needless suffering,' and give rise to 'sufficiently *imminent* dangers.' " *Id.,* at 50, 128 S.Ct. 1520 (quoting *Helling v. McKinney,* 509 U.S. 25, 33, 34–35, 113 S.Ct. 2475, 125 L.Ed.2d 22 (1993)). To prevail on such a claim, "there must be a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment.' " 553 U.S., at 50, 128 S.Ct. 1520 (quoting *Farmer v. Brennan,* 511 U.S. 825, 846, and n. 9, 114 S.Ct. 1970, 128 L.Ed.2d 811 (1994)). The controlling opinion also stated that prisoners "cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative." 553 U.S., at 51, 128 S.Ct. 1520. Instead, prisoners must identify an alternative that is "feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain." *Id.,* at 52, 128 S.Ct. 1520.

The controlling opinion summarized the requirements of an Eighth Amendment method-of-execution claim as follows: "A stay of execution may not be granted on grounds such as those asserted here unless the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain. [And] [h]e must show that the risk is substantial when compared to the known and available alternatives." *Id.,*

at 61, 128 S.Ct. 1520. The preliminary injunction posture of the present case thus requires petitioners to establish a likelihood that they can establish both that Oklahoma's lethal injection protocol creates a demonstrated risk of severe pain and that the risk is substantial when compared to the known and available alternatives.

The challenge in *Baze* failed both because the Kentucky inmates did not show that the risks they identified were substantial and imminent, *id.,* at 56, 128 S.Ct. 1520, and because they did not establish the existence of a known and available alternative method of execution that would entail a significantly less severe risk, *id.,* at 57–60, 128 S.Ct. 1520. Petitioners' arguments here fail for similar reasons. First, petitioners have not proved that any risk posed by midazolam is substantial ***2738** when compared to known and available alternative methods of execution. Second, they have failed to establish that the District Court committed clear error when it found that the use of midazolam will not result in severe pain and suffering. We address each reason in turn.

IV

Our first ground for affirmance is based on petitioners' failure to satisfy their burden of establishing that any risk of harm was substantial when compared to a known and available alternative method of execution. In their amended complaint, petitioners proffered that the State could use sodium thiopental as part of a single-drug protocol. They have since suggested that it might also be constitutional for Oklahoma to use pentobarbital. But the District Court found that both sodium thiopental and pentobarbital are now unavailable to Oklahoma's Department of Corrections. The Court of Appeals affirmed that finding, and it is not clearly erroneous. On the contrary, the record shows that Oklahoma has been unable to procure those drugs despite a good-faith effort to do so.

[5] Petitioners do not seriously contest this factual finding, and they have not identified any available drug or drugs that could be used in place of those that Oklahoma is now unable to obtain. Nor have they shown a risk of pain so great that other acceptable, available methods must be used. Instead, they argue that they need not identify a known and available method of execution that presents less risk. But this argument is inconsistent with the controlling opinion in *Baze,* 553 U.S., at 61, 128 S.Ct. 1520, which imposed a requirement that the Court now follows. [2]

Petitioners contend that the requirement to identify an alternative method of execution contravenes our pre-*Baze* decision in *Hill v. McDonough,* 547 U.S. 573, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006), but they misread that decision. The portion of the opinion in *Hill* on which they rely concerned a question of civil procedure, not a substantive Eighth Amendment question. In *Hill,* the issue was whether a challenge to a method of execution must be brought by means of an application for a writ of habeas corpus or a civil action under § 1983. *Id.,* at 576, 126 S.Ct. 2096. We held that a method-of-execution claim must be brought under § 1983 because such a claim does not attack the validity of the prisoner's conviction or death sentence. *Id.,* at 579–580, 126 S.Ct. 2096. The United States as *amicus curiae* argued that we should adopt a special pleading requirement to stop inmates from using § 1983 actions to attack, not just a particular means of execution, but the death penalty itself. To achieve this end, the United States proposed that an inmate asserting a method-of-execution claim should be required to plead an acceptable alternative method of execution. *Id.,* at 582, 126 S.Ct. 2096. We rejected that argument because "[s]pecific pleading requirements are mandated ***2739** by the Federal Rules of Civil Procedure, and not, as a general rule, through case-by-case determinations of the federal courts." *Ibid.* *Hill* thus held that § 1983 alone does not impose a heightened pleading requirement. *Baze,* on the other hand, addressed the substantive elements of an Eighth Amendment method-of-execution claim, and it made clear that the Eighth Amendment requires a prisoner to plead and prove a known and available alternative. Because petitioners failed to do this, the District Court properly held that they did not establish a likelihood of success on their Eighth Amendment claim.

Readers can judge for themselves how much distance there is between the principal dissent's argument against requiring prisoners to identify an alternative and the view, now announced by Justices BREYER and GINSBURG, that the death penalty is categorically unconstitutional. *Post,* p. 2759 (BREYER, J., dissenting). The principal dissent goes out of its way to suggest that a State would violate the Eighth Amendment if it used one of the methods of execution employed before the advent of lethal injection. *Post,* at 2770 – 2772. And the principal

dissent makes this suggestion even though the Court held in *Wilkerson* that this method (the firing squad) is constitutional and even though, in the words of the principal dissent, "there is some reason to think that it is relatively quick and painless." *Post,* at 2796. Tellingly silent about the methods of execution most commonly used before States switched to lethal injection (the electric chair and gas chamber), the principal dissent implies that it would be unconstitutional to use a method that "could be seen as a devolution to a more primitive era." *Ibid.* If States cannot return to any of the "more primitive" methods used in the past and if no drug that meets with the principal dissent's approval is available for use in carrying out a death sentence, the logical conclusion is clear. But we have time and again reaffirmed that capital punishment is not *per se* unconstitutional. See, *e.g., Baze,* 553 U.S., at 47, 128 S.Ct. 1520; *id.,* at 87–88, 128 S.Ct. 1520 (SCALIA, J., concurring in judgment); *Gregg,* 428 U.S., at 187, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and Stevens, JJ.); *id.,* at 226, 96 S.Ct. 2909 (White, J., concurring in judgment); *Resweber,* 329 U.S., at 464, 67 S.Ct. 374; *In re Kemmler,* 136 U.S., at 447, 10 S.Ct. 930; *Wilkerson,* 99 U.S., at 134–135. We decline to effectively overrule these decisions.

V

We also affirm for a second reason: The District Court did not commit clear error when it found that midazolam is highly likely to render a person unable to feel pain during an execution. We emphasize four points at the outset of our analysis.

[6] **[7]** First, we review the District Court's factual findings under the deferential "clear error" standard. This standard does not entitle us to overturn a finding "simply because [we are] convinced that [we] would have decided the case differently." *Anderson v. Bessemer City,* 470 U.S. 564, 573, 105 S.Ct. 1504, 84 L.Ed.2d 518 (1985).

Second, petitioners bear the burden of persuasion on this issue. *Baze, supra,* at 41, 128 S.Ct. 1520. Although petitioners expend great effort attacking peripheral aspects of Dr. Evans' testimony, they make little attempt to prove what is critical, *i.e.,* that the evidence they presented to the District Court establishes that the use of midazolam is sure or very likely to result in needless suffering.

[8] Third, numerous courts have concluded that the use of midazolam as the first drug in a three-drug protocol is likely to render an inmate insensate to pain that ***2740** might result from administration of the paralytic agent and potassium chloride. See, *e.g.,* 776 F.3d 721 (case below affirming the District Court); *Chavez v. Florida SP Warden,* 742 F.3d 1267 (affirming the District Court); *Banks v. State,* 150 So.3d 797 (Fla.2014) (affirming the lower court); *Howell v. State,* 133 So.3d 511 (Fla.2014) (same); *Muhammad v. State,* 132 So.3d 176 (Fla.2013) (same). (It is noteworthy that one or both of the two key witnesses in this case—Dr. Lubarsky for petitioners and Dr. Evans for respondents—were witnesses in the *Chavez, Howell,* and *Muhammad* cases.) "Where an intermediate court reviews, and affirms, a trial court's factual findings, this Court will not 'lightly overturn' the concurrent findings of the two lower courts." *Easley v. Cromartie,* 532 U.S. 234, 242, 121 S.Ct. 1452, 149 L.Ed.2d 430 (2001). Our review is even more deferential where, as here, multiple trial courts have reached the same finding, and multiple appellate courts have affirmed those findings. Cf. *Exxon Co., U.S.A. v. Sofec, Inc.,* 517 U.S. 830, 841, 116 S.Ct. 1813, 135 L.Ed.2d 113 (1996) (explaining that this Court " 'cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error' " (quoting *Graver Tank & Mfg. Co. v. Linde Air Products Co.,* 336 U.S. 271, 275, 69 S.Ct. 535, 93 L.Ed. 672 (1949))).

Fourth, challenges to lethal injection protocols test the boundaries of the authority and competency of federal courts. Although we must invalidate a lethal injection protocol if it violates the Eighth Amendment, federal courts should not "embroil [themselves] in ongoing scientific controversies beyond their expertise." *Baze, supra,* at 51, 128 S.Ct. 1520. Accordingly, an inmate challenging a protocol bears the burden to show, based on evidence presented to the court, that there is a substantial risk of severe pain.

A

[9] **[10]** Petitioners attack the District Court's findings of fact on two main grounds.[3] First, they argue that even if midazolam is powerful enough to induce unconsciousness, it is too weak to maintain unconsciousness and insensitivity to pain once the second

and third drugs are administered. Second, while conceding that the 500–milligram dose of midazolam is much higher than the normal therapeutic dose, they contend that this fact is irrelevant because midazolam has a "ceiling effect"—that is, at a certain point, an increase in the dose administered will not have any greater effect on the inmate. Neither argument succeeds.

The District Court found that midazolam is capable of placing a person "at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from the application of the second and third drugs." App. 77. This conclusion was not clearly ***2741** erroneous. Respondents' expert, Dr. Evans, testified that the proper administration of a 500–milligram dose of midazolam would make it "a virtual certainty" that any individual would be "at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from application of the 2nd and 3rd drugs" used in the Oklahoma protocol. *Id.,* at 302; see also *id.,* at 322. And petitioners' experts acknowledged that they had no contrary scientific proof. See *id.,* at 243–244 (Dr. Sasich stating that the ability of midazolam to render a person insensate to the second and third drugs "has not been subjected to scientific testing"); *id.*, at 176 (Dr. Lubarsky stating that "there is no scientific literature addressing the use of midazolam as a manner to administer lethal injections in humans").

In an effort to explain this dearth of evidence, Dr. Sasich testified that "[i]t's not my responsibility or the [Food and Drug Administration's] responsibility to prove that the drug doesn't work or is not safe." Tr. of Preliminary Injunction Hearing 357 (Tr.). Instead, he stated, "it's the responsibility of the proponent to show that the drug is safe and effective." *Ibid.* Dr. Sasich confused the standard imposed on a drug manufacturer seeking approval of a therapeutic drug with the standard that must be borne by a party challenging a State's lethal injection protocol. When a method of execution is authorized under state law, a party contending that this method violates the Eighth Amendment bears the burden of showing that the method creates an unacceptable risk of pain. Here, petitioners' own experts effectively conceded that they lacked evidence to prove their case beyond dispute.

Petitioners attempt to avoid this deficiency by criticizing respondents' expert. They argue that the District Court should not have credited Dr. Evans' testimony because he admitted that his findings were based on " 'extrapolat [ions]' " from studies done about much lower therapeutic doses of midazolam. See Brief for Petitioners 34 (citing Tr. 667–668; emphasis deleted). But because a 500–milligram dose is never administered for a therapeutic purpose, extrapolation was reasonable. And the conclusions of petitioners' experts were also based on extrapolations and assumptions. For example, Dr. Lubarsky relied on "extrapolation of the ceiling effect data." App. 177.

Based on the evidence that the parties presented to the District Court, we must affirm. Testimony from both sides supports the District Court's conclusion that midazolam can render a person insensate to pain. Dr. Evans testified that although midazolam is not an analgesic, it can nonetheless "render the person unconscious and 'insensate' during the remainder of the procedure." *Id.,* at 294. In his discussion about the ceiling effect, Dr. Sasich agreed that as the dose of midazolam increases, it is "expected to produce sedation, amnesia, and finally lack of response to stimuli such as pain (unconsciousness)." *Id.,* at 243. Petitioners argue that midazolam is not powerful enough to keep a person insensate to pain after the administration of the second and third drugs, but Dr. Evans presented creditable testimony to the contrary. See, *e.g.,* Tr. 661 (testifying that a 500–milligram dose of midazolam will induce a coma).[4] Indeed, low doses of midazolam ***2742** are sufficient to induce unconsciousness and are even sometimes used as the sole relevant drug in certain medical procedures. Dr. Sasich conceded, for example, that midazolam might be used for medical procedures like colonoscopies and gastroscopies. App. 267–268; see also Brief for Respondents 6–8.[5]

Petitioners emphasize that midazolam is not recommended or approved for use as the sole anesthetic during painful surgery, but there are two reasons why this is not dispositive. First, as the District Court found, the 500–milligram dose at issue here "is many times higher than a normal therapeutic dose of midazolam." App. 76. The effect of a small dose of midazolam has minimal probative value about the effect of a 500–milligram dose. Second, the fact that a low dose of midazolam is not the *best* drug for maintaining unconsciousness during surgery says little about whether a 500–milligram dose of midazolam is *constitutionally adequate* for purposes of conducting an execution. We recognized this point in *Baze,* where we concluded that although the medical standard of care might require the use of a blood pressure cuff and an electrocardiogram during surgeries, this does

not mean those procedures are required for an execution to pass Eighth Amendment scrutiny. 553 U.S., at 60, 128 S.Ct. 1520.

Oklahoma has also adopted important safeguards to ensure that midazolam is properly administered. The District Court emphasized three requirements in particular: The execution team must secure both a primary and backup IV access site, it must confirm the viability of the IV sites, and it must continuously monitor the offender's level of consciousness. The District Court did not commit clear error in concluding that these safeguards help to minimize any risk that might occur in the event that midazolam does not operate as intended. Indeed, we concluded in *Baze* that many of the safeguards that Oklahoma employs—including the establishment of a primary and backup IV and the presence of personnel to monitor an inmate—help in significantly reducing the risk that an execution protocol will violate the Eighth Amendment. *Id.,* at 55–56, 128 S.Ct. 1520. And many other safeguards that Oklahoma has adopted mirror those that the dissent in *Baze* complained were absent from Kentucky's protocol in that case. For example, the dissent argued that because a consciousness check before injection of the second drug "can reduce a risk of dreadful pain," Kentucky's failure to include that step in its procedure was unconstitutional. *Id.,* at 119, 128 S.Ct. 1520 (opinion of GINSBURG, J.). The dissent also complained that Kentucky did not monitor the effectiveness of the first drug or pause between injection of the first and second drugs. *Id.,* at 120–121, 128 S.Ct. 1520. Oklahoma has accommodated each of those concerns.

B

Petitioners assert that midazolam's "ceiling effect" undermines the District Court's ***2743** finding about the effectiveness of the huge dose administered in the Oklahoma protocol. Petitioners argue that midazolam has a "ceiling" above which any increase in dosage produces no effect. As a result, they maintain, it is wrong to assume that a 500–milligram dose has a much greater effect than a therapeutic dose of about 5 milligrams. But the mere fact that midazolam has such a ceiling cannot be dispositive. Dr. Sasich testified that "all drugs essentially have a ceiling effect." Tr. 343. The relevant question here is whether midazolam's ceiling effect occurs below the level of a 500–milligram dose and at a point at which the drug does not have the effect of rendering a person insensate to pain caused by the second and third drugs.

Petitioners provided little probative evidence on this point, and the speculative evidence that they did present to the District Court does not come close to establishing that its factual findings were clearly erroneous. Dr. Sasich stated in his expert report that the literature "indicates" that midazolam has a ceiling effect, but he conceded that he "was unable to determine the midazolam dose for a ceiling effect on unconsciousness because there is no literature in which such testing has been done." App. 243–244. Dr. Lubarsky's report was similar, *id.,* at 171–172, and the testimony of petitioners' experts at the hearing was no more compelling. Dr. Sasich frankly admitted that he did a "search to try and determine at what dose of midazolam you would get a ceiling effect," but concluded: "I could not find one." Tr. 344. The closest petitioners came was Dr. Lubarsky's suggestion that the ceiling effect occurs "[p]robably after about ... 40 to 50 milligrams," but he added that he had not actually done the relevant calculations, and he admitted: "I can't tell you right now" at what dose the ceiling effect occurs. App. 225. We cannot conclude that the District Court committed clear error in declining to find, based on such speculative evidence, that the ceiling effect negates midazolam's ability to render an inmate insensate to pain caused by the second and third drugs in the protocol.

The principal dissent discusses the ceiling effect at length, but it studiously avoids suggesting that petitioners presented probative evidence about the dose at which the ceiling effect occurs or about whether the effect occurs before a person becomes insensate to pain. The principal dissent avoids these critical issues by suggesting that such evidence is "irrelevant if there is no dose at which the drug can ... render a person 'insensate to pain.' " *Post,* at 2789. But the District Court heard evidence that the drug can render a person insensate to pain, and not just from Dr. Evans: Dr. Sasich (one of petitioners' own experts) testified that higher doses of midazolam are "expected to produce ... lack of response to stimuli such as pain." App. 243. [6]

In their brief, petitioners attempt to deflect attention from their failure of proof regarding midazolam's ceiling effect by criticizing Dr. Evans' testimony. But it was *petitioners*' burden to establish that midazolam's ceiling occurred at a dosage below the massive 500–milligram dose employed

in the Oklahoma protocol and at a point at which the drug failed to render the recipient insensate to pain. They did ***2744** not meet that burden, and their criticisms do not undermine Dr. Evans' central point, which the District Court credited, that a properly administered 500–milligram dose of midazolam will render the recipient unable to feel pain.

One of petitioners' criticisms of Dr. Evans' testimony is little more than a quibble about the wording chosen by Dr. Evans at one point in his oral testimony. Petitioners' expert, Dr. Lubarsky, stated in his report that midazolam "increases effective binding of [gamma-aminobutyric acid (GABA)] to its receptor to induce unconsciousness." [7] App. 172. Dr. Evans' report provided a similar explanation of the way in which midazolam works, see *id.,* at 293–294, and Dr. Lubarsky did not dispute the accuracy of that explanation when he testified at the hearing. Petitioners contend, however, that Dr. Evans erred when he said at the hearing that "[m]idazolam attaches to GABA receptors, *inhibiting GABA*." *Id.,* at 312 (emphasis added). Petitioners contend that this statement was incorrect because "far from *inhibiting* GABA, midazolam *facilitates its binding* to GABA receptors." Brief for Petitioners 38.

In making this argument, petitioners are simply quarrelling with the words that Dr. Evans used during oral testimony in an effort to explain how midazolam works in terms understandable to a layman. Petitioners do not suggest that the discussion of midazolam in Dr. Evans' expert report was inaccurate, and as for Dr. Evans' passing use of the term "inhibiting," Dr. Lubarsky's own expert report states that GABA's "*inhibition* of brain activity is accentuated by midazolam." App. 232 (emphasis added). Dr. Evans' oral use of the word "inhibiting"—particularly in light of his written testimony—does not invalidate the District Court's decision to rely on his testimony.

Petitioners also point to an apparent conflict between Dr. Evans' testimony and a declaration by Dr. Lubarsky (submitted after the District Court ruled) regarding the biological process that produces midazolam's ceiling effect. But even if Dr. Lubarsky's declaration is correct, it is largely beside the point. What matters for present purposes is the dosage at which the ceiling effect kicks in, not the biological process that produces the effect. And Dr. Lubarsky's declaration does not render the District Court's findings clearly erroneous with respect to that critical issue.

C

[11] Petitioners' remaining arguments about midazolam all lack merit. First, we are not persuaded by petitioners' argument that Dr. Evans' testimony should have been rejected because of some of the sources listed in his report. Petitioners criticize two of the "selected references" that Dr. Evans cited in his expert report: the Web site drugs.com and a material safety data sheet (MSDS) about midazolam. Petitioners' argument is more of a *Daubert* challenge to Dr. Evans' testimony than an argument that the District Court's findings were clearly erroneous. The District Court concluded that Dr. Evans was "well-qualified to give the expert testimony that he gave" and that "his testimony was the product of reliable principles and methods reliably applied to the facts of this case." App. 75–76. To the extent that the reliability of Dr. Evans' testimony is even before us, the District Court's conclusion that his testimony was based on reliable sources is reviewed under the deferential ***2745** "abuse-of-discretion" standard. *General Elec. Co. v. Joiner,* 522 U.S. 136, 142–143, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). Dr. Evans relied on multiple sources and his own expertise, and his testimony may not be disqualified simply because one source (drugs.com) warns that it " 'is not intended for medical advice' " and another (the MSDS) states that its information is provided " 'without any warranty, express or implied, regarding its correctness.' " Brief for Petitioners 36. Medical journals that both parties rely upon typically contain similar disclaimers. See, *e.g.,* Anesthesiology, Terms and Conditions of Use, online at http://anesthesiology.pubs.asahq.org/ss/terms.aspx ("None of the information on this Site shall be used to diagnose or treat any health problem or disease"). Dr. Lubarsky—petitioners' own expert—relied on an MSDS to argue that midazolam has a ceiling effect. And petitioners do not identify any incorrect statements from drugs.com on which Dr. Evans relied. In fact, although Dr. Sasich submitted a declaration to the Court of Appeals criticizing Dr. Evans' reference to drugs.com, that declaration does not identify a single fact from that site's discussion of midazolam that was materially inaccurate.

Second, petitioners argue that Dr. Evans' expert report contained a mathematical error, but we find this argument insignificant. Dr. Evans stated in his expert report that the lowest dose of midazolam resulting in human deaths, according to an MSDS, is 0.071 mg/kg delivered intravenously. App. 294. Dr. Lubarsky agreed with this statement. Specifically, he testified that fatalities have occurred in doses ranging from 0.04 to 0.07 mg/kg, and he stated that Dr. Evans' testimony to that effect was "a true statement" (though he added those fatalities occurred among the elderly). *Id.,* at 217. We do not understand petitioners to dispute the testimony of Dr. Evans and their own expert that 0.071 mg/kg is a potentially fatal dose of midazolam. Instead, they make much of the fact that the MSDS attached to Dr. Evans' report apparently contained a typographical error and reported the lowest toxic dose as 71 mg/kg. That Dr. Evans did not repeat that incorrect figure but instead reported the correct dose supports rather than undermines his testimony. In any event, the alleged error in the MSDS is irrelevant because the District Court expressly stated that it did not rely on the figure in the MSDS. See *id.,* at 75.

Third, petitioners argue that there is no consensus among the States regarding midazolam's efficacy because only four States (Oklahoma, Arizona, Florida, and Ohio) have used midazolam as part of an execution. Petitioners rely on the plurality's statement in *Baze* that "it is difficult to regard a practice as 'objectively intolerable' when it is in fact widely tolerated," and the plurality's emphasis on the fact that 36 States had adopted lethal injection and 30 States used the particular three-drug protocol at issue in that case. 553 U.S., at 53, 128 S.Ct. 1520. But while the near-universal use of the particular protocol at issue in *Baze* supported our conclusion that this protocol did not violate the Eighth Amendment, we did not say that the converse was true, *i.e.,* that other protocols or methods of execution are of doubtful constitutionality. That argument, if accepted, would hamper the adoption of new and potentially more humane methods of execution and would prevent States from adapting to changes in the availability of suitable drugs.

Fourth, petitioners argue that difficulties with Oklahoma's execution of Lockett and Arizona's July 2014 execution of Joseph Wood establish that midazolam is sure or very likely to cause serious pain. We are not persuaded. Aside from the ***2746** Lockett execution, 12 other executions have been conducted using the three-drug protocol at issue here, and those appear to have been conducted without any significant problems. See Brief for Respondents 32; Brief for State of Florida as *Amicus Curiae* 1. Moreover, Lockett was administered only 100 milligrams of midazolam, and Oklahoma's investigation into that execution concluded that the difficulties were due primarily to the execution team's inability to obtain an IV access site. And the Wood execution did not involve the protocol at issue here. Wood did not receive a single dose of 500 milligrams of midazolam; instead, he received fifteen 50–milligram doses over the span of two hours. [8] Brief for Respondents 12, n. 9. And Arizona used a different two-drug protocol that paired midazolam with hydromorphone, a drug that is not at issue in this case. *Ibid.* When all of the circumstances are considered, the Lockett and Wood executions have little probative value for present purposes.

Finally, we find it appropriate to respond to the principal dissent's groundless suggestion that our decision is tantamount to allowing prisoners to be "drawn and quartered, slowly tortured to death, or actually burned at the stake." *Post,* at 2795. That is simply not true, and the principal dissent's resort to this outlandish rhetoric reveals the weakness of its legal arguments.

VI

For these reasons, the judgment of the Court of Appeals for the Tenth Circuit is affirmed.

It is so ordered.

Justice SCALIA, with whom Justice THOMAS joins, concurring.

I join the opinion of the Court, and write to respond to Justice BREYER's plea for judicial abolition of the death penalty.

Welcome to Groundhog Day. The scene is familiar: Petitioners, sentenced to die for the crimes they committed (including, in the case of one petitioner since put to death, raping and murdering an 11–month–old baby), come before this Court asking us to nullify their sentences as "cruel and unusual" under the Eighth Amendment. They rely on this provision because it is the only provision

they *can* rely on. They were charged by a sovereign State with murder. They were afforded counsel and tried before a jury of their peers—tried twice, once to determine ***2747** whether they were guilty and once to determine whether death was the appropriate sentence. They were duly convicted and sentenced. They were granted the right to appeal and to seek postconviction relief, first in state and then in federal court. And now, acknowledging that their convictions are unassailable, they ask us for clemency, as though clemency were ours to give.

The response is also familiar: A vocal minority of the Court, waving over their heads a ream of the most recent abolitionist studies (a superabundant genre) as though they have discovered the lost folios of Shakespeare, insist that *now,* at long last, the death penalty must be abolished for good. Mind you, not once in the history of the American Republic has this Court ever suggested the death penalty is categorically impermissible. The reason is obvious: It is impossible to hold unconstitutional that which the Constitution explicitly *contemplates.* The Fifth Amendment provides that "[n]o person shall be held to answer for a capital ... crime, unless on a presentment or indictment of a Grand Jury," and that no person shall be "deprived of life ... without due process of law." Nevertheless, today Justice BREYER takes on the role of the abolitionists in this long-running drama, arguing that the text of the Constitution and two centuries of history must yield to his "20 years of experience on this Court," and inviting full briefing on the continued permissibility of capital punishment, *post,* at 2781 (dissenting opinion).

Historically, the Eighth Amendment was understood to bar only those punishments that added " 'terror, pain, or disgrace' " to an otherwise permissible capital sentence. *Baze v. Rees,* 553 U.S. 35, 96, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (THOMAS, J., concurring in judgment). Rather than bother with this troubling detail, Justice BREYER elects to contort the constitutional text. Redefining "cruel" to mean "unreliable," "arbitrary," or causing "excessive delays," and "unusual" to include a "decline in use," he proceeds to offer up a white paper devoid of any meaningful legal argument.

Even accepting Justice BREYER's rewriting of the Eighth Amendment, his argument is full of internal contradictions and (it must be said) gobbledy-gook. He says that the death penalty is cruel because it is unreliable; but it is *convictions,* not *punishments,* that are unreliable. Moreover, the "pressure on police, prosecutors, and jurors to secure a conviction," which he claims increases the risk of wrongful convictions in capital cases, flows from the nature of the crime, not the punishment that follows its commission. *Post,* at 2757 – 2758. Justice BREYER acknowledges as much: "[T]he crimes at issue in capital cases are typically horrendous murders, and thus accompanied by intense community pressure." *Ibid.* That same pressure would exist, and the same risk of wrongful convictions, if horrendous death-penalty cases were converted into equally horrendous life-without-parole cases. The reality is that any innocent defendant is infinitely better off appealing a death sentence than a sentence of life imprisonment. (Which, again, Justice BREYER acknowledges: "[C]ourts (or State Governors) are 130 times more likely to exonerate a defendant where a death sentence is at issue," *post,* at 2757.) The capital convict will obtain endless legal assistance from the abolition lobby (and legal favoritism from abolitionist judges), while the lifer languishes unnoticed behind bars.

Justice BREYER next says that the death penalty is cruel because it is arbitrary. To prove this point, he points to a study of 205 cases that "measured the 'egregiousness' of the murderer's conduct" ***2748** with "a system of metrics," and then "compared the egregiousness of the conduct of the 9 defendants sentenced to death with the egregiousness of the conduct of defendants in the remaining 196 cases [who were not sentenced to death]," *post,* at 2760. If only Aristotle, Aquinas, and Hume knew that moral philosophy could be so neatly distilled into a pocket-sized, *vade mecum* "system of metrics." Of course it cannot: Egregiousness is a moral judgment susceptible of few hard-and-fast rules. More importantly, egregiousness of the crime is only one of several factors that render a punishment condign —culpability, rehabilitative potential, and the need for deterrence also are relevant. That is why this Court has required an individualized consideration of all mitigating circumstances, rather than formulaic application of some egregiousness test.

It is because these questions are contextual and admit of no easy answers that we rely on juries to make judgments about the people and crimes before them. The fact that these judgments may vary across cases is an inevitable consequence of the jury trial, that cornerstone of Anglo–American judicial procedure. But when a punishment is authorized by law—if you kill you are subject to

death—the fact that some defendants receive mercy from their jury no more renders the underlying punishment "cruel" than does the fact that some guilty individuals are never apprehended, are never tried, are acquitted, or are pardoned.

Justice BREYER's third reason that the death penalty is cruel is that it entails delay, thereby (1) subjecting inmates to long periods on death row and (2) undermining the penological justifications of the death penalty. The first point is nonsense. Life without parole is an even lengthier period than the wait on death row; and if the objection is that death row is a more confining environment, the solution should be modifying the environment rather than abolishing the death penalty. As for the argument that delay undermines the penological rationales for the death penalty: In insisting that "the major alternative to capital punishment—namely, life in prison without possibility of parole—also incapacitates," *post,* at 2767, Justice BREYER apparently forgets that one of the plaintiffs *in this very case* was already in prison when he committed the murder that landed him on death row. Justice BREYER further asserts that "whatever interest in retribution might be served by the death penalty as currently administered, that interest can be served almost as well by a sentence of life in prison without parole," *post,* at 2769. My goodness. If he thinks the death penalty not much more harsh (and hence not much more retributive), why is he so keen to get rid of it? With all due respect, whether the death penalty and life imprisonment constitute more-or-less equivalent retribution is a question far above the judiciary's pay grade. Perhaps Justice BREYER is more forgiving—or more enlightened—than those who, like Kant, believe that death is the only just punishment for taking a life. I would not presume to tell parents whose life has been forever altered by the brutal murder of a child that life imprisonment is punishment enough.

And finally, Justice BREYER speculates that it does not "seem likely" that the death penalty has a "significant" deterrent effect. *Post,* at 2768. It seems very likely to me, and there are statistical studies that say so. See, *e.g.,* Zimmerman, State Executions, Deterrence, and the Incidence of Murder, 7 J. Applied Econ. 163, 166 (2004) ("[I]t is estimated that each state execution deters approximately fourteen murders per year on average"); Dezhbakhsh, Rubin, & Shepherd, ***2749** Does Capital Punishment Have a Deterrent Effect? New Evidence from Postmoratorium Panel Data, 5 Am. L. & Econ. Rev. 344 (2003) ("[E]ach execution results, on average, in eighteen fewer murders" per year); Sunstein & Vermeule, Is Capital Punishment Morally Required? Acts, Omissions, and Life–Life Tradeoffs, 58 Stan. L. Rev. 703, 713 (2005) ("All in all, the recent evidence of a deterrent effect from capital punishment seems impressive, especially in light of its 'apparent power and unanimity' "). But we federal judges live in a world apart from the vast majority of Americans. After work, we retire to homes in placid suburbia or to high-rise co-ops with guards at the door. We are not confronted with the threat of violence that is ever present in many Americans' everyday lives. The suggestion that the incremental deterrent effect of capital punishment does not seem "significant" reflects, it seems to me, a let-them-eat-cake obliviousness to the needs of others. Let the People decide how much incremental deterrence is appropriate.

Of course, this delay is a problem of the Court's own making. As Justice BREYER concedes, for more than 160 years, capital sentences were carried out in an average of two years or less. *Post,* at 2764. But by 2014, he tells us, it took an average of 18 years to carry out a death sentence. *Id.,* at 2764 – 2765. What happened in the intervening years? Nothing other than the proliferation of labyrinthine restrictions on capital punishment, promulgated by this Court under an interpretation of the Eighth Amendment that empowered it to divine "the evolving standards of decency that mark the progress of a maturing society," *Trop v. Dulles,* 356 U.S. 86, 101, 78 S.Ct. 590, 2 L.Ed.2d 630 (1958) (plurality opinion)—a task for which we are eminently ill suited. Indeed, for the past two decades, Justice BREYER has been the Drum Major in this parade. His invocation of the resultant delay as grounds for abolishing the death penalty calls to mind the man sentenced to death for killing his parents, who pleads for mercy on the ground that he is an orphan. Amplifying the surrealism of his argument, Justice BREYER uses the fact that many States have abandoned capital punishment—have abandoned it *precisely because of* the costs those suspect decisions have imposed—to conclude that it is now "unusual." *Post,* at 2772 – 2776. (A caution to the reader: Do not use the creative arithmetic that Justice BREYER employs in counting the number of States that use the death penalty when you prepare your next tax return; outside the world of our Eighth Amendment abolitionist-inspired jurisprudence, it will be regarded as more misrepresentation than math.)

If we were to travel down the path that Justice BREYER sets out for us and once again consider the constitutionality of the death penalty, I would ask that counsel also brief whether our cases that have abandoned the historical understanding of the Eighth Amendment, beginning with *Trop,* should be overruled. That case has caused more mischief to our jurisprudence, to our federal system, and to our society than any other that comes to mind. Justice BREYER's dissent is the living refutation of *Trop* 's assumption that this Court has the capacity to recognize "evolving standards of decency." Time and again, the People have voted to exact the death penalty as punishment for the most serious of crimes. Time and again, this Court has upheld that decision. And time and again, a vocal minority of this Court has insisted that things have "changed radically," *post,* at 2755, and has sought to replace the judgments of the People with their own standards of decency.

Capital punishment presents moral questions that philosophers, theologians, ***2750** and statesmen have grappled with for millennia. The Framers of our Constitution disagreed bitterly on the matter. For that reason, they handled it the same way they handled many other controversial issues: they left it to the People to decide. By arrogating to himself the power to overturn that decision, Justice BREYER does not just reject the death penalty, he rejects the Enlightenment.

Justice THOMAS, with whom Justice SCALIA joins, concurring.

I agree with the Court that petitioners' Eighth Amendment claim fails. That claim has no foundation in the Eighth Amendment, which prohibits only those "method[s] of execution" that are "deliberately designed to inflict pain." *Baze v. Rees,* 553 U.S. 35, 94, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (THOMAS, J., concurring in judgment). Because petitioners make no allegation that Oklahoma adopted its lethal injection protocol "to add elements of terror, pain, or disgrace to the death penalty," they have no valid claim. *Id.,* at 107, 128 S.Ct. 1520. That should have been the end of this case, but our precedents have predictably transformed the federal courts "into boards of inquiry charged with determining the 'best practices' for executions," *id.,* at 101, 128 S.Ct. 1520 (internal quotation marks omitted), necessitating the painstaking factual inquiry the Court undertakes today. Although I continue to believe that the broader interpretation of the Eighth Amendment advanced in the plurality opinion in *Baze* is erroneous, I join the Court's opinion in full because it correctly explains why petitioners' claim fails even under that controlling opinion.

I write separately to respond to Justice BREYER's dissent questioning the constitutionality of the death penalty generally. No more need be said about the constitutional arguments on which Justice BREYER relies, as my colleagues and I have elsewhere refuted them.[1] But Justice ***2751** BREYER's assertion, *post,* at 2760, that the death penalty in this country has fallen short of the aspiration that capital punishment be reserved for the "worst of the worst"—a notion itself based on an implicit proportionality principle that has long been discredited, see *Harmelin v. Michigan,* 501 U.S. 957, 966, 111 S.Ct. 2680, 115 L.Ed.2d 836 (1991) (opinion of SCALIA, J.)—merits further comment. His conclusion is based on an analysis that itself provides a powerful case against enforcing an imaginary constitutional rule against "arbitrariness."

The thrust of Justice Breyer's argument is that empirical studies performed by death penalty abolitionists reveal that the assignment of death sentences does not necessarily correspond to the "egregiousness" of the crimes, but instead appears to be correlated to "arbitrary" factors, such as the locality in which the crime was committed. Relying on these studies to determine the constitutionality of the death penalty fails to respect the values implicit in the Constitution's allocation of decisionmaking in this context. The Donohue study, on which Justice BREYER relies most heavily, measured the "egregiousness" (or "deathworthiness") of murders by asking lawyers to identify the legal grounds for aggravation in each case, and by asking law students to evaluate written summaries of the murders and assign "egregiousness" scores based on a rubric designed to capture and standardize their moral judgments. Donohue, An Empirical Evaluation of the Connecticut Death Penalty System Since 1973, Are There Unlawful Racial, Gender, and Geographic Disparities? 11 J. of Empirical Legal Studies 637, 644–645 (2014). This exercise in some ways approximates the function performed by jurors, but there is at least one critical difference: The law students make their moral judgments based on written summaries—they do not sit through hours, days, or weeks of evidence detailing the crime; they do not have an opportunity to assess the credibility of witnesses, to see the remorse of the defendant, to feel the

impact of the crime on the victim's family; they do not bear the burden of deciding the fate of another human being; and they are not drawn from the community whose sense of security and justice may have been torn asunder by an act of callous disregard for human life. They are like appellate judges and justices, reviewing only a paper record of each side's case for life or death.

There is a reason the choice between life and death, within legal limits, is left to the jurors and judges who sit through the trial, and not to legal elites (or law students). [2] That reason is memorialized not once, but twice, in our Constitution: Article III guarantees that "[t]he Trial of all ***2752** Crimes, except in cases of Impeachment, shall be by Jury" and that "such Trial shall be held in the State where the said Crimes shall have been committed." Art. III, § 2, cl. 3. And the Sixth Amendment promises that "[i]n all criminal prosecutions, the accused shall enjoy the right to a ... trial, by an impartial jury of the State and district wherein the crime shall have been committed." Those provisions ensure that capital defendants are given the option to be sentenced by a jury of their peers who, collectively, are better situated to make the moral judgment between life and death than are the products of contemporary American law schools.

It should come as no surprise, then, that the primary explanation a regression analysis revealed for the gap between the egregiousness scores and the actual sentences was not the race or sex of the offender or victim, but the locality in which the crime was committed. Donohue, *supra,* at 640; see also *post,* at 2761 (BREYER, J., dissenting). What is more surprising is that Justice BREYER considers this factor to be evidence of arbitrariness. See *ibid.* The constitutional provisions just quoted, which place such decisions in the hands of jurors and trial courts located where "the crime shall have been committed," seem deliberately designed to introduce that factor.

In any event, the results of these studies are inherently unreliable because they purport to control for egregiousness by quantifying moral depravity in a process that is itself arbitrary, not to mention dehumanizing. One such study's explanation of how the author assigned "depravity points" to identify the "worst of the worst" murderers proves the point well. McCord, Lightning Still Strikes, 71 Brooklyn L. Rev. 797, 833–834 (2005). Each aggravating factor received a point value based on the "blameworth[iness]" of the action associated with it. *Id.,* at 830. Killing a prison guard, for instance, earned a defendant three "depravity points" because it improved the case for complete incapacitation, while killing a police officer merited only two, because, "considered dispassionately," such acts do "not seem be a *sine qua non* of the worst criminals." *Id.,* at 834–836. (Do not worry, the author reassures us, "many killers of police officers accrue depravity points in other ways that clearly put them among the worst criminals." *Id.,* at 836.) Killing a child under the age of 12 was worth two depravity points, because such an act "seems particularly heartless," but killing someone over the age of 70 earned the murderer only one, for although "elderly victims tug at our hearts," they do so "less" than children "because the promise of a long life is less." *Id.,* at 836, 838. Killing to make a political statement was worth three depravity points; killing out of racial hatred, only two. *Id.,* at 835, 837. It goes on, but this small sample of the moral judgments on which this study rested shows just how unsuitable this evidence is to serve as a basis for a judicial decision declaring unconstitutional a punishment duly enacted in more than 30 States, and by the Federal Government.

We owe victims more than this sort of pseudoscientific assessment of their lives. It is bad enough to tell a mother that her child's murder is not "worthy" of society's ultimate expression of moral condemnation. But to do so based on cardboard stereotypes or cold mathematical calculations is beyond my comprehension. In my decades on the Court, I have not seen a capital crime that could not be considered sufficiently "blameworthy" to merit a death sentence (even when genuine constitutional errors justified a vacatur of that sentence). [3]

***2753** A small sample of the applications for a stay of execution that have come before the Court this Term alone proves my point. Mark Christeson was due to be executed in October 2014 for his role in the murder of Susan Brouk and her young children, Adrian and Kyle. After raping Ms. Brouk at gunpoint, he and his accomplice drove the family to a remote pond, where Christeson cut Ms. Brouk's throat with a bone knife. *State v. Christeson,* 50 S.W.3d 251, 257–258 (Mo.2001). Although bleeding profusely, she stayed alive long enough to tell her children she loved them and to watch as Christeson murdered them —her son, by cutting his throat twice and drowning him; her daughter, by pressing down on her throat until she suffocated. *Ibid.* Christeson and his accomplice then threw

Ms. Brouk—alive but barely breathing—into the pond to drown on top of her dead children. *Ibid.* This Court granted him a stay of execution. *Christeson v. Roper,* 574 U.S. ——, 135 S.Ct. 14, 190 L.Ed.2d 322 (2014). Lisa Ann Coleman was not so lucky. She was executed on September 17, 2014, for murdering her girlfriend's son, 9–year–old Davontae Williams, by slowly starving him to death. *Coleman v. State,* 2009 WL 4696064, *1 (Tex.Crim.App., Dec. 9, 2009). When he died, Davontae had over 250 distinct injuries—including cigarette burns and ligature marks—on his 36–pound frame. *Id.,* at *2. Infections from untreated wounds contributed to his other cause of death: pneumonia. *Id.,* at *1–*2. And Johnny Shane Kormondy, who met his end on January 15, 2015, did so after he and his two accomplices invaded the home of a married couple, took turns raping the wife and forcing her to perform oral sex at gunpoint—at one point, doing both simultaneously—and then put a bullet in her husband's head during the final rape. *Kormondy v. Secretary, Fla. Dept. of Corrections,* 688 F.3d 1244, 1247–1248 (C.A.11 2012).

Some of our most "egregious" cases have been those in which we have granted relief based on an unfounded Eighth Amendment claim. For example, we have granted relief in a number of egregious cases based on this Court's decision in *Atkins v. Virginia,* 536 U.S. 304, 122 S.Ct. 2242, 153 L.Ed.2d 335 (2002), exempting certain "mentally retarded" offenders from the death penalty. Last Term, the Court granted relief to a man who kidnaped, beat, raped, and murdered a 21–year–old pregnant newlywed, Karol Hurst, also murdering her unborn child, and then, on the same day, murdered a sheriff's deputy ***2754** acting in the line of duty. *Hall v. Florida,* 572 U.S. ——, ——, 134 S.Ct. 1986, 1990, 188 L.Ed.2d 1007 (2014). And in *Atkins* itself, the Court granted relief to a man who carjacked Eric Michael Nesbitt, forced him to withdraw money from a bank, drove him to a secluded area, and then shot him multiple times before leaving him to bleed to death. *Atkins v. Commonwealth,* 257 Va. 160, 166–167, 510 S.E.2d 445, 449–450 (1999).

The Court has also misinterpreted the Eighth Amendment to grant relief in egregious cases involving rape. In *Kennedy v. Louisiana,* 554 U.S. 407, 128 S.Ct. 2641, 171 L.Ed.2d 525 (2008), the Court granted relief to a man who had been sentenced to death for raping his 8–year–old stepdaughter. The rape was so violent that it "separated her cervix from the back of her vagina, causing her rectum to protrude into the vaginal structure," and tore her "entire perineum ... from the posterior fourchette to the anus." *Id.,* at 414, 128 S.Ct. 2641. The evidence indicated that the petitioner spent *at least* an hour and half attempting to destroy the evidence of his crime before seeking emergency assistance, even as his stepdaughter bled profusely from her injuries. *Id.,* at 415, 128 S.Ct. 2641. And in *Coker v. Georgia,* 433 U.S. 584, 97 S.Ct. 2861, 53 L.Ed.2d 982 (1977) (plurality opinion), the Court granted relief to a petitioner who had escaped from prison, broken into the home of a young married couple and their newborn, forced the wife to bind her husband, gagged her husband with her underwear, raped her (even after being told that she was recovering from a recent childbirth), and then kidnaped her after threatening her husband, *Coker v. State,* 234 Ga. 555, 556–557, 216 S.E.2d 782, 786–787 (1975). In each case, the Court crafted an Eighth Amendment right to be free from execution for the crime of rape—whether it be of an adult, *Coker,* 433 U.S., at 592, 97 S.Ct. 2861, or a child, *Kennedy, supra,* at 413, 128 S.Ct. 2641.

The Court's recent decision finding that the Eighth Amendment prohibits the execution of those who committed their crimes as juveniles is no different. See *Roper v. Simmons,* 543 U.S. 551, 125 S.Ct. 1183, 161 L.Ed.2d 1 (2005). Although the Court had rejected the claim less than two decades earlier, *Stanford v. Kentucky,* 492 U.S. 361, 109 S.Ct. 2969, 106 L.Ed.2d 306 (1989), it decided to revisit the issue for a petitioner who had slain his victim because "he wanted to murder someone" and believed he could "get away with it" because he was a few months shy of his 18th birthday. 543 U.S., at 556, 125 S.Ct. 1183. His randomly chosen victim was Shirley Crook, whom he and his friends kidnaped in the middle of the night, bound with duct tape and electrical wire, and threw off a bridge to drown in the river below. *Id.,* at 556–557, 125 S.Ct. 1183. The State of Alabama's brief in that case warned the Court that its decision would free from death row a number of killers who had been sentenced for crimes committed as juveniles. Brief for State of Alabama et al. as *Amici Curiae* in *Roper v. Simmons,* O.T. 2014, No. 03–633. Mark Duke, for example, murdered his father for refusing to loan him a truck, and his father's girlfriend and her two young daughters because he wanted no witnesses to the crime. *Id.,* at 4. He shot his father and his father's girlfriend pointblank in the face as they pleaded for their lives. *Id.,* at 5–6. He then tracked the girls down in their hiding places and slit their throats, leaving them alive for

several minutes as they drowned in their own blood. *Id.,* at 6–7.

Whatever one's views on the permissibility or wisdom of the death penalty, I doubt anyone would disagree that each of these crimes was egregious enough to merit the severest condemnation that society has to ***2755** offer. The only *constitutional* problem with the fact that these criminals were spared that condemnation, while others were not, is that their amnesty came in the form of unfounded claims. Arbitrariness has nothing to do with it.[4] To the extent that we are ill at ease with these disparate outcomes, it seems to me that the best solution is for the Court to stop making up Eighth Amendment claims in its ceaseless quest to end the death penalty through undemocratic means.

Justice BREYER, with whom Justice GINSBURG joins, dissenting.

For the reasons stated in Justice SOTOMAYOR's opinion, I dissent from the Court's holding. But rather than try to patch up the death penalty's legal wounds one at a time, I would ask for full briefing on a more basic question: whether the death penalty violates the Constitution.

The relevant legal standard is the standard set forth in the Eighth Amendment. The Constitution there forbids the "inflict[ion]" of "cruel and unusual punishments." Amdt. 8. The Court has recognized that a "claim that punishment is excessive is judged not by the standards that prevailed in 1685 when Lord Jeffreys presided over the 'Bloody Assizes' or when the Bill of Rights was adopted, but rather by those that currently prevail." *Atkins v. Virginia,* 536 U.S. 304, 311, 122 S.Ct. 2242, 153 L.Ed.2d 335 (2002). Indeed, the Constitution prohibits various gruesome punishments that were common in Blackstone's day. See 4 W. Blackstone, Commentaries on the Laws of England 369–370 (1769) (listing mutilation and dismembering, among other punishments).

Nearly 40 years ago, this Court upheld the death penalty under statutes that, in the Court's view, contained safeguards sufficient to ensure that the penalty would be applied reliably and not arbitrarily. See *Gregg v. Georgia,* 428 U.S. 153, 187, 96 S.Ct. 2909, 49 L.Ed.2d 859 (1976) (joint opinion of Stewart, Powell, and Stevens, JJ.); *Proffitt v. Florida,* 428 U.S. 242, 247, 96 S.Ct. 2960, 49 L.Ed.2d 913 (1976) (joint opinion of Stewart, Powell, and Stevens, JJ.); *Jurek v. Texas,* 428 U.S. 262, 268, 96 S.Ct. 2950, 49 L.Ed.2d 929 (1976) (joint opinion of Stewart, Powell, and Stevens, JJ.); but cf. *Woodson v. North Carolina,* 428 U.S. 280, 303, 96 S.Ct. 2978, 49 L.Ed.2d 944 (1976) (plurality opinion) (striking down mandatory death penalty); *Roberts v. Louisiana,* 428 U.S. 325, 331, 96 S.Ct. 3001, 49 L.Ed.2d 974 (1976) (plurality opinion) (similar). The circumstances and the evidence of the death penalty's application have changed radically since then. Given those changes, I believe that it is now time to reopen the question.

In 1976, the Court thought that the constitutional infirmities in the death penalty could be healed; the Court in effect delegated significant responsibility to the States to develop procedures that would protect against those constitutional problems. Almost 40 years of studies, surveys, and experience strongly indicate, however, that this effort has failed. Today's administration of the death penalty involves three fundamental constitutional defects: ***2756** (1) serious unreliability, (2) arbitrariness in application, and (3) unconscionably long delays that undermine the death penalty's penological purpose. Perhaps as a result, (4) most places within the United States have abandoned its use.

I shall describe each of these considerations, emphasizing changes that have occurred during the past four decades. For it is those changes, taken together with my own 20 years of experience on this Court, that lead me to believe that the death penalty, in and of itself, now likely constitutes a legally prohibited "cruel and unusual punishmen[t]." U.S. Const., Amdt. 8.

I

"Cruel"—Lack of Reliability

This Court has specified that the finality of death creates a "qualitative difference" between the death penalty and other punishments (including life in prison). *Woodson,* 428 U.S., at 305, 96 S.Ct. 2978 (plurality opinion). That "qualitative difference" creates "a corresponding difference in the need for reliability in the determination that death is the appropriate punishment in a specific case." *Ibid.* There is increasing evidence, however, that the death penalty as now applied lacks that requisite

reliability. Cf. *Kansas v. Marsh,* 548 U.S. 163, 207–211, 126 S.Ct. 2516, 165 L.Ed.2d 429 (2006) (Souter, J., dissenting) (DNA exonerations constitute "a new body of fact" when considering the constitutionality of capital punishment).

For one thing, despite the difficulty of investigating the circumstances surrounding an execution for a crime that took place long ago, researchers have found convincing evidence that, in the past three decades, innocent people have been executed. See, *e.g.,* Liebman, Fatal Injustice; Carlos DeLuna's Execution Shows That a Faster, Cheaper Death Penalty is a Dangerous Idea, L.A. Times, June 1, 2012, p. A19 (describing results of a 4–year investigation, later published as The Wrong Carlos: Anatomy of a Wrongful Execution (2014), that led its authors to conclude that Carlos DeLuna, sentenced to death and executed in 1989, six years after his arrest in Texas for stabbing a single mother to death in a convenience store, was innocent); Grann, Trial By Fire: Did Texas Execute An Innocent Man? The New Yorker, Sept. 7, 2009, p. 42 (describing evidence that Cameron Todd Willingham was convicted, and ultimately executed in 2004, for the apparently motiveless murder of his three children as the result of invalid scientific analysis of the scene of the house fire that killed his children). See also, *e.g.,* Press Release: Gov. Ritter Grants Posthumous Pardon in Case Dating Back to 1930s, Jan. 7, 2011, p. 1 (Colorado Governor granted full and unconditional posthumous pardon to Joe Arridy, a man with an IQ of 46 who was executed in 1936, because, according to the Governor, "an overwhelming body of evidence indicates the 23–year–old Arridy was innocent, including false and coerced confessions, the likelihood that Arridy was not in Pueblo at the time of the killing, and an admission of guilt by someone else"); R. Warden, Wilkie Collins's The Dead Alive: The Novel, the Case, and Wrongful Convictions 157–158 (2005) (in 1987, Nebraska Governor Bob Kerrey pardoned William Jackson Marion, who had been executed a century earlier for the murder of John Cameron, a man who later turned up alive; the alleged victim, Cameron, had gone to Mexico to avoid a shotgun wedding).

For another, the evidence that the death penalty has been wrongly *imposed* (whether or not it was carried out), is striking. As of 2002, this Court used the word "disturbing" to describe the number of instances in which individuals had been sentenced ***2757** to death but later exonerated. At that time, there was evidence of approximately 60 exonerations in capital cases. *Atkins,* 536 U.S., at 320, n. 25, 122 S.Ct. 2242; National Registry of Exonerations, online at http://www.law.umich.edu/special/exoneration/Pages/about.aspx (all Internet materials as visited June 25, 2015, and available in Clerk of Court's case file). (I use "exoneration" to refer to relief from *all* legal consequences of a capital conviction through a decision by a prosecutor, a Governor or a court, after new evidence of the defendant's innocence was discovered.) Since 2002, the number of exonerations in capital cases has risen to 115. *Ibid.*; National Registry of Exonerations, Exonerations in the United States, 1989–2012, pp. 6–7 (2012) (Exonerations 2012 Report) (defining exoneration); accord, Death Penalty Information Center (DPIC), Innocence: List of Those Freed from Death Row, online at http://www.deathpenaltyinfo.org/innocence-and-death-penalty (DPIC Innocence List) (calculating, under a slightly different definition of exoneration, the number of exonerations since 1973 as 154). Last year, in 2014, six death row inmates were exonerated based on actual innocence. All had been imprisoned for more than 30 years (and one for almost 40 years) at the time of their exonerations. National Registry of Exonerations, Exonerations in 2014, p. 2 (2015).

The stories of three of the men exonerated within the last year are illustrative. DNA evidence showed that Henry Lee McCollum did not commit the rape and murder for which he had been sentenced to death. Katz & Eckholm, DNA Evidence Clears Two Men in 1983 Murder, N.Y. Times, Sept. 3, 2014, p. A1. Last Term, this Court ordered that Anthony Ray Hinton, who had been convicted of murder, receive further hearings in state court; he was exonerated earlier this year because the forensic evidence used against him was flawed. *Hinton v. Alabama,* 571 U.S. ——, 134 S.Ct. 1081, 188 L.Ed.2d 1 (2014) (*per curiam*); Blinder, Alabama Man on Death Row for Three Decades Is Freed as State's Case Erodes, N.Y. Times, Apr. 4, 2014, p. A11. And when Glenn Ford, also convicted of murder, was exonerated, the prosecutor admitted that even "[a]t the time this case was tried there was evidence that would have cleared Glenn Ford." Stroud, Lead Prosecutor Apologizes for Role in Sending Man to Death Row, Shreveport Times, Mar. 27, 2015. All three of these men spent 30 years on death row before being exonerated. I return to these examples *infra*.

Furthermore, exonerations occur far more frequently where capital convictions, rather than ordinary criminal

convictions, are at issue. Researchers have calculated that courts (or State Governors) are 130 times more likely to exonerate a defendant where a death sentence is at issue. They are nine times more likely to exonerate where a capital murder, rather than a noncapital murder, is at issue. Exonerations 2012 Report 15–16, and nn. 24–26.

Why is that so? To some degree, it must be because the law that governs capital cases is more complex. To some degree, it must reflect the fact that courts scrutinize capital cases more closely. But, to some degree, it likely also reflects a *greater likelihood of an initial wrongful conviction*. How could that be so? In the view of researchers who have conducted these studies, it could be so because the crimes at issue in capital cases are typically horrendous murders, and thus accompanied by intense community pressure on police, prosecutors, and jurors to secure a conviction. This pressure creates a greater likelihood of convicting the wrong person. See Gross, Jacoby, Matheson, Montgomery, & Patil, ***2758** Exonerations in the United States 1989 Through 2003, 95 J. Crim. L. & C. 523, 531–533 (2005); Gross & O'Brien, Frequency and Predictors of False Conviction: Why We Know So Little, and New Data on Capital Cases, 5 J. Empirical L. Studies 927, 956–957 (2008) (noting that, in comparing those who were exonerated from death row to other capital defendants who were not so exonerated, the initial police investigations tended to be shorter for those exonerated); see also B. Garrett, Convicting the Innocent: Where Criminal Prosecutions Go Wrong (2011) (discussing other common causes of wrongful convictions generally including false confessions, mistaken eyewitness testimony, untruthful jailhouse informants, and ineffective defense counsel).

In the case of Cameron Todd Willingham, for example, who (as noted earlier) was executed despite likely innocence, the State Bar of Texas recently filed formal misconduct charges against the lead prosecutor for his actions—actions that may have contributed to Willingham's conviction. Possley, Prosecutor Accused of Misconduct in Death Penalty Case, Washington Post, Mar. 19, 2015, p. A3. And in Glenn Ford's case, the prosecutor admitted that he was partly responsible for Ford's wrongful conviction, issuing a public apology to Ford and explaining that, at the time of Ford's conviction, he was "not as interested in justice as [he] was in winning." Stroud, *supra*.

Other factors may also play a role. One is the practice of death-qualification; no one can serve on a capital jury who is not willing to impose the death penalty. See Rozelle, The Principled Executioner: Capital Juries' Bias and the Benefits of True Bifurcation, 38 Ariz. S.L.J. 769, 772–793, 807 (2006) (summarizing research and concluding that "[f]or over fifty years, empirical investigation has demonstrated that death qualification skews juries toward guilt and death"); Note, Mandatory Voir Dire Questions in Capital Cases: A Potential Solution to the Biases of Death Qualification, 10 Roger Williams Univ. L. Rev. 211, 214–223 (2004) (similar).

Another is the more general problem of flawed forensic testimony. See Garrett, *supra,* at 7. The Federal Bureau of Investigation (FBI), for example, recently found that flawed microscopic hair analysis was used in 33 of 35 capital cases under review; 9 of the 33 had already been executed. FBI, National Press Releases, FBI Testimony on Microscopic Hair Analysis Contained Errors in at Least 90 Percent of Cases in Ongoing Review, Apr. 20, 2015. See also Hsu, FBI Admits Errors at Trials: False Matches on Crime–Scene Hair, Washington Post, Apr. 19, 2015, p. A1 (in the District of Columbia, which does not have the death penalty, five of seven defendants in cases with flawed hair analysis testimony were eventually exonerated).

In light of these and other factors, researchers estimate that about 4% of those sentenced to death are actually innocent. See Gross, O'Brien, Hu, & Kennedy, Rate of False Conviction of Criminal Defendants Who Are Sentenced to Death, 111 Proceeding of the National Academy of Sciences 7230 (2014) (full-scale study of all death sentences from 1973 through 2004 estimating that 4.1% of those sentenced to death are actually innocent); Risinger, Innocents Convicted: An Empirically Justified Factual Wrongful Conviction Rate, 97 J. Crim. L. & C. 761 (2007) (examination of DNA exonerations in death penalty cases for murder-rapes between 1982 and 1989 suggesting an analogous rate of between 3.3% and 5%).

Finally, if we expand our definition of "exoneration" (which we limited to errors suggesting the defendant was actually innocent) and thereby also categorize as "erroneous" instances in which courts failed ***2759** to follow legally required procedures, the numbers soar. Between 1973 and 1995, courts identified prejudicial errors in 68% of the capital cases before them.

Gelman, Liebman, West, & Kiss, A Broken System: The Persistent Patterns of Reversals of Death Sentences in the United States, 1 J. Empirical L. Studies 209, 217 (2004). State courts on direct and postconviction review overturned 47% of the sentences they reviewed. *Id.,* at 232. Federal courts, reviewing capital cases in habeas corpus proceedings, found error in 40% of those cases. *Ibid.*

This research and these figures are likely controversial. Full briefing would allow us to scrutinize them with more care. But, at a minimum, they suggest a serious problem of reliability. They suggest that there are too many instances in which courts sentence defendants to death without complying with the necessary procedures; and they suggest that, in a significant number of cases, the death sentence is imposed on a person who did not commit the crime. See Earley, A Pink Cadillac, An IQ of 63, and A Fourteen–Year–Old from South Carolina: Why I Can No Longer Support the Death Penalty, 49 U. Rich. L. Rev. 811, 813 (2015) ("I have come to the conclusion that the death penalty is based on a false utopian premise. That false premise is that we have had, do have, will have 100% accuracy in death penalty convictions and executions"); Earley, I Oversaw 36 Executions. Even Death Penalty Supporters Can Push for Change, Guardian, May 12, 2014 (Earley presided over 36 executions as Virginia Attorney General from 1998–2001); but see *ante,* at 2747 – 2748 (SCALIA, J., concurring) (apparently finding no special constitutional problem arising from the fact that the execution of an innocent person is irreversible). Unlike 40 years ago, we now have plausible *evidence* of unreliability that (perhaps due to DNA evidence) is stronger than the evidence we had before. In sum, there is significantly more research-based evidence today indicating that courts sentence to death individuals who may well be actually innocent or whose convictions (in the law's view) do not warrant the death penalty's application.

II

"Cruel"—Arbitrariness

The arbitrary imposition of punishment is the antithesis of the rule of law. For that reason, Justice Potter Stewart (who supplied critical votes for the holdings in *Furman v. Georgia,* 408 U.S. 238, 92 S.Ct. 2726, 33 L.Ed.2d 346 (1972) (*per curiam*), and *Gregg*) found the death penalty unconstitutional as administered in 1972:

> "These death sentences are cruel and unusual in the same way that being struck by lightning is cruel and unusual. For, of all the people convicted of [death-eligible crimes], many just as reprehensible as these, the[se] petitioners are among a capriciously selected random handful upon which the sentence of death has in fact been imposed." *Furman,* 408 U.S., at 309–310, 92 S.Ct. 2726 (concurring opinion).

See also *id.,* at 310, 92 S.Ct. 2726 ("[T]he Eighth and Fourteenth Amendments cannot tolerate the infliction of a sentence of death under legal systems that permit this unique penalty to be so wantonly and so freakishly imposed"); *id.,* at 313, 92 S.Ct. 2726 (White, J., concurring) ("[T]he death penalty is exacted with great infrequency even for the most atrocious crimes and ... there is no meaningful basis for distinguishing the few cases in which it is imposed from the many cases in which it is not").

When the death penalty was reinstated in 1976, this Court acknowledged that the death penalty is (and would be) unconstitutional ***2760** if "inflicted in an arbitrary and capricious manner." *Gregg,* 428 U.S., at 188, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and Stevens, JJ.); see also *id.,* at 189, 96 S.Ct. 2909 ("[W]here discretion is afforded a sentencing body on a matter so grave as the determination of whether a human life should be taken or spared, that discretion must be suitably directed and limited so as to minimize the risk of wholly arbitrary and capricious action"); *Godfrey v. Georgia,* 446 U.S. 420, 428, 100 S.Ct. 1759, 64 L.Ed.2d 398 (1980) (plurality opinion) (similar).

The Court has consequently sought to make the application of the death penalty less arbitrary by restricting its use to those whom Justice Souter called " 'the worst of the worst.' " *Kansas v. Marsh,* 548 U.S., at 206, 126 S.Ct. 2516 (dissenting opinion); see also *Roper v. Simmons,* 543 U.S. 551, 568, 125 S.Ct. 1183, 161 L.Ed.2d 1 (2005) ("Capital punishment must be limited to those offenders who commit a narrow category of the most serious crimes and whose extreme culpability makes them the most deserving of execution" (internal quotation marks omitted)); *Kennedy v. Louisiana,* 554 U.S. 407, 420, 128 S.Ct. 2641, 171 L.Ed.2d 525 (2008) (citing *Roper, supra,* at 568, 125 S.Ct. 1183).

Despite the *Gregg* Court's hope for fair administration of the death penalty, 40 years of further experience make it increasingly clear that the death penalty is imposed arbitrarily, *i.e.,* without the "reasonable consistency" legally necessary to reconcile its use with the Constitution's commands. *Eddings v. Oklahoma,* 455 U.S. 104, 112, 102 S.Ct. 869, 71 L.Ed.2d 1 (1982).

Thorough studies of death penalty sentences support this conclusion. A recent study, for example, examined all death penalty sentences imposed between 1973 and 2007 in Connecticut, a State that abolished the death penalty in 2012. Donohue, An Empirical Evaluation of the Connecticut Death Penalty System Since 1973: Are There Unlawful Racial, Gender, and Geographic Disparities? 11 J. Empirical Legal Studies 637 (2014). The study reviewed treatment of all homicide defendants. It found 205 instances in which Connecticut law made the defendant eligible for a death sentence. *Id.,* at 641–643. Courts imposed a death sentence in 12 of these 205 cases, of which 9 were sustained on appeal. *Id.,* at 641. The study then measured the "egregiousness" of the murderer's conduct in those 9 cases, developing a system of metrics designed to do so. *Id.,* at 643–645. It then compared the egregiousness of the conduct of the 9 defendants sentenced to death with the egregiousness of the conduct of defendants in the remaining 196 cases (those in which the defendant, though found guilty of a death-eligible offense, was ultimately not sentenced to death). Application of the studies' metrics made clear that only 1 of those 9 defendants was indeed the "worst of the worst" (or was, at least, within the 15% considered most "egregious"). The remaining eight were not. Their behavior was no worse than the behavior of at least 33 and as many as *170* other defendants (out of a total pool of 205) who had not been sentenced to death. *Id.,* at 678–679.

Such studies indicate that the factors that most clearly ought to affect application of the death penalty—namely, comparative egregiousness of the crime—often do not. Other studies show that circumstances that ought *not* to affect application of the death penalty, such as race, gender, or geography, often *do*.

Numerous studies, for example, have concluded that individuals accused of murdering white victims, as opposed to black or other minority victims, are more likely to receive the death penalty. See GAO, ***2761** Report to the Senate and House Committees on the Judiciary: Death Penalty Sentencing 5 (GAO/GGD–90–57, 1990) (82% of the 28 studies conducted between 1972 and 1990 found that race of victim influences capital murder charge or death sentence, a "finding ... remarkably consistent across data sets, states, data collection methods, and analytic techniques"); Shatz & Dalton, Challenging the Death Penalty with Statistics: *Furman, McCleskey,* and a Single County Case Study, 34 Cardozo L. Rev. 1227, 1245–1251 (2013) (same conclusion drawn from 20 plus studies conducted between 1990 and 2013).

Fewer, but still many, studies have found that the gender of the defendant or the gender of the victim makes a not-otherwise-warranted difference. *Id.,* at 1251–1253 (citing many studies).

Geography also plays an important role in determining who is sentenced to death. See *id.,* at 1253–1256. And that is not simply because some States permit the death penalty while others do not. Rather *within* a death penalty State, the imposition of the death penalty heavily depends on the county in which a defendant is tried. Smith, The Geography of the Death Penalty and its Ramifications, 92 B. U. L. Rev. 227, 231–232 (2012) (hereinafter Smith); see also Donohue, *supra,* at 673 ("[T]he single most important influence from 1973–2007 explaining whether a death-eligible defendant [in Connecticut] would be sentenced to death was whether the crime occurred in Waterbury [County]"). Between 2004 and 2009, for example, just 29 counties (fewer than 1% of counties in the country) accounted for approximately half of all death sentences imposed nationwide. Smith 233. And in 2012, just 59 counties (fewer than 2% of counties in the country) accounted for *all* death sentences imposed nationwide. DPIC, The 2% Death Penalty: How A Minority of Counties Produce Most Death Cases At Enormous Costs to All 9 (Oct. 2013).

What accounts for this county-by-county disparity? Some studies indicate that the disparity reflects the decisionmaking authority, the legal discretion, and ultimately the power of the local prosecutor. See, *e.g.,* Goelzhauser, Prosecutorial Discretion Under Resource Constraints: Budget Allocations and Local Death–Charging Decisions, 96 Judicature 161, 162–163 (2013); Barnes, Sloss, & Thaman, Place Matters (Most): An Empirical Study of Prosecutorial Decision–Making in Death–Eligible Cases, 51 Ariz. L. Rev. 305 (2009)

(analyzing Missouri); Donohue, An Empirical Evaluation of the Connecticut Death Penalty System, at 681 (Connecticut); Marceau, Kamin, & Foglia, Death Eligibility in Colorado: Many Are Called, Few Are Chosen, 84 U. Colo. L. Rev. 1069 (2013) (Colorado); Shatz & Dalton, *supra,* at 1260–1261 (Alameda County).

Others suggest that the availability of resources for defense counsel (or the lack thereof) helps explain geographical differences. See, *e.g.,* Smith 258–265 (counties with higher death-sentencing rates tend to have weaker public defense programs); Liebman & Clarke, Minority Practice, Majority's Burden: The Death Penalty Today, 9 Ohio S. J. Crim. L. 255, 274 (2011) (hereinafter Liebman & Clarke) (similar); see generally Bright, Counsel for the Poor: The Death Sentence Not for the Worst Crime but for the Worst Lawyer, 103 Yale L. J. 1835 (1994).

Still others indicate that the racial composition of and distribution within a county plays an important role. See, *e.g.,* Levinson, Smith, & Young, Devaluing Death: An Empirical Study of Implicit Racial Bias on Jury–Eligible Citizens in Six Death Penalty States, 89 N.Y.U. L. Rev. 513, 533–536 (2014) (summarizing research on ***2762** this point); see also Shatz & Dalton, *supra,* at 1275 (describing research finding that death-sentencing rates were lowest in counties with the highest nonwhite population); cf. Cohen & Smith, The Racial Geography of the Federal Death Penalty, 85 Wash. L. Rev. 425 (2010) (arguing that the federal death penalty is sought disproportionately where the federal district, from which the jury will be drawn, has a dramatic racial difference from the county in which the federal crime occurred).

Finally, some studies suggest that political pressures, including pressures on judges who must stand for election, can make a difference. See *Woodward v. Alabama,* 571 U.S. ——, ——, 134 S.Ct. 405, 408, 187 L.Ed.2d 449 (2013) (SOTOMAYOR, J., dissenting from denial of certiorari) (noting that empirical evidence suggests that, when Alabama judges reverse jury recommendations, these "judges, who are elected in partisan proceedings, appear to have succumbed to electoral pressures"); *Harris v. Alabama,* 513 U.S. 504, 519, 115 S.Ct. 1031, 130 L.Ed.2d 1004 (1995) (Stevens, J., dissenting) (similar); Gelman, 1 J. Empirical L. Studies, at 247 (elected state judges are less likely to reverse flawed verdicts in capital cases in small towns than in larger communities).

Thus, whether one looks at research indicating that irrelevant or improper factors—such as race, gender, local geography, and resources—*do* significantly determine who receives the death penalty, or whether one looks at research indicating that proper factors—such as "egregiousness"—do *not* determine who receives the death penalty, the legal conclusion must be the same: The research strongly suggests that the death penalty is imposed arbitrarily.

Justice THOMAS catalogues the tragic details of various capital cases, *ante,* at 2752 – 2755 (concurring opinion), but this misses my point. Every murder is tragic, but unless we return to the mandatory death penalty struck down in *Woodson,* 428 U.S., at 304–305, 96 S.Ct. 2978, the constitutionality of capital punishment rests on its limited application to the worst of the worst, *supra,* at 2759 – 2760. And this extensive body of evidence suggests that it is not so limited.

Four decades ago, the Court believed it possible to interpret the Eighth Amendment in ways that would significantly limit the arbitrary application of the death sentence. See *Gregg,* 428 U.S., at 195, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and Stevens, JJ.) ("[T]he concerns expressed in *Furman* that the penalty of death not be imposed in an arbitrary or capricious manner can be met"). But that no longer seems likely.

The Constitution does not prohibit the use of prosecutorial discretion. *Id.,* at 199, and n. 50, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and Stevens, JJ.); *McCleskey v. Kemp,* 481 U.S. 279, 307–308, and n. 28, 311–312, 107 S.Ct. 1756, 95 L.Ed.2d 262 (1987). It has not proved possible to increase capital defense funding significantly. Smith, The Supreme Court and the Politics of Death, 94 Va. L. Rev. 283, 355 (2008) ("Capital defenders are notoriously underfunded, particularly in states ... that lead the nation in executions"); American Bar Assn. (ABA) Guidelines for the Appointment and Performance of Defense Counsel in Death Penalty Cases, Guideline 9.1, Commentary (rev. ed. Feb. 2003), in 31 Hofstra L. Rev. 913, 985 (2003) ("[C]ompensation of attorneys for death penalty representation remains notoriously inadequate"). And courts cannot easily inquire into judicial motivation. See, *e.g., Harris, supra.*

Moreover, racial and gender biases may, unfortunately, reflect deeply rooted community biases (conscious or unconscious), ***2763** which, despite their legal irrelevance, may affect a jury's evaluation of mitigating evidence, see *Callins v. Collins,* 510 U.S. 1141, 1153, 114 S.Ct. 1127, 127 L.Ed.2d 435 (1994) (Blackmun, J., dissenting from denial of certiorari) ("Perhaps it should not be surprising that the biases and prejudices that infect society generally would influence the determination of who is sentenced to death"). Nevertheless, it remains the jury's task to make the individualized assessment of whether the defendant's mitigation evidence entitles him to mercy. See, *e.g., Penry v. Lynaugh,* 492 U.S. 302, 319, 109 S.Ct. 2934, 106 L.Ed.2d 256 (1989); *Lockett v. Ohio,* 438 U.S. 586, 604–605, 98 S.Ct. 2954, 57 L.Ed.2d 973 (1978) (opinion of Burger, C.J.); *Woodson,* 428 U.S., at 304–305, 96 S.Ct. 2978 (plurality opinion).

Finally, since this Court held that comparative proportionality review is not constitutionally required, *Pulley v. Harris,* 465 U.S. 37, 104 S.Ct. 871, 79 L.Ed.2d 29 (1984), it seems unlikely that appeals can prevent the arbitrariness I have described. See Kaufman–Osborn, Capital Punishment, Proportionality Review, and Claims of Fairness (with Lessons from Washington State), 79 Wash. L. Rev. 775, 791–792 (2004) (after *Pulley,* many States repealed their statutes requiring comparative proportionality review, and most state high courts "reduced proportionality review to a perfunctory exercise" (internal quotation marks omitted)).

The studies bear out my own view, reached after considering thousands of death penalty cases and last-minute petitions over the course of more than 20 years. I see discrepancies for which I can find no rational explanations. Cf. *Godfrey,* 446 U.S., at 433, 100 S.Ct. 1759 (plurality opinion) ("There is no principled way to distinguish this case, in which the death penalty was imposed, from the many cases in which it was not"). Why does one defendant who committed a single-victim murder receive the death penalty (due to aggravators of a prior felony conviction and an after-the-fact robbery), while another defendant does not, despite having kidnapped, raped, and murdered a young mother while leaving her infant baby to die at the scene of the crime. Compare *State v. Badgett,* 361 N.C. 234, 644 S.E.2d 206 (2007), and Pet. for Cert. in *Badgett v. North Carolina,* O.T. 2006, No. 07–6156, with Charbonneau, Andre Edwards Sentenced to Life in Prison for 2001 Murder, WRAL, Mar. 26, 2004, online at http://www.wral.com/news/local/story/109648. Why does one defendant who committed a single-victim murder receive the death penalty (due to aggravators of a prior felony conviction and acting recklessly with a gun), while another defendant does not, despite having committed a "triple murder" by killing a young man and his pregnant wife? Compare *Commonwealth v. Boxley,* 596 Pa. 620, 948 A.2d 742 (2008), and Pet. for Cert., O.T. 2008, No. 08–6172, with Shea, Judge Gives Consecutive Life Sentences for Triple Murder, Philadelphia Inquirer, June 29, 2004, p. B5. For that matter, why does one defendant who participated in a single-victim murder-for-hire scheme (plus an after-the-fact robbery) receive the death penalty, while another defendant does not, despite having stabbed his wife 60 times and killed his 6–year–old daughter and 3–year–old son while they slept? See Donohue, Capital Punishment in Connecticut, 1973–2007: A Comprehensive Evaluation from 4686 Murders to One Execution, pp. 128–134 (2013), online at http://works.bepress.com/john_ donohue/87. In each instance, the sentences compared were imposed in the same State at about the same time.

The question raised by these examples (and the many more I could give but do not), as well as by the research to which I ***2764** have referred, is the same question Justice Stewart, Justice Powell, and others raised over the course of several decades: The imposition and implementation of the death penalty seems capricious, random, indeed, arbitrary. From a defendant's perspective, to receive that sentence, and certainly to find it implemented, is the equivalent of being struck by lightning. How then can we reconcile the death penalty with the demands of a Constitution that first and foremost insists upon a rule of law?

III

"Cruel"—Excessive Delays

The problems of reliability and unfairness almost inevitably lead to a third independent constitutional problem: excessively long periods of time that individuals typically spend on death row, alive but under sentence of death. That is to say, delay is in part a problem that the Constitution's own demands create. Given the special need for reliability and fairness in death penalty cases, the Eighth Amendment does, and must, apply to the

death penalty "with special force." *Roper,* 543 U.S., at 568, 125 S.Ct. 1183. Those who face "that most severe sanction must have a fair opportunity to show that the Constitution prohibits their execution." *Hall v. Florida,* 572 U.S. ——, ——, 134 S.Ct. 1986, 2001, 188 L.Ed.2d 1007 (2014). At the same time, the Constitution insists that "every safeguard" be "observed" when "a defendant's life is at stake." *Gregg,* 428 U.S., at 187, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and Stevens, JJ.); *Furman,* 408 U.S., at 306, 92 S.Ct. 2726 (Stewart, J., concurring) (death "differs from all other forms of criminal punishment, not in degree but in kind"); *Woodson, supra,* at 305, 96 S.Ct. 2978 (plurality opinion) ("Death, in its finality, differs more from life imprisonment than a 100–year prison term differs from one of only a year or two").

These procedural necessities take time to implement. And, unless we abandon the procedural requirements that assure fairness and reliability, we are forced to confront the problem of increasingly lengthy delays in capital cases. Ultimately, though these legal causes may help to explain, they do not mitigate the harms caused by delay itself.

A

Consider first the statistics. In 2014, 35 individuals were executed. Those executions occurred, on average, nearly 18 years after a court initially pronounced its sentence of death. DPIC, Execution List 2014, online at http://www.deathpenaltyinfo.org/execution–list–2014 (showing an average delay of 17 years, 7 months). In some death penalty States, the average delay is longer. In an oral argument last year, for example, the State admitted that the last 10 prisoners executed in Florida had spent an average of nearly 25 years on death row before execution. Tr. of Oral Arg. in *Hall v. Florida,* O.T. 2013, No. 12–10882, p. 46.

The length of the average delay has increased dramatically over the years. In 1960, the average delay between sentencing and execution was two years. See Aarons, Can Inordinate Delay Between a Death Sentence and Execution Constitute Cruel and Unusual Punishment? 29 Seton Hall L. Rev. 147, 181 (1998). Ten years ago (in 2004) the average delay was about 11 years. See Dept. of Justice, Bureau of Justice Statistics (BJS), T. Snell, Capital Punishment, 2013—Statistical Tables 14 (Table 10) (rev. Dec. 2014) (hereinafter BJS 2013 Stats). By last year the average had risen to about 18 years. DPIC, Execution List 2014, *supra*. Nearly half of the 3,000 inmates now on death row have been ***2765** there for more than 15 years. And, at present execution rates, it would take more than 75 years to carry out those 3,000 death sentences; thus, the average person on death row would spend an additional 37.5 years there before being executed. BJS 2013 Stats, at 14, 18 (Tables 11 and 15).

I cannot find any reasons to believe the trend will soon be reversed.

B

These lengthy delays create two special constitutional difficulties. See *Johnson v. Bredesen,* 558 U.S. 1067, 1069, 130 S.Ct. 541, 175 L.Ed.2d 552 (2009) (Stevens, J., statement respecting denial of certiorari). First, a lengthy delay in and of itself is especially cruel because it "subjects death row inmates to decades of especially severe, dehumanizing conditions of confinement." *Ibid.*; *Gomez v. Fierro,* 519 U.S. 918, 117 S.Ct. 285, 136 L.Ed.2d 204 (1996) (Stevens, J., dissenting) (excessive delays from sentencing to execution can themselves "constitute cruel and unusual punishment prohibited by the Eighth Amendment"); see also *Lackey v. Texas,* 514 U.S. 1045, 115 S.Ct. 1421, 131 L.Ed.2d 304 (1995) (memorandum of Stevens, J., respecting denial of certiorari); *Knight v. Florida,* 528 U.S. 990, 993, 120 S.Ct. 459, 145 L.Ed.2d 370 (1999) (BREYER, J., dissenting from denial of certiorari). Second, lengthy delay undermines the death penalty's penological rationale. *Johnson, supra,* at 1069, 130 S.Ct. 541; *Thompson v. McNeil,* 556 U.S. 1114, 1115, 129 S.Ct. 1299, —— L.Ed.2d —— (2009) (statement of Stevens, J., respecting denial of certiorari).

1

Turning to the first constitutional difficulty, nearly all death penalty States keep death row inmates in isolation for 22 or more hours per day. American Civil Liberties Union (ACLU), A Death Before Dying: Solitary Confinement on Death Row 5 (July 2013) (ACLU Report). This occurs even though the ABA has suggested that death row inmates be housed in conditions similar to the general population, and the United Nations Special Rapporteur on Torture has called for a global ban on

solitary confinement longer than 15 days. See *id.,* at 2, 4; ABA Standards for Criminal Justice: Treatment of Prisoners 6 (3d ed. 2011). And it is well documented that such prolonged solitary confinement produces numerous deleterious harms. See, *e.g.,* Haney, Mental Health Issues in Long–Term Solitary and "Supermax" Confinement, 49 Crime & Delinquency 124, 130 (2003) (cataloguing studies finding that solitary confinement can cause prisoners to experience "anxiety, panic, rage, loss of control, paranoia, hallucinations, and self-mutilations," among many other symptoms); Grassian, Psychiatric Effects of Solitary Confinement, 22 Wash U. J. L. & Policy 325, 331 (2006) ("[E]ven a few days of solitary confinement will predictably shift the [brain's] electroencephalogram (EEG) pattern toward an abnormal pattern characteristic of stupor and delirium"); accord, *In re Medley,* 134 U.S. 160, 167–168, 10 S.Ct. 384, 33 L.Ed. 835 (1890); see also *Davis v. Ayala,* —— U.S. ——, 135 S.Ct. 2187, —— L.Ed.2d —— (2015) (KENNEDY, J., concurring).

The dehumanizing effect of solitary confinement is aggravated by uncertainty as to whether a death sentence will in fact be carried out. In 1890, this Court recognized that, "when a prisoner sentenced by a court to death is confined in the penitentiary awaiting the execution of the sentence, one of the most horrible feelings to which he can be subjected during that time is the uncertainty during the whole of it." *Medley, supra,* at 172, 10 S.Ct. 384. The Court was there *describing a delay of a* ***2766** *mere four weeks.* In the past century and a quarter, little has changed in this respect—except for duration. Today we must describe delays measured, not in weeks, but in decades. *Supra,* at 2764 – 2765.

Moreover, we must consider death warrants that have been issued and revoked, not once, but repeatedly. See, *e.g.,* Pet. for Cert. in *Suárez Medina v. Texas,* O.T. 2001, No. 02–5752, pp. 35–36 (filed Aug. 13, 2002) ("On fourteen separate occasions since Mr. Suárez Medina's death sentence was imposed, he has been informed of the time, date, and manner of his death. At least eleven times, he has been asked to describe the disposal of his bodily remains"); Lithwick, Cruel but not Unusual, Slate, Apr. 1, 2011, online at http://www.slate.com/articles/news_and_politics/jurisprudence/2011/04/cruel_but_not_unusual.html (John Thompson had seven death warrants signed before he was exonerated); see also, *e.g.,* WFMZ–TV 69 News, Michael John Parrish's Execution Warrant Signed by Governor Corbett (Aug. 18, 2014), online at http:// www.wfmz.com/news/Regional-Poconos-Coal/Local/michael-john-parrishs-execution-warrant-signed-by-governor-corbett/27595356 (former Pennsylvania Governor signed 36 death warrants in his first 3.5 years in office even though Pennsylvania has not carried out an execution since 1999).

Several inmates have come within hours or days of execution before later being exonerated. Willie Manning was *four hours* from his scheduled execution before the Mississippi Supreme Court stayed the execution. See Robertson, With Hours to Go, Execution is Postponed, N.Y. Times, Apr. 8, 2015, p. A17. Two years later, Manning was exonerated after the evidence against him, including flawed testimony from an FBI hair examiner, was severely undermined. Nave, Why Does the State Still Want to Kill Willie Jerome Manning? Jackson Free Press, Apr. 29, 2015. Nor is Manning an outlier case. See, *e.g.,* Martin, Randall Adams, 61, Dies; Freed With Help of Film, N.Y. Times, June 26, 2011, p. 24 (Randall Adams: stayed by this Court three days before execution; later exonerated); N. Davies, White Lies 231, 292, 298, 399 (1991) (Clarence Lee Brandley: execution stayed twice, once 6 days and once 10 days before; later exonerated); M. Edds, An Expendable Man 93 (2003) (Earl Washington, Jr.: stayed 9 days before execution; later exonerated).

Furthermore, given the negative effects of confinement and uncertainty, it is not surprising that many inmates volunteer to be executed, abandoning further appeals. See, *e.g.,* ACLU Report 8; Rountree, Volunteers for Execution: Directions for Further Research into Grief, Culpability, and Legal Structures, 82 UMKC L. Rev. 295 (2014) (11% of those executed have dropped appeals and volunteered); ACLU Report 3 (account of " 'guys who dropped their appeals because of the intolerable conditions' "). Indeed, one death row inmate, who was later exonerated, still said he would have preferred to die rather than to spend years on death row pursuing his exoneration. Strafer, Volunteering for Execution: Competency, Voluntariness and the Propriety of Third Party Intervention, 74 J. Crim. L. & C. 860, 869 (1983). Nor is it surprising that many inmates consider, or commit, suicide. *Id.,* at 872, n. 44 (35% of those confined on death row in Florida attempted suicide).

Others have written at great length about the constitutional problems that delays create, and, rather

than repeat their facts, arguments, and conclusions, I simply refer to some of their writings. See, *e.g., Johnson,* 558 U.S., at 1069, 130 S.Ct. 541 (statement of Stevens, J.) (delay "subjects ***2767** death row inmates to decades of especially severe, dehumanizing conditions of confinement"); *Furman,* 408 U.S., at 288, 92 S.Ct. 2726 (Brennan, J., concurring) ("long wait between the imposition of sentence and the actual infliction of death" is "inevitable" and often "exacts a frightful toll"); *Solesbee v. Balkcom,* 339 U.S. 9, 14, 70 S.Ct. 457, 94 L.Ed. 604 (1950) (Frankfurter, J., dissenting) ("In the history of murder, the onset of insanity while awaiting execution of a death sentence is not a rare phenomenon"); *People v. Anderson,* 6 Cal.3d 628, 649, 493 P.2d 880, 894 (1972) (collecting sources) ("[C]ruelty of capital punishment lies not only in the execution itself and the pain incident thereto, but also in the dehumanizing effects of the lengthy imprisonment prior to execution during which the judicial and administrative procedures essential to due process of law are carried out" (footnote omitted)); *District Attorney for Suffolk Dist. v. Watson,* 381 Mass. 648, 673, 411 N.E.2d 1274, 1287 (1980) (Braucher, J., concurring) (death penalty unconstitutional under State Constitution in part because "[it] will be carried out only after agonizing months and years of uncertainty"); see also *Riley v. Attorney General of Jamaica,* [1983] 1 A.C. 719, 734–735 (P.C. 1982) (Lord Scarman, joined by Lord Brightman, dissenting) ("execution after inordinate delay" would infringe prohibition against "cruel and unusual punishments" in § 10 of the "Bill of Rights of 1689," the precursor to our Eighth Amendment); *Pratt v. Attorney Gen. of Jamaica,* [1994] 2 A.C. 1, 4 (P.C. 1993); *id.,* at 32–33 (collecting cases finding inordinate delays unconstitutional or the equivalent); *State* v. *Makwanyane* 1995 (3) SA391 (CC) (S. Afr.); *Catholic Commission for Justice & Peace in Zimbabwe v. Attorney–General,* [1993] 1 Zim. L. R. 242, 282 (inordinate delays unconstitutional); *Soering v. United Kingdom,* 11 Eur. Ct. H. R. (ser. A), p. 439 (1989) (extradition of murder suspect to United States would violate the European Convention on Human Rights in light of risk of delay before execution); *United States v. Burns,* [2001] 1 S.C.R. 283, 353, ¶ 123 (similar).

2

The second constitutional difficulty resulting from lengthy delays is that those delays undermine the death penalty's penological rationale, perhaps irreparably so. The rationale for capital punishment, as for any punishment, classically rests upon society's need to secure deterrence, incapacitation, retribution, or rehabilitation. Capital punishment by definition does not rehabilitate. It does, of course, incapacitate the offender. But the major alternative to capital punishment—namely, life in prison without possibility of parole—also incapacitates. See *Ring v. Arizona,* 536 U.S. 584, 615, 122 S.Ct. 2428, 153 L.Ed.2d 556 (2002) (BREYER, J., concurring in judgment).

Thus, as the Court has recognized, the death penalty's penological rationale in fact rests almost exclusively upon a belief in its tendency to deter and upon its ability to satisfy a community's interest in retribution. See, *e.g., Gregg,* 428 U.S., at 183, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and Stevens, JJ.). Many studies have examined the death penalty's deterrent effect; some have found such an effect, whereas others have found a lack of evidence that it deters crime. Compare *ante,* at 2748 – 2749 (SCALIA, J., concurring) (collecting studies finding deterrent effect), with *e.g.,* Sorensen, Wrinkle, Brewer, & Marquart, Capital Punishment and Deterrence: Examining the Effect of Executions on Murder in Texas, 45 Crime & Delinquency 481 (1999) (no evidence of a deterrent effect); Bonner & Fessenden, Absence of Executions: A Special Report, ***2768** States With No Death Penalty Share Lower Homicide Rates, N.Y. Times, Sept. 22, 2000, p. A1 (from 1980–2000, homicide rate in death-penalty States was 48% to 101% higher than in non-death-penalty States); Radelet & Akers, Deterrence and the Death Penalty: The Views of the Experts, 87 J. Crim. L. & C. 1, 8 (1996) (over 80% of criminologists believe existing research fails to support deterrence justification); Donohue & Wolfers, Uses and Abuses of Empirical Evidence in the Death Penalty Debate, 58 Stan. L. Rev. 791, 794 (2005) (evaluating existing statistical evidence and concluding that there is "profound uncertainty" about the existence of a deterrent effect).

Recently, the National Research Council (whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine) reviewed 30 years of empirical evidence and concluded that it was insufficient to establish a deterrent effect and thus should "not be used to inform" discussion about the deterrent value of the death penalty. National Research Council, Deterrence and the Death Penalty 2 (D. Nagin & J. Pepper eds. 2012); accord, *Baze v. Rees,* 553 U.S. 35, 79, 128 S.Ct. 1520, 170 L.Ed.2d 420

(2008) (Stevens, J., concurring in judgment) ("Despite 30 years of empirical research in the area, there remains no reliable statistical evidence that capital punishment in fact deters potential offenders").

I recognize that a "lack of evidence" for a proposition does not prove the contrary. See *Ring, supra,* at 615, 122 S.Ct. 2428 (one might believe the studies "inconclusive"). But suppose that we add to these studies the fact that, today, very few of those sentenced to death are actually executed, and that even those executions occur, on average, after nearly two decades on death row. DPIC, Execution List 2014, *supra*. Then, does it still seem likely that the death penalty has a significant deterrent effect?

Consider, for example, what actually happened to the 183 inmates sentenced to death in 1978. As of 2013 (35 years later), 38 (or 21% of them) had been executed; 132 (or 72%) had had their convictions or sentences overturned or commuted; and 7 (or 4%) had died of other (likely natural) causes. Six (or 3%) remained on death row. BJS 2013 Stats, at 19 (Table 16).

The example illustrates a general trend. Of the 8,466 inmates under a death sentence at some point between 1973 and 2013, 16% were executed, 42% had their convictions or sentences overturned or commuted, and 6% died by other causes; the remainder (35%) are still on death row. *Id.,* at 20 (Table 17); see also Baumgartner & Dietrich, Most Death Penalty Sentences Are Overturned: Here's Why That Matters, Washington Post Blog, Monkey Cage, Mar. 17, 2015 (similar).

Thus an offender who is sentenced to death is two or three times more likely to find his sentence overturned or commuted than to be executed; and he has a good chance of dying from natural causes before any execution (or exoneration) can take place. In a word, executions are *rare*. And an individual contemplating a crime but evaluating the potential punishment would know that, in any event, he faces a potential sentence of life without parole.

These facts, when recurring, must have some offsetting effect on a potential perpetrator's fear of a death penalty. And, even if that effect is no more than slight, it makes it difficult to believe (given the studies of deterrence cited earlier) that such a rare event significantly deters horrendous crimes. See *Furman,* 408 U.S., at 311–312, 92 S.Ct. 2726 (White, J., concurring) (It cannot "be said with confidence that society's need for specific deterrence ***2769** justifies death for so few when for so many in like circumstances life imprisonment or shorter prison terms are judged sufficient").

But what about retribution? Retribution is a valid penological goal. I recognize that surviving relatives of victims of a horrendous crime, or perhaps the community itself, may find vindication in an execution. And a community that favors the death penalty has an understandable interest in representing their voices. But see A. Sarat, Mercy on Trial: What It Means To Stop an Execution 130 (2005) (Illinois Governor George Ryan explained his decision to commute all death sentences on the ground that it was "cruel and unusual" for "family members to go through this ... legal limbo for [20] years").

The relevant question here, however, is whether a "community's sense of retribution" can often find vindication in "a death that comes," if at all, "only several decades after the crime was committed." *Valle v. Florida,* 564 U.S. ——, ——, 132 S.Ct. 1, 2, 180 L.Ed.2d 940 (2011) (BREYER, J., dissenting from denial of stay). By then the community is a different group of people. The offenders and the victims' families have grown far older. Feelings of outrage may have subsided. The offender may have found himself a changed human being. And sometimes repentance and even forgiveness can restore meaning to lives once ruined. At the same time, the community and victims' families will know that, even without a further death, the offender will serve decades in prison under a sentence of life without parole.

I recognize, of course, that this may not always be the case, and that sometimes the community believes that an execution could provide closure. Nevertheless, the delays and low probability of execution must play some role in any calculation that leads a community to insist on death as retribution. As I have already suggested, they may well attenuate the community's interest in retribution to the point where it cannot by itself amount to a significant justification for the death penalty. *Id.,* at ——, 132 S.Ct., at 2. In any event, I believe that whatever interest in retribution might be served by the death penalty as currently administered, that interest can be served almost as well by a sentence of life in prison without parole (a sentence that every State now permits, see ACLU,

A Living Death: Life Without Parole for Nonviolent Offenses 11, and n. 10 (2013)).

Finally, the fact of lengthy delays undermines any effort to justify the death penalty in terms of its prevalence when the Founders wrote the Eighth Amendment. When the Founders wrote the Constitution, there were no 20– or 30–year delays. Execution took place soon after sentencing. See P. Mackey, Hanging in the Balance: The Anti–Capital Punishment Movement in New York State, 1776–1861, p. 17 (1982); T. Jefferson, A Bill for Proportioning Crimes and Punishments (1779), reprinted in The Complete Jefferson 90, 95 (S. Padover ed. 1943); 2 Papers of John Marshall 207–209 (C. Cullen & H. Johnson eds. 1977) (describing petition for commutation based in part on 5–month delay); *Pratt v. Attorney Gen. of Jamaica,* [1994] 2 A. C., at 17 (same in United Kingdom) (collecting cases). And, for reasons I shall describe, *infra,* at 2770 – 2773, we cannot return to the quick executions in the founding era.

3

The upshot is that lengthy delays both aggravate the cruelty of the death penalty and undermine its jurisprudential rationale. And this Court has said that, if the death penalty does not fulfill the goals of deterrence or retribution, "it is nothing more than the purposeless and needless imposition of pain and suffering and hence ***2770** an unconstitutional punishment." *Atkins,* 536 U.S., at 319, 122 S.Ct. 2242 (quoting *Enmund v. Florida,* 458 U.S. 782, 798, 102 S.Ct. 3368, 73 L.Ed.2d 1140 (1982); internal quotation marks omitted); see also *Gregg,* 428 U.S., at 183, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and Stevens, JJ.) ("sanction imposed cannot be so totally without penological justification that it results in the gratuitous infliction of suffering"); *Furman, supra,* at 312, 92 S.Ct. 2726 (White, J., concurring) (a "penalty with such negligible returns to the State would be patently excessive and cruel and unusual punishment violative of the Eighth Amendment"); *Thompson,* 556 U.S., at 1115, 129 S.Ct. 1299 (statement of Stevens, J., respecting denial of certiorari) (similar).

Indeed, Justice Lewis Powell (who provided a crucial vote in *Gregg*) came to much the same conclusion, albeit after his retirement from this Court. Justice Powell had come to the Court convinced that the Federal Constitution did not outlaw the death penalty but rather left the matter up to individual States to determine. *Furman, supra,* at 431–432, 92 S.Ct. 2726 (Powell, J., dissenting); see also J. Jeffries, Justice Lewis F. Powell, Jr., p. 409 (2001) (describing Powell, during his time on the Court, as a "fervent partisan" of "the constitutionality of capital punishment").

Soon after Justice Powell's retirement, Chief Justice Rehnquist appointed him to chair a committee addressing concerns about delays in capital cases, the Ad Hoc Committee on Federal Habeas Corpus in Capital Cases (Committee). The Committee presented a report to Congress, and Justice Powell testified that "[d]elay robs the penalty of much of its deterrent value." Habeas Corpus Reform, Hearings before the Senate Committee on the Judiciary, 100th Cong., 1st and 2d Sess., 35 (1989 and 1990). Justice Powell, according to his official biographer, ultimately concluded that capital punishment:

> " 'serves no useful purpose.' The United States was 'unique among the industrialized nations of the West in maintaining the death penalty,' and it was enforced so rarely that it could not deter. More important, the haggling and delay and seemingly endless litigation in every capital case brought the law itself into disrepute." Jeffries, *supra,* at 452.

In short, the problem of excessive delays led Justice Powell, at least in part, to conclude that the death penalty was unconstitutional.

As I have said, today delays are much worse. When Chief Justice Rehnquist appointed Justice Powell to the Committee, the average delay between sentencing and execution was 7 years and 11 months, compared with 17 years and 7 months today. Compare BJS, L. Greenfeld, Capital Punishment, 1990, p. 11 (Table 12) (Sept. 1991) with *supra,* at 18–19.

C

One might ask, why can Congress or the States not deal directly with the delay problem? Why can they not take steps to shorten the time between sentence and execution, and thereby mitigate the problems just raised? The answer is that shortening delay is much more difficult than one might think. And that is in part because efforts to do so risk causing procedural harms that also undermine the death penalty's constitutionality.

For one thing, delays have helped to make application of the death penalty more reliable. Recall the case of Henry Lee McCollum, whom DNA evidence exonerated 30 years after his conviction. Katz & Eckholm, N.Y. Times, at A1. If McCollum had been executed earlier, he would not have lived to see the day when DNA evidence exonerated him and implicated ***2771** another man; that man is already serving a life sentence for a rape and murder that he committed just a few weeks after the murder McCollum was convicted of. *Ibid.* In fact, this Court had earlier denied review of McCollum's claim over the public dissent of only one Justice. *McCollum v. North Carolina,* 512 U.S. 1254, 114 S.Ct. 2784, 129 L.Ed.2d 895 (1994). And yet a full 20 years after the Court denied review, McCollum was exonerated by DNA evidence. There are a significant number of similar cases, some of which I have discussed earlier. See also DPIC Innocence List, *supra* (Nathson Fields, 23 years; Paul House, 23 years; Nicholas Yarris, 21 years; Anthony Graves, 16 years; Damon Thibodeaux, 15 years; Ricky Jackson, Wiley Bridgeman, and Kwame Ajamu, all exonerated for the same crime 39 years after their convictions).

In addition to those who are exonerated on the ground that they are innocent, there are other individuals whose sentences or convictions have been overturned for other reasons (as discussed above, state and federal courts found error in 68% of the capital cases they reviewed between 1973 and 1995). See Part I, *supra*. In many of these cases, a court will have found that the individual did not merit the death penalty in a special sense—namely, he failed to receive all the procedural protections that the law requires for the death penalty's application. By eliminating some of these protections, one likely could reduce delay. But which protections should we eliminate? Should we eliminate the trial-related protections we have established for capital defendants: that they be able to present to the sentencing judge or jury all mitigating circumstances, *Lockett v. Ohio,* 438 U.S. 586, 98 S.Ct. 2954, 57 L.Ed.2d 973; that the State provide guidance adequate to reserve the application of the death penalty to particularly serious murders, *Gregg,* 428 U.S. 153, 96 S.Ct. 2909, 49 L.Ed.2d 859; that the State provide adequate counsel and, where warranted, adequate expert assistance, *Powell v. Alabama,* 287 U.S. 45, 53 S.Ct. 55, 77 L.Ed. 158 (1932); *Wiggins v. Smith,* 539 U.S. 510, 123 S.Ct. 2527, 156 L.Ed.2d 471 (2003); *Ake v. Oklahoma,* 470 U.S. 68, 105 S.Ct. 1087, 84 L.Ed.2d 53 (1985); or that a jury must find the aggravating factors necessary to impose the death penalty, *Ring,* 536 U.S. 584, 122 S.Ct. 2428, 153 L.Ed.2d 556; see also *id.,* at 614, 122 S.Ct. 2428 (BREYER, J., concurring in judgment)? Should we no longer ensure that the State does not execute those who are seriously intellectually disabled, *Atkins,* 536 U.S. 304, 122 S.Ct. 2242, 153 L.Ed.2d 335? Should we eliminate the requirement that the manner of execution be constitutional, *Baze,* 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420, or the requirement that the inmate be mentally competent at the time of his execution, *Ford v. Wainwright,* 477 U.S. 399, 106 S.Ct. 2595, 91 L.Ed.2d 335 (1986)? Or should we get rid of the criminal protections that all criminal defendants receive—for instance, that defendants claiming violation of constitutional guarantees (say "due process of law") may seek a writ of habeas corpus in federal courts? See, *e.g., O'Neal v. McAninch,* 513 U.S. 432, 115 S.Ct. 992, 130 L.Ed.2d 947 (1995). My answer to these questions is "surely not." But see *ante,* at 2748 – 2750 (SCALIA, J., concurring).

One might, of course, argue that courts, particularly federal courts providing additional layers of review, apply these and other requirements too strictly, and that causes delay. But, it is difficult for judges, as it would be difficult for anyone, *not* to apply legal requirements punctiliously when the consequence of failing to do so may well be death, particularly the death of an innocent person. See, *e.g.,* ***2772** *Zant v. Stephens,* 462 U.S. 862, 885, 103 S.Ct. 2733, 77 L.Ed.2d 235 (1983) ("[A]lthough not every imperfection in the deliberative process is sufficient, even in a capital case, to set aside a state-court judgment, the severity of the sentence mandates careful scrutiny in the review of any colorable claim of error"); *Kyles v. Whitley,* 514 U.S. 419, 422, 115 S.Ct. 1555, 131 L.Ed.2d 490 (1995) ("[O]ur duty to search for constitutional error with painstaking care is never more exacting than it is in a capital case" (internal quotation marks omitted)); *Thompson,* 556 U.S., at 1116, 129 S.Ct. 1299 (statement of Stevens, J.) ("Judicial process takes time, but the error rate in capital cases illustrates its necessity").

Moreover, review by courts at every level helps to ensure reliability; if this Court had not ordered that Anthony Ray Hinton receive further hearings in state court, see *Hinton v. Alabama,* 571 U.S. ——, 134 S.Ct. 1081, 188 L.Ed.2d 1, he may well have been executed rather than exonerated. In my own view, our legal system's complexity, our federal system with its separate state and federal courts, our constitutional guarantees, our commitment to fair

procedure, and, above all, a special need for reliability and fairness in capital cases, combine to make significant procedural "reform" unlikely in practice to reduce delays to an acceptable level.

And that fact creates a dilemma: A death penalty system that seeks procedural fairness and reliability brings with it delays that severely aggravate the cruelty of capital punishment and significantly undermine the rationale for imposing a sentence of death in the first place. See *Knight,* 528 U.S., at 998, 120 S.Ct. 459 (BREYER, J., dissenting from denial of certiorari) (one of the primary causes of the delay is the States' "failure to apply constitutionally sufficient procedures at the time of initial [conviction or] sentencing"). But a death penalty system that minimizes delays would undermine the legal system's efforts to secure reliability and procedural fairness.

In this world, or at least in this Nation, we can have a death penalty that at least arguably serves legitimate penological purposes *or* we can have a procedural system that at least arguably seeks reliability and fairness in the death penalty's application. We cannot have both. And that simple fact, demonstrated convincingly over the past 40 years, strongly supports the claim that the death penalty violates the Eighth Amendment. A death penalty system that is unreliable or procedurally unfair would violate the Eighth Amendment. *Woodson,* 428 U.S., at 305, 96 S.Ct. 2978 (plurality opinion); *Hall,* 572 U.S., at ——, 134 S.Ct., at 2001; *Roper,* 543 U.S., at 568, 125 S.Ct. 1183. And so would a system that, if reliable and fair in its application of the death penalty, would serve no legitimate penological purpose. *Furman,* 408 U.S., at 312, 92 S.Ct. 2726 (White, J., concurring); *Gregg, supra,* at 183, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and Stevens, JJ.); *Atkins, supra,* at 319, 122 S.Ct. 2242.

IV

"Unusual"—Decline in Use of the Death Penalty

The Eighth Amendment forbids punishments that are cruel and *unusual.* Last year, in 2014, only seven States carried out an execution. Perhaps more importantly, in the last two decades, the imposition and implementation of the death penalty have increasingly become unusual. I can illustrate the significant decline in the use of the death penalty in several ways.

An appropriate starting point concerns the trajectory of the number of annual death sentences nationwide, from the 1970's to present day. In 1977—just after ***2773** the Supreme Court made clear that, by modifying their legislation, States could reinstate the death penalty—137 people were sentenced to death. BJS 2013 Stats, at 19 (Table 16). Many States having revised their death penalty laws to meet *Furman*' s requirements, the number of death sentences then increased. Between 1986 and 1999, 286 persons on average were sentenced to death each year. BJS 2013 Stats, at 14, 19 (Tables 11 and 16). But, approximately 15 years ago, the numbers began to decline, and they have declined rapidly ever since. See Appendix A, *infra* (showing sentences from 1977–2014). In 1999, 279 persons were sentenced to death. BJS 2013 Stats, at 19 (Table 16). Last year, just 73 persons were sentenced to death. DPIC, The Death Penalty in 2014: Year End Report 1 (2015).

That trend, a significant decline in the last 15 years, also holds true with respect to the number of annual executions. See Appendix B, *infra* (showing executions from 1977–2014). In 1999, 98 people were executed. BJS, Data Collection: National Prisoner Statistics Program (BJS Prisoner Statistics) (available in Clerk of Court's case file). Last year, that number was only 35. DPIC, The Death Penalty in 2014, *supra,* at 1.

Next, one can consider state-level data. Often when deciding whether a punishment practice is, constitutionally speaking, "unusual," this Court has looked to the number of States engaging in that practice. *Atkins,* 536 U.S., at 313–316, 122 S.Ct. 2242; *Roper, supra,* at 564–566, 125 S.Ct. 1183. In this respect, the number of active death penalty States has fallen dramatically. In 1972, when the Court decided *Furman*, the death penalty was lawful in 41 States. Nine States had abolished it. E. Mandery, A Wild Justice: The Death and Resurrection of Capital Punishment in America 145 (2013). As of today, 19 States have abolished the death penalty (along with the District of Columbia), although some did so prospectively only. See DPIC, States With and Without the Death Penalty, online at http://www.deathpenalty info.org/states-and-without-death-penalty. In 11 other States that maintain the death penalty on the books, no execution has taken place for more than eight years: Arkansas (last execution 2005); California (2006); Colorado (1997); Kansas (no

executions since the death penalty was reinstated in 1976); Montana (2006); Nevada (2006); New Hampshire (no executions since the death penalty was reinstated in 1976); North Carolina (2006); Oregon (1997); Pennsylvania (1999); and Wyoming (1992). DPIC, Executions by State and Year, online at http://www.death penaltyinfo.org/node/5741.

Accordingly, 30 States have either formally abolished the death penalty or have not conducted an execution in more than eight years. Of the 20 States that have conducted at least one execution in the past eight years, 9 have conducted fewer than five in that time, making an execution in those States a fairly rare event. BJS Prisoner Statistics (Delaware, Idaho, Indiana, Kentucky, Louisiana, South Dakota, Tennessee, Utah, Washington). That leaves 11 States in which it is fair to say that capital punishment is not "unusual." And just three of those States (Texas, Missouri, and Florida) accounted for 80% of the executions nationwide (28 of the 35) in 2014. See DPIC, Number of Executions by State and Region Since 1976, online at http://www.deathpenalty info.org/number–executions–state–and–region–1976. Indeed, last year, only seven States conducted an execution. DPIC, Executions by State and Year, *supra* ; DPIC, Death Sentences in the United States From 1977 by State and by Year, online at http://www.deathpenaltyinfo.org/death–sentences–united–states–1977–2008. In ***2774** other words, in 43 States, no one was executed.

In terms of population, if we ask how many Americans live in a State that at least occasionally carries out an execution (at least one within the prior three years), the answer two decades ago was 60% or 70%. Today, that number is 33%. See Appendix C, *infra*.

At the same time, use of the death penalty has become increasingly concentrated geographically. County-by-county figures are relevant, for decisions to impose the death penalty typically take place at a county level. See *supra,* at 2761 – 2762. County-level sentencing figures show that, between 1973 and 1997, 66 of America's 3,143 counties accounted for approximately 50% of all death sentences imposed. Liebman & Clarke 264–265; cf. *id.,* at 266. (counties with 10% of the Nation's population imposed 43% of its death sentences). By the early 2000's, the death penalty was only actively practiced in a very small number of counties: between 2004 and 2009, only 35 counties imposed 5 or more death sentences, *i.e.,* approximately one per year. See Appendix D, *infra* (such counties colored in red) (citing Ford, The Death Penalty's Last Stand, The Atlantic, Apr. 21, 2015). And more recent data show that the practice has diminished yet further: between 2010 and 2015 (as of June 22), only 15 counties imposed five or more death sentences. See Appendix E, *infra*. In short, the number of active death penalty counties is small and getting smaller. And the overall statistics on county-level executions bear this out. Between 1976 and 2007, there were no executions in 86% of America's counties. Liebman & Clarke 265–266, and n. 47; cf. *ibid.* (counties with less than 5% of the Nation's population carried out over half of its executions from 1976–2007).

In sum, if we look to States, in more than 60% there is effectively no death penalty, in an additional 18% an execution is rare and unusual, and 6%, *i.e.,* three States, account for 80% of all executions. If we look to population, about 66% of the Nation lives in a State that has not carried out an execution in the last three years. And if we look to counties, in 86% there is effectively no death penalty. It seems fair to say that it is now unusual to find capital punishment in the United States, at least when we consider the Nation as a whole. See *Furman,* 408 U.S., at 311, 92 S.Ct. 2726 (1972) (White, J., concurring) (executions could be so infrequently carried out that they "would cease to be a credible deterrent or measurably to contribute to any other end of punishment in the criminal justice system ... when imposition of the penalty reaches a certain degree of infrequency, it would be very doubtful that any existing general need for retribution would be measurably satisfied").

Moreover, we have said that it " 'is not so much the number of these States that is significant, but the consistency of the direction of change.' " *Roper,* 543 U.S., at 566, 125 S.Ct. 1183 (quoting *Atkins, supra,* at 315, 122 S.Ct. 2242) (finding significant that five States had abandoned the death penalty for juveniles, four legislatively and one judicially, since the Court's decision in *Stanford v. Kentucky,* 492 U.S. 361, 109 S.Ct. 2969, 106 L.Ed.2d 306 (1989)). Judged in that way, capital punishment has indeed become unusual. Seven States have abolished the death penalty in the last decade, including (quite recently) Nebraska. DPIC, States With and Without the Death Penalty, *supra*. And several States have come within a single vote of eliminating the death penalty. Seelye, Measure to Repeal Death Penalty Fails by a Single Vote in New Hampshire Senate, N.Y. Times,

Apr. 17, 2014, p. A12; Dennison, House Deadlocks on Bill To Abolish ***2775** Death Penalty in Montana, Billings Gazette, Feb. 23, 2015; see also Offredo, Delaware Senate Passes Death Penalty Repeal Bill, Delaware News Journal, Apr. 3, 2015. Eleven States, as noted earlier, have not executed anyone in eight years. *Supra,* at 2773 – 2774. And several States have formally stopped executing inmates. See Yardley, Oregon's Governor Says He Will Not Allow Executions, N.Y. Times, Nov. 23, 2011, p. A14 (Oregon); Governor of Colorado, Exec. Order No. D2013–006, May 22, 2013 (Colorado); Lovett, Executions Are Suspended by Governor in Washington, N.Y. Times, Feb. 12, 2014, p. A12 (Washington); Begley, Pennsylvania Stops Using the Death Penalty, Time, Feb. 13, 2015 (Pennsylvania); see also Welsh–Huggins, Associated Press, Ohio Executions Rescheduled, Jan. 30, 2015 (Ohio).

Moreover, the direction of change is consistent. In the past two decades, no State without a death penalty has passed legislation to reinstate the penalty. See *Atkins, supra,* at 315–316, 122 S.Ct. 2242; DPIC, States With and Without the Death Penalty, *supra*. Indeed, even in many States most associated with the death penalty, remarkable shifts have occurred. In Texas, the State that carries out the most executions, the number of executions fell from 40 in 2000 to 10 in 2014, and the number of death sentences fell from 48 in 1999 to 9 in 2013 (and 0 thus far in 2015). DPIC, Executions by State and Year, *supra* ; BJS, T. Snell, Capital Punishment, 1999, p. 6 (Table 5) (Dec. 2000) (hereinafter BJS 1999 Stats); BJS 2013 Stats, at 19 (Table 16); von Drehle, Bungled Executions, Backlogged Courts, and Three More Reasons the Modern Death Penalty Is a Failed Experiment, Time, June 8, 2015, p. 26. Similarly dramatic declines are present in Virginia, Oklahoma, Missouri, and North Carolina. BJS 1999 Stats, at 6 (Table 5); BJS 2013 Stats, at 19 (Table 16).

These circumstances perhaps reflect the fact that a majority of Americans, when asked to choose between the death penalty and life in prison without parole, now choose the latter. Wilson, Support for Death Penalty Still High, But Down, Washington Post, GovBeat, June 5, 2014, online at www. washingtonpost.com/blogs/govbeat/wp/2014/06/05/support-for-death-penalty-still-high-but-down; see also ALI, Report of the Council to the Membership on the Matter of the Death Penalty 4 (Apr. 15, 2009) (withdrawing Model Penal Code section on capital punishment section from the Code, in part because of doubts that the American Law Institute could "recommend procedures that would" address concerns about the administration of the death penalty); cf. *Gregg,* 428 U.S., at 193–194, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and Stevens, JJ.) (relying in part on Model Penal Code to conclude that a "carefully drafted statute" can satisfy the arbitrariness concerns expressed in *Furman*).

I rely primarily upon domestic, not foreign events, in pointing to changes and circumstances that tend to justify the claim that the death penalty, constitutionally speaking, is "unusual." Those circumstances are sufficient to warrant our reconsideration of the death penalty's constitutionality. I note, however, that many nations—indeed, 95 of the 193 members of the United Nations—have formally abolished the death penalty and an additional 42 have abolished it in practice. Oakford, UN Vote Against Death Penalty Highlights Global Abolitionist Trend-and Leaves the U.S. Stranded, Vice News, Dec. 19, 2014, online at https://news.vice.com/article/un-vote-against-death-penalty-highlights-global-abolitionist-trend-and-leaves-the-us-stranded. In 2013, only 22 countries in the world carried out an execution. International Commission Against ***2776** Death Penalty, Review 2013, pp. 2–3. No executions were carried out in Europe or Central Asia, and the United States was the only country in the Americas to execute an inmate in 2013. *Id.,* at 3. Only eight countries executed more than 10 individuals (the United States, China, Iran, Iraq, Saudi Arabia, Somalia, Sudan, Yemen). *Id.,* at 2. And almost 80% of all known executions took place in three countries: Iran, Iraq, and Saudi Arabia. Amnesty International, Death Sentences and Executions 2013, p. 3 (2014). (This figure does not include China, which has a large population, but where precise data cannot be obtained. *Id.,* at 2.)

V

I recognize a strong counterargument that favors constitutionality. We are a court. Why should we not leave the matter up to the people acting democratically through legislatures? The Constitution foresees a country that will make most important decisions democratically. Most nations that have abandoned the death penalty have done so through legislation, not judicial decision.

And legislators, unlike judges, are free to take account of matters such as monetary costs, which I do not claim are relevant here. See, *e.g.,* Berman, Nebraska Lawmakers Abolish the Death Penalty, Narrowly Overriding Governor's Veto, Washington Post Blog, Post Nation, May 27, 2015 (listing cost as one of the reasons why Nebraska legislators recently repealed the death penalty in that State); cf. California Commission on the Fair Administration of Justice, Report and Recommendations on the Administration of the Death Penalty in California 117 (June 30, 2008) (death penalty costs California $137 million per year; a comparable system of life imprisonment without parole would cost $11.5 million per year), online at http://www.ccfaj.org/rr-dp-official.html; Dáte, The High Price of Killing Killers, Palm Beach Post, Jan. 4, 2000, p. 1A (cost of each execution is $23 million above cost of life imprisonment without parole in Florida).

The answer is that the matters I have discussed, such as lack of reliability, the arbitrary application of a serious and irreversible punishment, individual suffering caused by long delays, and lack of penological purpose are quintessentially judicial matters. They concern the infliction—indeed the unfair, cruel, and unusual infliction—of a serious punishment upon an individual. I recognize that in 1972 this Court, in a sense, turned to Congress and the state legislatures in its search for standards that would increase the fairness and reliability of imposing a death penalty. The legislatures responded. But, in the last four decades, considerable evidence has accumulated that those responses have not worked.

Thus we are left with a judicial responsibility. The Eighth Amendment sets forth the relevant law, and we must interpret that law. See *Marbury v. Madison,* 1 Cranch 137, 177, 2 L.Ed. 60 (1803); *Hall,* 572 U.S., at ——, 134 S.Ct., at 2000 ("That exercise of independent judgment is the Court's judicial duty"). We have made clear that " 'the Constitution contemplates that in the end our own judgment will be brought to bear on the question of the acceptability of the death penalty under the Eighth Amendment.' " *Id.,* at ——, 134 S.Ct., at 1999 (quoting *Coker v. Georgia,* 433 U.S. 584, 597, 97 S.Ct. 2861, 53 L.Ed.2d 982 (1977) (plurality opinion)); see also *Thompson v. Oklahoma,* 487 U.S. 815, 833, n. 40, 108 S.Ct. 2687, 101 L.Ed.2d 702 (1988) (plurality opinion).

For the reasons I have set forth in this opinion, I believe it highly likely that the ***2777** death penalty violates the Eighth Amendment. At the very least, the Court should call for full briefing on the basic question.

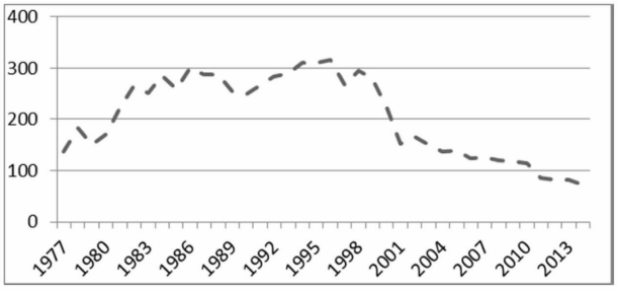
With respect, I dissent.

Appendix A

APPENDICES

A

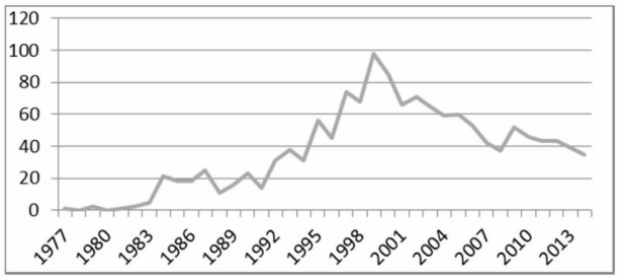
Death Sentences Imposed 1977–2014



Appendix B

B

Executions 1977–2014



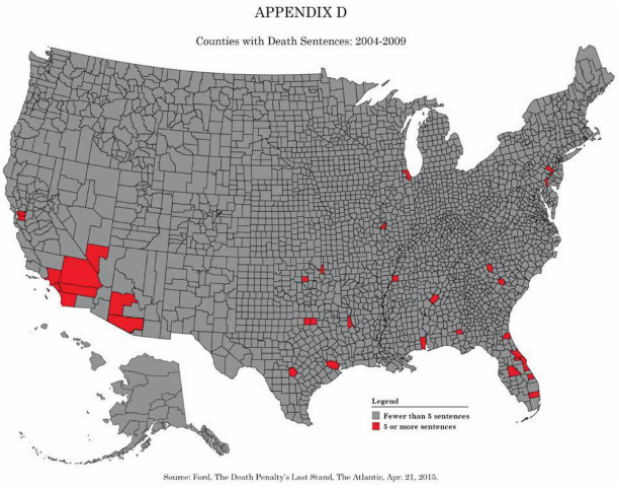
***2778** Appendix C

C

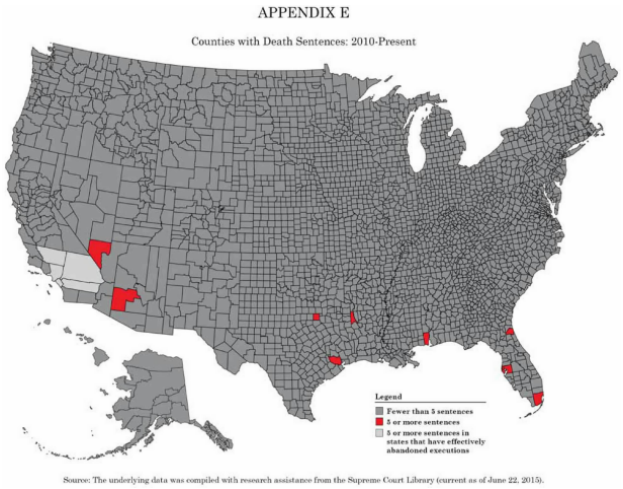
Percentage of U.S. population in States that conducted an execution within prior 3 years

Year	Percentage
1994	54%
1995	60%
1996	63%
1997	63%
1998	61%
1999	70%
2000	68%
2001	67%
2002	57%
2003	53%
2004	52%
2005	52%
2006	55%
2007	57%
2008	53%
2009	39%
2010	43%
2011	42%
2012	39%
2013	34%
2014	33%

***2779** Appendix D



***2780** Appendix E



Justice SOTOMAYOR, with whom Justice GINSBURG, Justice BREYER, and Justice KAGAN join, dissenting.

Petitioners, three inmates on Oklahoma's death row, challenge the constitutionality of the State's lethal injection protocol. The State plans to execute petitioners using three drugs: midazolam, rocuronium bromide, and potassium chloride. The latter two drugs are intended to paralyze the inmate and stop his heart. ***2781** But they do so in a torturous manner, causing burning, searing pain. It is thus critical that the first drug, midazolam, do what it is supposed to do, which is to render and keep the inmate unconscious. Petitioners claim that midazolam cannot be expected to perform that function, and they have presented ample evidence showing that the State's planned use of this drug poses substantial, constitutionally intolerable risks.

Nevertheless, the Court today turns aside petitioners' plea that they at least be allowed a stay of execution while they seek to prove midazolam's inadequacy. The Court achieves this result in two ways: first, by deferring to the District Court's decision to credit the scientifically unsupported and implausible testimony of a single expert witness; and second, by faulting petitioners for failing to satisfy the wholly novel requirement of proving the availability of an alternative means for their own executions. On both counts the Court errs. As a result, it leaves petitioners exposed to what may well be the chemical equivalent of being burned at the stake.

I

A

The Eighth Amendment succinctly prohibits the infliction of "cruel and unusual punishments." Seven years ago, in *Baze v. Rees,* 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008), the Court addressed the application of this mandate to Kentucky's lethal injection protocol. At that time, Kentucky, like at least 29 of the 35 other States with the death penalty, utilized a series of three drugs to perform executions: (1) sodium thiopental, a "fast-acting barbiturate sedative that induces a deep, comalike unconsciousness when given in the amounts used for lethal injection"; (2) pancuronium bromide, "a paralytic agent that inhibits all muscular-skeletal movements and ... stops respiration"; and (3) potassium chloride, which "interferes with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest." *Id.,* at 44, 128 S.Ct. 1520 (plurality opinion of ROBERTS, C.J.).

In *Baze,* it was undisputed that absent a "proper dose of sodium thiopental," there would be a "substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride." *Id.,* at 53, 128 S.Ct. 1520. That is because, if given to a conscious inmate, pancuronium bromide would leave him or her asphyxiated and unable to demonstrate "any outward sign of distress," while potassium chloride would cause "excruciating pain." *Id.,* at 71, 128 S.Ct. 1520 (Stevens, J., concurring in judgment). But the *Baze* petitioners conceded that if administered as intended, Kentucky's method of execution would nevertheless "result in a humane death," *id.,* at 41, 128 S.Ct. 1520 (plurality opinion), as the "proper administration" of sodium thiopental "eliminates any meaningful risk that a prisoner would experience pain from the subsequent injections of pancuronium and potassium chloride," *id.,* at 49, 128 S.Ct. 1520. Based on that premise, the Court ultimately rejected the challenge to Kentucky's protocol, with the plurality opinion concluding that the State's procedures for administering these three drugs ensured there was no "objectively intolerable risk" of severe pain. *Id.,* at 61–62, 128 S.Ct. 1520 (internal quotation marks omitted).

B

For many years, Oklahoma performed executions using the same three drugs at issue in *Baze*. After *Baze* was decided, however, the primary producer of sodium thiopental refused to continue permitting ***2782** the drug to be used in executions. *Ante,* at 2756 – 2757. Like a number of other States, Oklahoma opted to substitute pentobarbital, another barbiturate, in its place. But in March 2014, shortly before two scheduled executions, Oklahoma found itself unable to secure this drug. App. 144.

The State rescheduled the executions for the following month to give it time to locate an alternative anesthetic. In less than a week, a group of officials from the Oklahoma Department of Corrections and the Attorney General's office selected midazolam to serve as a replacement for pentobarbital. *Id.,* at 145, 148–149.

Soon thereafter, Oklahoma used midazolam for the first time in its execution of Clayton Lockett. That execution did not go smoothly. Ten minutes after an intravenous (IV) line was set in Lockett's groin area and 100 milligrams of midazolam were administered, an attending physician declared Lockett unconscious. *Id.,* at 392–393. When the paralytic and potassium chloride were administered, however, Lockett awoke. *Ibid.* Various witnesses reported that Lockett began to writhe against his restraints, saying, "[t]his s* * * is f* * *ing with my mind," "something is wrong," and "[t]he drugs aren't working." *Id.,* at 53 (internal quotation marks omitted). State officials ordered the blinds lowered, then halted the execution. *Id.,* at 393, 395. But 10 minutes later—approximately 40 minutes after the execution began—Lockett was pronounced dead. *Id.,* at 395.

The State stayed all future executions while it sought to determine what had gone wrong in Lockett's. Five months later, the State released an investigative report identifying a flaw in the IV line as the principal difficulty: The IV had failed to fully deliver the lethal drugs into Lockett's veins. *Id.,* at 398. An autopsy determined, however, that the concentration of midazolam in Lockett's blood was more than sufficient to render an average person unconscious. *Id.,* at 397, 405.

In response to this report, the State modified its lethal injection protocol. The new protocol contains a number of procedures designed to guarantee that members of the execution team are able to insert the IV properly,

and charges them with ensuring that the inmate is unconscious. *Id.,* at 57–66, 361–369. But the protocol continues to authorize the use of the same three-drug formula used to kill Lockett—though it does increase the intended dose of midazolam from 100 milligrams to 500 milligrams. *Id.,* at 61. The State has indicated that it plans to use this drug combination in all upcoming executions, subject to only an immaterial substitution of paralytic agents. *Ante,* at 2758 – 2759.

C

In June 2014, inmates on Oklahoma's death row filed a 42 U.S.C. § 1983 suit against respondent prison officials challenging the constitutionality of Oklahoma's method of execution. After the State released its revised execution protocol, the four inmates whose executions were most imminent—Charles Warner, along with petitioners Richard Glossip, John Grant, and Benjamin Cole—moved for a preliminary injunction. They contended, among other things, that the State's intended use of midazolam would violate the Eighth Amendment because, unlike sodium thiopental or pentobarbital, the drug "is incapable of producing a state of unawareness that will be reliably maintained after either of the other two pain-producing drugs ... is injected." Amended Complaint ¶ 101.

The District Court held a 3–day evidentiary hearing, at which petitioners relied principally on the testimony of two experts: Dr. David Lubarsky, an anesthesiologist, ***2783** and Dr. Larry Sasich, a doctor of pharmacy. The State, in turn, based its case on the testimony of Dr. Roswell Evans, also a doctor of pharmacy.

To a great extent, the experts' testimony overlapped. All three experts agreed that midazolam is from a class of sedative drugs known as benzodiazepines (a class that includes Valium and Xanax), and that it has no analgesic —or pain-relieving—effects. App. 205 (Lubarsky), 260–261 (Sasich), 311 (Evans). They further agreed that while midazolam can be used to render someone unconscious, it is not approved by the Federal Drug Administration (FDA) for use as, and is not in fact used as, a "sole drug to produce and maintain anesthesia in surgical proceedings." *Id.,* at 307, 327 (Evans); see *id.,* at 171 (Lubarsky); *id.,* at 262 (Sasich). Finally, all three experts recognized that midazolam is subject to a ceiling effect, which means that there is a point at which increasing the dose of the drug does not result in any greater effect. *Id.,* at 172 (Lubarsky), 243 (Sasich), 331 (Evans).

The experts' opinions diverged, however, on the crucial questions of how this ceiling effect operates, and whether it will prevent midazolam from keeping a condemned inmate unconscious when the second and third lethal injection drugs are administered. Dr. Lubarsky testified that while benzodiazepines such as midazolam may, like barbiturate drugs such as sodium thiopental and pentobarbital, induce unconsciousness by inhibiting neuron function, they do so in a materially different way. *Id.,* at 207. More specifically, Dr. Lubarsky explained that both barbiturates and benzodiazepines initially cause sedation by facilitating the binding of a naturally occurring chemical called gamma-aminobutyric acid (GABA) with GABA receptors, which then impedes the flow of electrical impulses through the neurons in the central nervous system. *Id.,* at 206. But at higher doses, barbiturates also act as a GABA substitute and mimic its neuron-suppressing effects. *Ibid.* By contrast, benzodiazepines lack this mimicking function, which means their effect is capped at a lower level of sedation. *Ibid.* Critically, according to Dr. Lubarsky, this ceiling on midazolam's sedative effect is reached before full anesthesia can be achieved. *Ibid.* Thus, in his view, while "midazolam unconsciousness is ... sufficient" for "minor procedure[s]," Tr. of Preliminary Injunction Hearing 132–133 (Tr.), it is incapable of keeping someone "insensate and immobile in the face of [more] noxious stimuli," including the extreme pain and discomfort associated with administration of the second and third drugs in Oklahoma's lethal injection protocol, App. 218. Dr. Sasich endorsed Dr. Lubarsky's description of the ceiling effect, and offered similar reasons for reaching the same conclusion. See *id.,* at 243, 248, 262.

In support of these assertions, both experts cited a variety of evidence. Dr. Lubarsky emphasized, in particular, Arizona's 2014 execution of Joseph Wood, which had been conducted using midazolam and the drug hydromorphone rather than the three-drug cocktail Oklahoma intends to employ.[1] *Id.,* at 176. Despite being administered 750 milligrams of midazolam, Wood had continued breathing and moving for nearly two hours—which, according to Dr. Lubarsky, would not have occurred "during extremely deep levels of anesthesia." *Id.,* at 177. Both experts also cited various scientific articles and

textbooks to support their conclusions. For instance, ***2784** Dr. Lubarsky relied on a study measuring the brain activity of rats that were administered midazolam, which showed that the drug's impact significantly tailed off at higher doses. See Hovinga et al., Pharmacokinetic–EEG Effect Relationship of Midazolam in Aging BN/BiRij Rats, 107 British J. Pharmacology 171, 173, Fig. 2 (1992). He also pointed to a pharmacology textbook that confirmed his description of how benzodiazepines and barbiturates produce their effects, see Stoelting & Hillier 127–128, 140–144, and a survey article concluding that "[m]idazolam cannot be used alone ... to maintain adequate anesthesia," Reves, Fragen, Vinik, & Greenblatt, Midazolam: Pharmacology and Uses, 62 Anesthesiology 310, 318 (1985) (Reves). For his part, Dr. Sasich referred to a separate survey article, which similarly recognized and described the ceiling effect to which benzodiazepines are subject. See Saari, Uusi–Oukari, Ahonen, & Olkkola, Enhancement of GABAergic Activity: Neuropharmacological Effects of Benzodiazepines and Therapeutic Use in Anesthesiology, 63 Pharamacological Rev. 243, 244, 250 (2011) (Saari).

By contrast, Dr. Evans, the State's expert, asserted that a 500–milligram dose of midazolam would "render the person unconscious and 'insensate' during the remainder of the [execution] procedure." App. 294. He rested this conclusion on two interrelated propositions.

First, observing that a therapeutic dose of midazolam to treat anxiety is less than 5 milligrams for a 70–kilogram adult, Dr. Evans emphasized that Oklahoma's planned administration of 500 milligrams of the drug was "at least 100 times the normal therapeutic dose." *Ibid.* While he acknowledged that "[t]here are no studies that have been done ... administering that much ... midazolam ... to anybody," he noted that deaths had occurred in doses as low as 0.04 to 0.07 milligrams per kilogram (2.8 to 4.9 milligrams for a 70–kilogram adult), and contended that a 500–milligram dose would itself cause death within less than an hour—a conclusion he characterized as "essentially an extrapolation from a toxic effect." *Id.,* at 327; see *id.,* at 308.

Second, in explaining how he reconciled his opinion with the evidence of midazolam's ceiling effect, Dr. Evans testified that while "GABA receptors are found across the entire body," midazolam's ceiling effect is limited to the "spinal cord" and there is "no ceiling effect" at the "higher level of [the] brain." *Id.,* at 311–312. Consequently, in his view, "as you increase the dose of midazolam, it's a linear effect, so you're going to continue to get an impact from higher doses of the drug," *id.,* at 332, until eventually "you're paralyzing the brain," *id.,* at 314. Dr. Evans also understood the chemical source of midazolam's ceiling effect somewhat differently from petitioners' experts. Although he agreed that midazolam produces its effect by "binding to [GABA] receptors," *id.,* at 293, he appeared to believe that midazolam produced sedation by "inhibiting GABA" from attaching to GABA receptors, not by promoting GABA's sedative effects, *id.,* at 312. Thus, when asked about Dr. Lubarsky's description of the ceiling effect, Dr. Evans characterized the phenomenon as stemming from "the competitive nature of substances trying to attach to GABA receptors." *Id.,* at 313.

Dr. Evans cited no scholarly research in support of his opinions. Instead, he appeared to rely primarily on two sources: the Web site www.drugs.com, and a "Material Safety Data Sheet" produced by a midazolam manufacturer. See *id.,* at 303. Both simply contained general information that covered the experts' areas of agreement.

***2785** D

The District Court denied petitioners' motion for a preliminary injunction. It began by making a series of factual findings regarding the characteristics of midazolam and its use in Oklahoma's execution protocol. Most relevant here, the District Court found that "[t]he proper administration of 500 milligrams of midazolam ... would make it a virtual certainty that an individual will be at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from the application of the second and third drugs." *Id.,* at 77. Respecting petitioners' contention that there is a "ceiling effect which prevents an increase in dosage from having a corresponding incremental effect on anesthetic depth," the District Court concluded:

> "Dr. Evans testified persuasively ... that whatever the ceiling effect of midazolam may be with respect to anesthesia, which takes effect at the spinal cord level, there is no ceiling effect with respect to the ability of a 500 milligram dose of midazolam to effectively paralyze

the brain, a phenomenon which is not anesthesia but does have the effect of shutting down respiration and eliminating the individual's awareness of pain." *Id.,* at 78.

Having made these findings, the District Court held that petitioners had shown no likelihood of success on the merits of their Eighth Amendment claim for two independent reasons. First, it determined that petitioners had "failed to establish that proceeding with [their] execution[s] ... on the basis of the revised protocol presents ... 'an objectively intolerable risk of harm.' " *Id.,* at 96. Second, the District Court held that petitioners were unlikely to prevail because they had not identified any " 'known and available alternative' " means by which they could be executed—a requirement it understood *Baze* to impose. *Id.,* at 97. The District Court concluded that the State "ha[d] affirmatively shown that sodium thiopental and pentobarbital, the only alternatives to which the [petitioners] have even alluded, are not available to the [State]." *Id.,* at 98.

The Court of Appeals for the Tenth Circuit affirmed. *Warner v. Gross,* 776 F.3d 721 (2015). It, like the District Court, held that petitioners were unlikely to prevail on the merits because they had failed to prove the existence of " 'known and available alternatives.' " *Id.,* at 732. "In any event," the court continued, it was unable to conclude that the District Court's factual findings had been clearly erroneous, and thus petitioners had also "failed to establish that the use of midazolam in their executions ... creates a demonstrated risk of severe pain." *Ibid.*

Petitioners and Charles Warner filed a petition for certiorari and an application to stay their executions. The Court denied the stay application, and Charles Warner was executed on January 15, 2015. See *Warner v. Gross,* 574 U.S. ——, 135 S.Ct. 824, 190 L.Ed.2d 903 (2015) (SOTOMAYOR, J., dissenting from denial of certiorari). The Court subsequently granted certiorari and, at the request of the State, stayed petitioners' pending executions.

II

I begin with the second of the Court's two holdings: that the District Court properly found that petitioners did not demonstrate a likelihood of showing that Oklahoma's execution protocol poses an unconstitutional risk of pain. In reaching this conclusion, the Court sweeps aside substantial evidence showing that, while midazolam may be able to *induce* unconsciousness, it cannot be utilized to *maintain* unconsciousness in the face of agonizing stimuli. Instead, like the District ***2786** Court, the Court finds comfort in Dr. Evans' wholly unsupported claims that 500 milligrams of midazolam will "paralyz[e] the brain." In so holding, the Court disregards an objectively intolerable risk of severe pain.

A

Like the Court, I would review for clear error the District Court's finding that 500 milligrams of midazolam will render someone sufficiently unconscious " 'to resist the noxious stimuli which could occur from the application of the second and third drugs.' " *Ante,* at 2740 (quoting App. 77). Unlike the Court, however, I would do so without abdicating our duty to examine critically the factual predicates for the District Court's finding—namely, Dr. Evans' testimony that midazolam has a "ceiling effect" only "at the spinal cord level," and that a "500 milligram dose of midazolam" can therefore "effectively paralyze the brain." *Id.,* at 78. To be sure, as the Court observes, such scientific testimony may at times lie at the boundaries of federal courts' expertise. See *ante,* at 2739 – 2740. But just because a purported expert says something does not make it so. Especially when important constitutional rights are at stake, federal district courts must carefully evaluate the premises and evidence on which scientific conclusions are based, and appellate courts must ensure that the courts below have in fact carefully considered all the evidence presented. Clear error exists "when although there is evidence to support" a finding, "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.,* 333 U.S. 364, 395, 68 S.Ct. 525, 92 L.Ed. 746 (1948). Here, given the numerous flaws in Dr. Evans' testimony, there can be little doubt that the District Court clearly erred in relying on it.

To begin, Dr. Evans identified no scientific literature to support his opinion regarding midazolam's properties at higher-than-normal doses. Apart from a Material Safety Data Sheet that was relevant only insofar as it suggests that a low dose of midazolam may occasionally be toxic,

see *ante,* at 2745—an issue I discuss further below—Dr. Evans' testimony seems to have been based on the Web site www.drugs.com. The Court may be right that "petitioners do not identify any incorrect statements from drugs.com on which Dr. Evans relied." *Ante,* at 2745. But that is because there were *no* statements from drugs.com that supported the critically disputed aspects of Dr. Evans' opinion. If anything, the Web site supported petitioners' contentions, as it expressly cautioned that midazolam "[s]hould not be used alone for maintenance of anesthesia," App. H to Pet. for Cert. 6159, and contained no warning that an excessive dose of midazolam could "paralyze the brain," see *id.,* at 6528–6529.

Most importantly, nothing from drugs.com—or, for that matter, any other source in the record—corroborated Dr. Evans' key testimony that midazolam's ceiling effect is limited to the spinal cord and does not pertain to the brain. Indeed, the State appears to have disavowed Dr. Evans' spinal-cord theory, refraining from even mentioning it in its brief despite the fact that the District Court expressly relied on this testimony as the basis for finding that larger doses of midazolam will have greater anesthetic effects. App. 78. The Court likewise assiduously avoids defending this theory.

That is likely because this aspect of Dr. Evans' testimony was not just unsupported, but was directly refuted by the studies and articles cited by Drs. Lubarsky and Sasich. Both of these experts relied on ***2787** academic texts describing benzodiazepines' ceiling effect and explaining why it prevents these drugs from rendering a person completely insensate. See Stoelting & Hillier 141, 144 (describing midazolam's ceiling effect and contrasting the drug with barbiturates); Saari 244 (observing that "abolishment of perception of environmental stimuli cannot usually be generated"). One study further made clear that the ceiling effect is apparent in the brain. See *id.,* at 250.

These scientific sources also appear to demonstrate that Dr. Evans' spinal-cord theory—*i.e.,* that midazolam's ceiling effect is limited to the spinal cord—was premised on a basic misunderstanding of midazolam's mechanism of action. I say "appear" not because the sources themselves are unclear about how midazolam operates: They plainly state that midazolam functions by promoting GABA's inhibitory effects on the central nervous system. See, *e.g.,* Stoelting & Hillier 140. Instead, I use "appear" because discerning the rationale underlying Dr. Evans' testimony is difficult. His spinal-cord theory might, however, be explained at least in part by his apparent belief that rather than promoting GABA's inhibitory effects, midazolam produces sedation by "compet[ing]" with GABA and thus "inhibit[ing]" GABA's effect. App. 312–313.[2] Regardless, I need not delve too deeply into Dr. Evans' alternative scientific reality. It suffices to say that to the extent that Dr. Evans' testimony was based on his understanding of the source of midazolam's pharmacological properties, that understanding was wrong.

These inconsistencies and inaccuracies go to the very heart of Dr. Evans' expert opinion, as they were the key components of his professed belief that one can extrapolate from what is known about midazolam's effect at low doses to conclude that the drug would "paralyz[e] the brain" at Oklahoma's planned dose. *Id.,* at 314. All three experts recognized that there had been no scientific testing on the use of this amount of midazolam in conjunction with these particular lethal injection drugs. See *ante,* at 2740 – 2741; App. 176 (Lubarsky), 243–244 (Sasich), 327 (Evans). For this reason, as the Court correctly observes, "extrapolation was reasonable." *Ante,* at 2741. But simply because extrapolation may be reasonable or even required does not mean that every conceivable method of extrapolation can be credited, or that all estimates stemming from purported extrapolation are worthy of belief. Dr. Evans' view was that because 40 milligrams of midazolam could be used to induce unconsciousness, App. 294, and because more drug will generally produce more effect, a significantly larger dose of 500 milligrams would not just induce unconsciousness but allow for its maintenance in the face of extremely painful stimuli, and ultimately ***2788** even cause death itself. In his words: "[A]s you increase the dose of midazolam, it's a linear effect, so you're going to continue to get an impact from higher doses of the drug." *Id.,* at 332. If, however, there is a ceiling with respect to midazolam's effect on the brain—as petitioners' experts established there is—then such simplistic logic is not viable. In this context, more is not necessarily better, and Dr. Evans was plainly wrong to presume it would be.

If Dr. Evans had any other basis for the "extrapolation" that led him to conclude 500 milligrams of midazolam would "paralyz[e] the brain," *id.,* at 314, it was even further divorced from scientific evidence and logic.

Having emphasized that midazolam had been known to cause approximately 80 deaths, Dr. Evans asserted that his opinion regarding the efficacy of Oklahoma's planned use of the drug represented "essentially an extrapolation from a *toxic* effect." *Id.,* at 327 (emphasis added); see *id.,* at 308. Thus, Dr. Evans appeared to believe—and again, I say "appeared" because his rationale is not clear—that because midazolam caused *some* deaths, it would necessarily cause complete unconsciousness and then death at especially high doses. But Dr. Evans also thought, and Dr. Lubarsky confirmed, that these midazolam fatalities had occurred at very low doses—well below what any expert said would produce unconsciousness. See *id.,* at 207, 308. These deaths thus seem to represent the rare, unfortunate side effects that one would expect to see with any drug at normal therapeutic doses; they provide no indication of the effect one would expect midazolam to have on the brain at substantially higher doses. Deaths occur with almost any product. One might as well say that because some people occasionally die from eating one peanut, one hundred peanuts would necessarily induce a coma and death in anyone. [3]

In sum, then, Dr. Evans' conclusions were entirely unsupported by any study or third-party source, contradicted by the extrinsic evidence proffered by petitioners, inconsistent with the scientific understanding of midazolam's properties, and apparently premised on basic logical errors. Given these glaring flaws, the District Court's acceptance of Dr. Evans' claim that 500 milligrams of midazolam would "paralyz[e] the brain" cannot be credited. This is not a case "[w]here there are two permissible views of the evidence," and the District Court chose one; rather, it is one where the trial judge credited "one of two or more witnesses" even though that witness failed to tell "a coherent and facially plausible story that is not contradicted by extrinsic evidence." *Anderson v. Bessemer City,* 470 U.S. 564, 574–575, 105 S.Ct. 1504, 84 L.Ed.2d 518 (1985). In other words, this is a case in which the District Court clearly erred. See *ibid.*

B

Setting aside the District Court's erroneous factual finding that 500 milligrams of midazolam will necessarily "paralyze the brain," the question is whether the Court is nevertheless correct to hold that petitioners ***2789** failed to demonstrate that the use of midazolam poses an "objectively intolerable risk" of severe pain. See *Baze,* 553 U.S., at 50, 128 S.Ct. 1520 (plurality opinion) (internal quotation marks omitted). I would hold that they made this showing. That is because, in stark contrast to Dr. Evans, petitioners' experts were able to point to objective evidence indicating that midazolam cannot serve as an effective anesthetic that "render[s] a person insensate to pain caused by the second and third [lethal injection] drugs." *Ante,* at 2743.

As observed above, these experts cited multiple sources supporting the existence of midazolam's ceiling effect. That evidence alone provides ample reason to doubt midazolam's efficacy. Again, to prevail on their claim, petitioners need only establish an intolerable *risk* of pain, not a certainty. See *Baze,* 553 U.S., at 50, 128 S.Ct. 1520. Here, the State is attempting to use midazolam to produce an effect the drug has never previously been demonstrated to produce, and despite studies indicating that at some point increasing the dose will not actually increase the drug's effect. The State is thus proceeding in the face of a very real risk that the drug will not work in the manner it claims.

Moreover, and perhaps more importantly, the record provides good reason to think this risk is substantial. The Court insists that petitioners failed to provide "probative evidence" as to whether "midazolam's ceiling effect occurs below the level of a 500–milligram dose and at a point at which the drug does not have the effect of rendering a person insensate to pain." *Ante,* at 2743. It emphasizes that Dr. Lubarsky was unable to say "at what dose the ceiling effect occurs," and could only estimate that it was " '[p]robably after about ... 40 to 50 milligrams.' " *Ante,* at 2743 (quoting App. 225).

But the precise *dose* at which midazolam reaches its ceiling effect is irrelevant if there is no dose at which the drug can, in the Court's words, render a person "insensate to pain." *Ante,* at 2743. On this critical point, Dr. Lubarsky was quite clear. [4] He explained that the drug "does not work to produce" a "lack of consciousness as noxious stimuli are applied," and is "not sufficient to produce a surgical plane of anesthesia in human beings." App. 204. He also noted that "[t]he drug would never be used and has never been used as a sole anesthetic to give anesthesia during a surgery," *id.,* at 223, and asserted that "the drug was not approved by the FDA as a sole anesthetic because after the use of fairly large doses that

were sufficient to reach the ceiling effect and produce induction of unconsciousness, the patients responded to the surgery," *id.,* at 219. Thus, Dr. Lubarsky may not have been able to ***2790** identify whether this effect would be reached at 40, 50, or 60 milligrams or some higher threshold, but he could specify that at no level would midazolam reliably keep an inmate unconscious once the second and third drugs were delivered. [5]

These assertions were amply supported by the evidence of the manner in which midazolam is and can be used. All three experts agreed that midazolam is utilized as the sole sedative only in minor procedures. Dr. Evans, for example, acknowledged that while midazolam may be used as the sole drug in some procedures that are not "terribly invasive," even then "you would [generally] see it used in combination with a narcotic." *Id.,* at 307. And though, as the Court observes, Dr. Sasich believed midazolam could be "used for medical procedures like colonoscopies and gastroscopies," *ante,* at 2742, he insisted that these procedures were not necessarily painful, and that it would be a "big jump" to conclude that midazolam would be effective to maintain unconsciousness throughout an execution. Tr. 369–370. Indeed, the record provides no reason to think that these procedures cause excruciating pain remotely comparable to that produced by the second and third lethal injection drugs Oklahoma intends to use.

As for more painful procedures, the consensus was also clear: Midazolam is not FDA-approved for, and is not used as, a sole drug to maintain unconsciousness. See App. 171 (Lubarsky), 262 (Sasich), 327 (Evans). One might infer from the fact that midazolam *is not* used as the sole anesthetic for more serious procedures that it *cannot* be used for them. But drawing such an inference is unnecessary, as petitioners' experts invoked sources expressly stating as much. In particular, Dr. Lubarsky pointed to a survey article that cited four separate authorities and declared that "[m]idazolam cannot be used alone ... to maintain adequate anesthesia." Reves 318; see also Stoelting & Hillier 145 (explaining that midazolam is used for "induction of anesthesia," and that, "*[i]n combination with other drugs,* [it] may be used for maintenance of anesthesia" (emphasis added)).

This evidence was alone sufficient, but if one wanted further support for these conclusions it was provided by the Lockett and Wood executions. The procedural flaws that marred the Lockett execution created the conditions for an unintended (and grotesque) experiment on midazolam's efficacy. Due to problems with the IV line, Lockett was not fully paralyzed after the second and third drugs were administered. He had, however, been administered more than enough midazolam to "render an average person unconscious," as the District Court found. App. 57. When Lockett awoke and began to writhe and speak, he demonstrated the critical difference between midazolam's ability to render an inmate unconscious and its ability to maintain the inmate in that state. The Court insists that Lockett's execution involved "only 100 milligrams of midazolam," *ante,* at 2746, but as ***2791** explained previously, more is not necessarily better given midazolam's ceiling effect.

The Wood execution is perhaps even more probative. Despite being given over 750 milligrams of midazolam, Wood gasped and snorted for nearly two hours. These reactions were, according to Dr. Lubarsky, inconsistent with Wood being fully anesthetized, App. 177–178, and belie the claim that a lesser dose of 500 milligrams would somehow suffice. The Court attempts to distinguish the Wood execution on the ground that the timing of Arizona's administration of midazolam was different. *Ante,* at 2745 – 2746. But as Dr. Lubarsky testified, it did not "matter" whether in Wood's execution the "midazolam was introduced all at once or over ... multiple doses," because "[t]he drug has a sufficient half life that the effect is cumulative." App. 220; see also Saari 253 (midazolam's "elimination half-life ranges from 1.7 to 3.5 h [ours]"). [6] Nor does the fact that Wood's dose of midazolam was paired with hydromorphone rather than a paralytic and potassium chromide, see *ante,* at 2746, appear to have any relevance—other than that the use of this analgesic drug may have meant that Wood did not experience the same degree of searing pain that an inmate executed under Oklahoma's protocol may face.

By contrast, Florida's use of this same three-drug protocol in 11 executions, see *ante,* at 2745 – 2746 (citing Brief for State of Florida as *Amicus Curiae* 1), tells us virtually nothing. Although these executions have featured no obvious mishaps, the key word is "obvious." Because the protocol involves the administration of a powerful paralytic, it is, as Drs. Sasich and Lubarsky explained, impossible to tell whether the condemned inmate in fact remained unconscious. App. 218, 273; see also *Baze,* 553 U.S., at 71, 128 S.Ct. 1520 (Stevens, J., concurring in

judgment). Even in these executions, moreover, there have been indications of the inmates' possible awareness. See Brief for State of Alabama et al. as *Amici Curiae* 9–13 (describing the 11 Florida executions, and noting that some allegedly involved blinking and other movement after administration of the three drugs). [7]

Finally, none of the State's "safeguards" for administering these drugs would seem to mitigate the substantial risk that midazolam will not work, as the Court contends. See *ante,* at 2742 – 2743. Protections ensuring that officials have properly secured a viable IV site will not enable midazolam to have an effect that it is chemically incapable of having. Nor is there any indication that the State's monitoring of the inmate's consciousness will be able to anticipate whether the inmate will *remain* unconscious while the second and third drugs are administered. No one questions whether midazolam can induce unconsciousness. The problem, as Lockett's execution vividly illustrates, is that an unconscious inmate may be awakened by the pain and respiratory distress caused by administration of the second and third ***2792** drugs. At that point, even if it were possible to determine whether the inmate is conscious—dubious, given the use of a paralytic—it is already too late. Presumably for these reasons, the Tenth Circuit characterized the District Court's reliance on these procedural mechanisms as "not relevant to its rejection of [petitioners'] claims regarding the inherent characteristics of midazolam." *Warner,* 776 F.3d, at 733.

C

The Court not only disregards this record evidence of midazolam's inadequacy, but also fails to fully appreciate the procedural posture in which this case arises. Petitioners have not been accorded a full hearing on the merits of their claim. They were granted only an abbreviated evidentiary proceeding that began less than three months after the State issued its amended execution protocol; they did not even have the opportunity to present rebuttal evidence after Dr. Evans testified. They sought a preliminary injunction, and thus were not required to prove their claim, but only to show that they were likely to succeed on the merits. See *Winter v. Natural Resources Defense Council, Inc.,* 555 U.S. 7, 20, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008); *Hill v. McDonough,* 547 U.S. 573, 584, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006).

Perhaps the State could prevail after a full hearing, though this would require more than Dr. Evans' unsupported testimony. At the preliminary injunction stage, however, petitioners presented compelling evidence suggesting that midazolam will not work as the State intends. The State, by contrast, offered absolutely no contrary evidence worth crediting. Petitioners are thus at the very least *likely* to prove that, due to midazolam's inherent deficiencies, there is a constitutionally intolerable risk that they will be awake, yet unable to move, while chemicals known to cause "excruciating pain" course through their veins. *Baze,* 553 U.S., at 71, 128 S.Ct. 1520 (Stevens, J., concurring in judgment).

III

The Court's determination that the use of midazolam poses no objectively intolerable risk of severe pain is factually wrong. The Court's conclusion that petitioners' challenge also fails because they identified no available alternative means by which the State may kill them is legally indefensible.

A

This Court has long recognized that certain methods of execution are categorically off-limits. The Court first confronted an Eighth Amendment challenge to a method of execution in *Wilkerson v. Utah,* 99 U.S. 130, 25 L.Ed. 345 (1879). Although *Wilkerson* approved the particular method at issue—the firing squad—it made clear that "public dissection," "burning alive," and other "punishments of torture ... in the same line of unnecessary cruelty, are forbidden by [the Eighth A]mendment to the Constitution." *Id.,* at 135–136. Eleven years later, in rejecting a challenge to the first proposed use of the electric chair, the Court again reiterated that "if the punishment prescribed for an offense against the laws of the State were manifestly cruel and unusual, as burning at the stake, crucifixion, breaking on the wheel, or the like, it would be the duty of the courts to adjudge such penalties to be within the constitutional prohibition." *In re Kemmler,* 136 U.S. 436, 446, 10 S.Ct. 930, 34 L.Ed. 519 (1890).

In the more than a century since, the Members of this Court have often had cause to debate the full scope of

the Eighth Amendment's prohibition of cruel ***2793** and unusual punishment. See, *e.g., Furman v. Georgia,* 408 U.S. 238, 92 S.Ct. 2726, 33 L.Ed.2d 346 (1972). But there has been little dispute that it at the very least precludes the imposition of "barbarous physical punishments." *Rhodes v. Chapman,* 452 U.S. 337, 345, 101 S.Ct. 2392, 69 L.Ed.2d 59 (1981); see, *e.g., Solem v. Helm,* 463 U.S. 277, 284, 103 S.Ct. 3001, 77 L.Ed.2d 637 (1983); *id.,* at 312–313, 103 S.Ct. 3001 (Burger, C.J., dissenting); *Baze,* 553 U.S., at 97–99, 128 S.Ct. 1520 (THOMAS, J., concurring in judgment); *Harmelin v. Michigan,* 501 U.S. 957, 976, 111 S.Ct. 2680, 115 L.Ed.2d 836 (1991) (opinion of SCALIA, J.). Nor has there been any question that the Amendment prohibits such "inherently barbaric punishments *under all circumstances*." *Graham v. Florida,* 560 U.S. 48, 59, 130 S.Ct. 2011, 176 L.Ed.2d 825 (2010) (emphasis added). Simply stated, the "Eighth Amendment *categorically* prohibits the infliction of cruel and unusual punishments." *Penry v. Lynaugh,* 492 U.S. 302, 330, 109 S.Ct. 2934, 106 L.Ed.2d 256 (1989) (emphasis added).

B

The Court today, however, would convert this categorical prohibition into a conditional one. A method of execution that is intolerably painful—even to the point of being the chemical equivalent of burning alive—will, the Court holds, be unconstitutional *if,* and only if, there is a "known and available alternative" method of execution. *Ante,* at 2762 – 2763. It deems *Baze* to foreclose any argument to the contrary. *Ante,* at 2762.

Baze held no such thing. In the first place, the Court cites only the plurality opinion in *Baze* as support for its known-and-available-alternative requirement. See *ibid.* Even assuming that the *Baze* plurality set forth such a requirement—which it did not—none of the Members of the Court whose concurrences were necessary to sustain the *Baze* Court's judgment articulated a similar view. See 553 U.S., at 71–77, 87, 128 S.Ct. 1520 (Stevens, J., concurring in judgment); *id.,* at 94, 99–107, 128 S.Ct. 1520 (THOMAS, J., concurring in judgment); *id.,* at 107–108, 113, 128 S.Ct. 1520 (BREYER, J., concurring in judgment). In general, "the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds." *Marks v. United States,* 430 U.S. 188, 193, 97 S.Ct. 990, 51 L.Ed.2d 260 (1977) (internal quotation marks omitted). And as the Court observes, *ante,* at 2738, n. 2, the opinion of Justice THOMAS, joined by Justice SCALIA, took the broadest position with respect to the degree of intent that state officials must have in order to have violated the Eighth Amendment, concluding that only a method of execution deliberately designed to inflict pain, and not one simply designed with deliberate indifference to the risk of severe pain, would be unconstitutional. 553 U.S., at 94, 128 S.Ct. 1520 (THOMAS, J., concurring in judgment). But this understanding of the Eighth Amendment's intent requirement is unrelated to, and thus not any broader or narrower than, the requirement the Court now divines from *Baze*. Because the position that a plaintiff challenging a method of execution under the Eighth Amendment must prove the availability of an alternative means of execution did not "represent the views of a majority of the Court," it was not the holding of the *Baze* Court. *CTS Corp. v. Dynamics Corp. of America,* 481 U.S. 69, 81, 107 S.Ct. 1637, 95 L.Ed.2d 67 (1987).

In any event, even the *Baze* plurality opinion provides no support for the Court's proposition. To be sure, that opinion contains the following sentence: "[The condemned] must show that the risk is substantial ***2794** when compared to the known and available alternatives." 553 U.S., at 61, 128 S.Ct. 1520. But the meaning of that key sentence and the limits of the requirement it imposed are made clear by the sentence directly preceding it: "A stay of execution may not be granted *on grounds such as those asserted here* unless the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain." *Ibid.* (emphasis added). In *Baze,* the very premise of the petitioners' Eighth Amendment claim was that they had "identified a significant risk of harm [in Kentucky's protocol] that [could] be eliminated by adopting alternative procedures." *Id.,* at 51, 128 S.Ct. 1520. Their basic theory was that even if the risk of pain was only, say, 25%, that risk would be objectively intolerable if there was an obvious alternative that would reduce the risk to 5%. See Brief for Petitioners in *Baze v. Rees,* O.T. 2007, No. 07–5439, p. 29 ("In view of the severity of the pain risked and the ease with which it could be avoided, Petitioners should not have been required to show a high likelihood that they would suffer such pain ..."). Thus, the "grounds ... asserted" for relief in *Baze* were that the State's protocol was intolerably risky given the alternative procedures the State could have employed.

Addressing this claim, the *Baze* plurality clarified that "a condemned prisoner cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative," 553 U.S., at 51, 128 S.Ct. 1520; instead, to succeed in a challenge of this type, the comparative risk must be "substantial," *id.,* at 61, 128 S.Ct. 1520. Nowhere did the plurality suggest that *all* challenges to a State's method of execution would require this sort of comparative-risk analysis. Recognizing the relevance of available alternatives is not at all the same as concluding that their absence precludes a claimant from showing that a chosen method carries objectively intolerable risks. If, for example, prison officials chose a method of execution that has a 99% chance of causing lingering and excruciating pain, certainly that risk would be objectively intolerable whether or not the officials ignored other methods in making this choice. Irrespective of the existence of alternatives, there are some risks "so grave that it violates contemporary standards of decency to expose *anyone* unwillingly to" them. *Helling v. McKinney,* 509 U.S. 25, 36, 113 S.Ct. 2475, 125 L.Ed.2d 22 (1993) (emphasis in original).

That the *Baze* plurality's statement regarding a condemned inmate's ability to point to an available alternative means of execution pertained only to challenges premised on the existence of such alternatives is further evidenced by the opinion's failure to distinguish or even mention the Court's unanimous decision in *Hill v. McDonough,* 547 U.S. 573, 126 S.Ct. 2096, 165 L.Ed.2d 44. *Hill* held that a § 1983 plaintiff challenging a State's method of execution need not "identif[y] an alternative, authorized method of execution." *Id.,* at 582, 126 S.Ct. 2096. True, as the Court notes, *ante,* at 2738 – 2739, *Hill* did so in the context of addressing § 1983's pleading standard, rejecting the proposed alternative-means requirement because the Court saw no basis for the "[i]mposition of heightened pleading requirements." 547 U.S., at 582, 126 S.Ct. 2096. But that only confirms that the Court in *Hill* did not view the availability of an alternative means of execution as an element of an Eighth Amendment claim: If it had, then requiring the plaintiff to plead this element would not have meant imposing a heightened standard at all, but rather would have been entirely consistent with "traditional pleading requirements." ***2795** *Ibid.*; see *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). The *Baze* plurality opinion should not be understood to have so carelessly tossed aside *Hill* 's underlying premise less than two years later.

C

In reengineering *Baze* to support its newfound rule, the Court appears to rely on a flawed syllogism. If the death penalty is constitutional, the Court reasons, then there must be a means of accomplishing it, and thus some available method of execution must be constitutional. See *ante,* at 2732 – 2733, 2738 – 2739. But even accepting that the death penalty is, in the abstract, consistent with evolving standards of decency, but see *ante,* p. 2760 – 2761 (BREYER, J., dissenting), the Court's conclusion does not follow. The constitutionality of the death penalty may inform our conception of the degree of pain that would render a particular method of imposing it unconstitutional. See *Baze,* 553 U.S., at 47, 128 S.Ct. 1520 (plurality opinion) (because "[s]ome risk of pain is inherent in any method of execution," "[i]t is clear ... the Constitution does not demand the avoidance of all risk of pain"). But a method of execution that is "barbarous," *Rhodes,* 452 U.S., at 345, 101 S.Ct. 2392, or "involve[s] torture or a lingering death," *Kemmler,* 136 U.S., at 447, 10 S.Ct. 930, does not become less so just because it is the only method currently available to a State. If all available means of conducting an execution constitute cruel and unusual punishment, then conducting the execution will constitute cruel and usual punishment. Nothing compels a State to perform an execution. It does not get a constitutional free pass simply because it desires to deliver the ultimate penalty; its ends do not justify any and all means. If a State wishes to carry out an execution, it must do so subject to the constraints that our Constitution imposes on it, including the obligation to ensure that its chosen method is not cruel and unusual. Certainly the condemned has no duty to devise or pick a constitutional instrument of his or her own death.

For these reasons, the Court's available-alternative requirement leads to patently absurd consequences. Petitioners contend that Oklahoma's current protocol is a barbarous method of punishment—the chemical equivalent of being burned alive. But under the Court's new rule, it would not matter whether the State intended to use midazolam, or instead to have petitioners drawn and quartered, slowly tortured to death, or actually burned at the stake: because petitioners failed to prove

the availability of sodium thiopental or pentobarbital, the State could execute them using whatever means it designated. But see *Baze,* 553 U.S., at 101–102, 128 S.Ct. 1520 (THOMAS, J., concurring in judgment) ("It strains credulity to suggest that the defining characteristic of burning at the stake, disemboweling, drawing and quartering, beheading, and the like was that they involved risks of pain that could be eliminated by using alternative methods of execution"). [8] The Eighth Amendment cannot possibly countenance such a result.

D

In concocting this additional requirement, the Court is motivated by a desire to preserve States' ability to conduct executions ***2796** in the face of changing circumstances. See *ante,* at 2732 – 2734, 2745 – 2746. It is true, as the Court details, that States have faced "practical obstacle[s]" to obtaining lethal injection drugs since *Baze* was decided. *Ante,* at 2732 – 2733. One study concluded that recent years have seen States change their protocols "with a frequency that is unprecedented among execution methods in this country's history." Denno, Lethal Injection Chaos Post–*Baze,* 102 Geo. L. J. 1331, 1335 (2014).

But why such developments compel the Court's imposition of further burdens on those facing execution is a mystery. Petitioners here had no part in creating the shortage of execution drugs; it is odd to punish them for the actions of pharmaceutical companies and others who seek to disassociate themselves from the death penalty—actions which are, of course, wholly lawful. Nor, certainly, should these rapidly changing circumstances give us any greater confidence that the execution methods ultimately selected will be sufficiently humane to satisfy the Eighth Amendment. Quite the contrary. The execution protocols States hurriedly devise as they scramble to locate new and untested drugs, see *supra,* at 2781 – 2782, are all the more likely to be cruel and unusual—presumably, these drugs would have been the States' first choice were they in fact more effective. But see Denno, The Lethal Injection Quandry: How Medicine Has Dismantled the Death Penalty, 76 Ford. L. Rev. 49, 65–79 (2007) (describing the hurried and unreasoned process by which States first adopted the original three-drug protocol). Courts' review of execution methods should be more, not less, searching when States are engaged in what is in effect human experimentation.

It is also worth noting that some condemned inmates may read the Court's surreal requirement that they identify the means of their death as an invitation to propose methods of executions less consistent with modern sensibilities. Petitioners here failed to meet the Court's new test because of their assumption that the alternative drugs to which they pointed, pentobarbital and sodium thiopental, were available to the State. See *ante,* at 2737 – 2738. This was perhaps a reasonable assumption, especially given that neighboring Texas and Missouri still to this day continue to use pentobarbital in executions. See The Death Penalty Institute, Execution List 2015, online at www.deathpenaltyinfo.org/execution–list–2015 (as visited June 26, 2015, and available in the Clerk of the Court's case file).

In the future, however, condemned inmates might well decline to accept States' current reliance on lethal injection. In particular, some inmates may suggest the firing squad as an alternative. Since the 1920's, only Utah has utilized this method of execution. See S. Banner, The Death Penalty 203 (2002); Johnson, Double Murderer Executed by Firing Squad in Utah, N.Y. Times, June 19, 2010, p. A12. But there is evidence to suggest that the firing squad is significantly more reliable than other methods, including lethal injection using the various combinations of drugs thus far developed. See A. Sarat, Gruesome Spectacles: Botched Executions and America's Death Penalty, App. A, p. 177 (2014) (calculating that while 7.12% of the 1,054 executions by lethal injection between 1900 and 2010 were "botched," none of the 34 executions by firing squad had been). Just as important, there is some reason to think that it is relatively quick and painless. See Banner, *supra,* at 203.

Certainly, use of the firing squad could be seen as a devolution to a more primitive era. See *Wood v. Ryan,* 759 F.3d 1076, 1103 (C.A.9 2014) (Kozinski, C.J., dissenting from denial of rehearing en banc). ***2797** That is not to say, of course, that it would therefore be unconstitutional. But lethal injection represents just the latest iteration of the States' centuries-long search for "neat and non-disfiguring homicidal methods." C. Brandon, The Electric Chair: An Unnatural American History 39 (1999) (quoting Editorial, New York Herald, Aug. 10, 1884); see generally Banner, *supra,* at 169–

207. A return to the firing squad—and the blood and physical violence that comes with it—is a step in the opposite direction. And some might argue that the visible brutality of such a death could conceivably give rise to its own Eighth Amendment concerns. See *Campbell v. Wood,* 511 U.S. 1119, 1121–1123, 114 S.Ct. 2125, 128 L.Ed.2d 682 (1994) (Blackmun, J., dissenting from denial of stay of execution and certiorari); *Glass v. Louisiana,* 471 U.S. 1080, 1085, 105 S.Ct. 2159, 85 L.Ed.2d 514 (1985) (Brennan, J., dissenting from denial of certiorari). At least from a condemned inmate's perspective, however, such visible yet relatively painless violence may be vastly preferable to an excruciatingly painful death hidden behind a veneer of medication. The States may well be reluctant to pull back the curtain for fear of how the rest of us might react to what we see. But we deserve to know the price of our collective comfort before we blindly allow a State to make condemned inmates pay it in our names.

* * *

"By protecting even those convicted of heinous crimes, the Eighth Amendment reaffirms the duty of the government to respect the dignity of all persons." *Roper v. Simmons,* 543 U.S. 551, 560, 125 S.Ct. 1183, 161 L.Ed.2d 1 (2005). Today, however, the Court absolves the State of Oklahoma of this duty. It does so by misconstruing and ignoring the record evidence regarding the constitutional insufficiency of midazolam as a sedative in a three-drug lethal injection cocktail, and by imposing a wholly unprecedented obligation on the condemned inmate to identify an available means for his or her own execution. The contortions necessary to save this particular lethal injection protocol are not worth the price. I dissent.

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Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.,* 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

1 The three other drug combinations that Oklahoma may administer are: (1) a single dose of pentobarbital, (2) a single dose of sodium thiopental, and (3) a dose of midazolam followed by a dose of hydromorphone.

2 Justice SOTOMAYOR's dissent (hereinafter principal dissent), *post,* at 2793 – 2794, inexplicably refuses to recognize that THE CHIEF JUSTICE's opinion in *Baze* sets out the holding of the case. In *Baze,* the opinion of THE CHIEF JUSTICE was joined by two other Justices. Justices SCALIA and THOMAS took the broader position that a method of execution is consistent with the Eighth Amendment unless it is deliberately designed to inflict pain. 553 U.S., at 94, 128 S.Ct. 1520 (THOMAS, J. concurring in judgment). Thus, as explained in *Marks v. United States,* 430 U.S. 188, 193, 97 S.Ct. 990, 51 L.Ed.2d 260 (1977), THE CHIEF JUSTICE's opinion sets out the holding of the case. It is for this reason that petitioners base their argument on the rule set out in that opinion. See Brief for Petitioners 25, 28.

3 Drs. Lubarsky and Sasich, petitioners' key witnesses, both testified that midazolam is inappropriate for a third reason, namely, that it creates a risk of "paradoxical reactions" such as agitation, hyperactivity, and combativeness. App. 175 (expert report of Dr. Lubarsky); *id.,* at 242, 244 (expert report of Dr. Sasich). The District Court found, however, that the frequency with which a paradoxical reaction occurs "is speculative" and that the risk "occurs with the highest frequency in low therapeutic doses." *Id.,* at 78. Indeed, Dr. Sasich conceded that the incidence or risk of paradoxical reactions with midazolam "is unknown" and that reports estimate the risk to vary only "from 1% to above 10%." *Id.,* at 244. Moreover, the mere fact that a method of execution might result in some unintended side effects does not amount to an Eighth Amendment violation. "[T]he Constitution does not demand the avoidance of all risk of pain." *Baze,* 553 U.S., at 47, 128 S.Ct. 1520 (plurality opinion).

4 The principal dissent misunderstands the record when it bizarrely suggests that midazolam is about as dangerous as a peanut. *Post,* at 2788. Dr. Evans and Dr. Lubarsky agreed that midazolam has caused fatalities in doses as low as 0.04 to 0.07 milligrams per kilogram. App. 217, 294. Even if death from such low doses is a "rare, unfortunate side effec[t]," *post,* at 2788, the District Court found that a massive 500–milligram dose—many times higher than the lowest dose reported to have produced death—will likely cause death in under an hour. App. 76–77.

5 Petitioners' experts also declined to testify that a 500–milligram dose of midazolam is always insufficient to place a person in a coma and render him insensate to pain. Dr. Lubarsky argued only that the 500–milligram dose cannot "reliably"

produce a coma. *Id.,* 228. And when Dr. Sasich was asked whether he could say to a reasonable degree of certainty that a 500–milligram dose of midazolam would not render someone unconscious, he replied that he could not. *Id.,* at 271–272. A product label for midazolam that Dr. Sasich attached to his expert report also acknowledged that an overdose of midazolam can cause a coma. See Expert Report of Larry D. Sasich, in No. 14–6244 (CA10), p. 34.

6 The principal dissent emphasizes Dr. Lubarsky's supposedly contrary testimony, but the District Court was entitled to credit Dr. Evans (and Dr. Sasich) instead of Dr. Lubarsky on this point. And the District Court had strong reasons not to credit Dr. Lubarsky, who even argued that a protocol that includes *sodium thiopental* is "constructed to produce egregious harm and suffering." App. 227.

7 GABA is "an amino acid that functions as an inhibitory neurotransmitter in the brain and spinal cord." Mosby's Medical Dictionary 782 (7th ed. 2006).

8 The principal dissent emphasizes Dr. Lubarsky's testimony that it is irrelevant that Wood was administered the drug over a 2–hour period. *Post,* at 2790 – 2791. But Dr. Evans disagreed and testified that if a 750–milligram dose "was spread out over a long period of time," such as one hour (*i.e.,* half the time at issue in the Wood execution), the drug might not be as effective as if it were administered all at once. Tr. 667. The principal dissent states that this "pronouncement was entirely unsupported," *post,* at 2791, n. 6, but it was supported by Dr. Evans' expertise and decades of experience. And it would be unusual for an expert testifying on the stand to punctuate each sentence with citation to a medical journal.

After the Wood execution, Arizona commissioned an independent assessment of its execution protocol and the Wood execution. According to that report, the IV team leader, medical examiner, and an independent physician all agreed that the dosage of midazolam "would result in heavy sedation." Ariz. Dept. of Corrections, Assessment and Review of the Ariz. Dept. of Corrections Execution Protocols 46, 48 (Dec. 15, 2014), online at https:// corrections.az.gov/sites/default/files/documents/PDFs/arizona_final_report_ 12_15_14_w_cover.pdf. And far from blaming midazolam for the Wood execution, the report recommended that Arizona replace its two-drug protocol with Oklahoma's three-drug protocol that includes a 500–milligram dose of midazolam as the first drug. *Id.,* at 49.

1 Generally: *Baze v. Rees,* 553 U.S. 35, 94–97, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (THOMAS, J., concurring in judgment) (explaining that the Cruel and Unusual Punishments Clause does not prohibit the death penalty, but only torturous punishments); *Graham v. Collins,* 506 U.S. 461, 488, 113 S.Ct. 892, 122 L.Ed.2d 260 (1993) (THOMAS, J., concurring); *Gardner v. Florida,* 430 U.S. 349, 371, 97 S.Ct. 1197, 51 L.Ed.2d 393 (1977) (Rehnquist, J., dissenting) ("The prohibition of the Eighth Amendment relates to the character of the punishment, and not to the process by which it is imposed"). On reliability: *Kansas v. Marsh,* 548 U.S. 163, 181, 126 S.Ct. 2516, 165 L.Ed.2d 429 (2006) (noting that the death penalty remains constitutional despite imperfections in the criminal justice system); *McGautha v. California,* 402 U.S. 183, 221, 91 S.Ct. 1454, 28 L.Ed.2d 711 (1971) ("[T]he Federal Constitution, which marks the limits of our authority in these cases, does not guarantee trial procedures that are the best of all worlds, or that accord with the most enlightened ideas of students of the infant science of criminology, or even those that measure up to the individual predilections of members of this Court"). On arbitrariness: *Ring v. Arizona,* 536 U.S. 584, 610, 122 S.Ct. 2428, 153 L.Ed.2d 556 (2002) (SCALIA, J., concurring) (explaining that what compelled States to specify " 'aggravating factors' " designed to limit the death penalty to the worst of the worst was this Court's baseless jurisprudence concerning juror discretion); *McCleskey v. Kemp,* 481 U.S. 279, 308–312, 107 S.Ct. 1756, 95 L.Ed.2d 262 (1987) (noting that various procedures, including the right to a jury trial, constitute a defendant's protection against arbitrariness in the application of the death penalty). On excessive delays: *Knight v. Florida,* 528 U.S. 990, 120 S.Ct. 459, 145 L.Ed.2d 370 (1999) (THOMAS, J., concurring in denial of certiorari) ("I am unaware of any support in the American constitutional tradition or in this Court's precedent for the proposition that a defendant can avail himself of the panoply of appellate and collateral procedures and then complain when his execution is delayed"); see also *Johnson v. Bredesen,* 558 U.S. 1067, 1070, 130 S.Ct. 541, 175 L.Ed.2d 552 (2009) (THOMAS, J., concurring in denial of certiorari). And on the decline in use of the death penalty: *Atkins v. Virginia,* 536 U.S. 304, 345, 122 S.Ct. 2242, 153 L.Ed.2d 335 (2002) (SCALIA, J., dissenting); *Woodson v. North Carolina,* 428 U.S. 280, 308–310, 96 S.Ct. 2978, 49 L.Ed.2d 944 (1976) (Rehnquist, J., dissenting).

2 For some, a faith in the jury seems to be correlated to that institution's likelihood of *preventing* imposition of the death penalty. See, *e.g., Ring v. Arizona,* 536 U.S. 584, 614, 122 S.Ct. 2428, 153 L.Ed.2d 556 (2002) (BREYER, J., concurring in judgment) (arguing that "the Eighth Amendment requires that a jury, not a judge, make the decision to sentence a defendant to death"); *Wainwright v. Witt,* 469 U.S. 412, 440, n. 1, 105 S.Ct. 844, 83 L.Ed.2d 841 (1985) (Brennan, J., dissenting) ("However heinous Witt's crime, the majority's vivid portrait of its gruesome details has no bearing on the issue before us. It is not for this Court to decide whether Witt deserves to die. That decision must first be made by a jury of his peers").

3 For his part, Justice BREYER explains that his experience on the Court has shown him "discrepancies for which [he] can find no rational explanations." *Post,* at 2763. Why, he asks, did one man receive death for a single-victim murder, while another received life for murdering a young mother and nearly killing her infant? *Ibid.* The outcomes in those two cases may not be morally compelled, but there was certainly a rational explanation for them: The first man, who had previously confessed to another murder, killed a disabled man who had offered him a place to stay for the night. *State v. Badgett,* 361 N.C. 234, 239–240, 644 S.E.2d 206, 209–210 (2007). The killer stabbed his victim's throat and prevented him from seeking medical attention until he bled to death. *Ibid.* The second man expressed remorse for his crimes and claimed to suffer from mental disorders. See Charbonneau, Andre Edwards Sentenced to Life in Prison for 2001 Murder, WRAL, Mar. 26, 2004, online at http://www.wral. com/news/local/story/109648 (all Internet materials as visited June 25, 2015, and available in Clerk of Court's case file); Charbonneau, Jury Finds Andre Edwards Guilty of First–Degree Murder, WRAL, Mar. 23, 2004, online at http://www.wral.com/news/local/story/109563. The other "discrepancies" similarly have "rational" explanations, even if reasonable juries could have reached different results.

4 Justice BREYER appears to acknowledge that our decision holding mandatory death penalty schemes unconstitutional, *Woodson v. North Carolina,* 428 U.S. 280, 96 S.Ct. 2978, 49 L.Ed.2d 944 (1976) (plurality opinion), may have introduced the problem of arbitrary application. *Post,* at 2762. I agree that *Woodson* eliminated one reliable legislative response to concerns about arbitrariness. *Graham v. Collins,* 506 U.S. 461, 486, 113 S.Ct. 892, 122 L.Ed.2d 260 (1993) (THOMAS, J., concurring). Because that decision was also questionable on constitutional grounds, *id.,* at 486–488, 113 S.Ct. 892, I would be willing to revisit it in a future case.

1 Hydromorphone is a powerful analgesic similar to morphine or heroin. See R. Stoelting & S. Hillier, Pharmacology & Physiology in Anesthetic Practice 87–88 (4th ed. 2006) (Stoelting & Hillier).

2 The Court disputes this characterization of Dr. Evans' testimony, insisting that Dr. Evans accurately described midazolam's properties in the written report he submitted prior to the hearing below, and suggesting that petitioners' experts would have "dispute[d] the accuracy" of this explanation were it in fact wrong. *Ante,* at 2744. But Dr. Evans' written report simply said midazolam "produces different levels of central nervous system (CNS) depression through binding to [GABA] receptors." App. 293. That much is true. Only after Drs. Sasich and Lubarsky testified did Dr. Evans further claim that midazolam produced CNS depression by binding to GABA receptors *and thereby preventing GABA itself from binding to those receptors*—which is where he went wrong. The Court's further observation that Dr. Lubarsky also used a variant on the word "inhibiting" in his testimony—in saying that GABA's " '*inhibition* of brain activity is accentuated by midazolam,' " *ante,* at 2744 (quoting App. 232)—is completely nonresponsive. "Inhibiting" is a perfectly good word; the problem here is the manner in which Dr. Evans used it in a sentence.

3 For all the reasons discussed in Part II–B, *infra,* and contrary to the Court's claim, see *ante,* at 2741 – 2742, n. 4, there are good reasons to doubt that 500 milligrams of midazolam will, in light of the ceiling effect, inevitably kill someone. The closest the record comes to providing support for this contention is the fleeting mention in the FDA-approved product label that one of the possible consequences of midazolam overdosage is coma. See *ante,* at 2742, n. 5. Moreover, even if this amount of the drug could kill some people in "under an hour," *ante,* at 2742, n. 4, that would not necessarily mean that the condemned would be insensate during the approximately 10 minutes it takes for the paralytic and potassium chloride to do their work.

4 Dr. Sasich, as the Court emphasizes, was perhaps more hesitant to reach definitive conclusions, see *ante,* at 2742, and n. 5, 2743 – 2744, but the statements highlighted by the Court largely reflect his (truthful) observations that no testing has been done at doses of 500 milligrams, and his inability to pinpoint the precise dose at which midazolam's ceiling effect might be reached. Dr. Sasich did not, as the Court suggests, claim that midazolam's ceiling effect would be reached only after a person became fully insensate to pain. *Ante,* at 2743 – 2744. What Dr. Sasich actually said was: "As the dose increases, the benzodiazepines are expected to produce sedation, amnesia, and finally lack of response to stimuli such as pain (unconsciousness)." App. 243. In context, it is clear that Dr. Sasich was simply explaining that a drug like midazolam can be used to *induce* unconsciousness—an issue that was and remains undisputed—not that it could render an inmate sufficiently unconscious to resist all noxious stimuli. Indeed, it was midazolam's possible inability to serve the latter function that led Dr. Sasich to conclude that "it is not an appropriate drug to use when administering a paralytic followed by potassium chloride." *Id.,* at 248.

5 The Court claims that the District Court could have properly disregarded Dr. Lubarsky's testimony because he asserted that a protocol with sodium thiopental would " 'produce egregious harm and suffering.' " *Ante,* at 2743, n. 6 (quoting App. 227). But Dr. Lubarsky did not testify that, like midazolam, sodium thiopental would not render an inmate fully insensate even if properly administered; rather, he simply observed that he had previously contended that *protocols* using that drug were ineffective. See App. 227. He was presumably referring to an article he coauthored that found many condemned

inmates were not being successfully delivered the dose of sodium thiopental necessary to fully anesthetize them. See *Baze,* 553 U.S., at 67, 128 S.Ct. 1520 (ALITO, J., concurring) (discussing this study).

6 The Court asserts that the State refuted these contentions, pointing to Dr. Evans' testimony that 750 milligrams of the drug "might not have the effect that was sought" if administered over an hour. Tr. 667; see *ante,* at 2745 – 2746, n. 6. But as has been the theme here, this pronouncement was entirely unsupported, and appears to be contradicted by the secondary sources cited by petitioners' experts.

7 The fact that courts in Florida have approved the use of midazolam in this fashion is arguably slightly more relevant, though it is worth noting that the majority of these decisions were handed down before the Lockett and Wood executions, and that some relied, as here, on Dr. Evans' testimony. See *ante,* at 2739 – 2740.

8 The Court protests that its holding does not extend so far, deriding this description of the logical implications of its legal rule as "simply not true" and "outlandish rhetoric." *Ante,* at 2746. But presumably when the Court imposes a "requirement o[n] all Eighth Amendment method-of-execution claims," that requirement in fact applies to "*all* " methods of execution, without exception. *Ante,* at 2731 (emphasis added).

KeyCite Yellow Flag - Negative Treatment
Declined to Extend by The Estate of Lockett by and through Lockett v. Fallin, 10th Cir.(Okla.), November 15, 2016

128 S.Ct. 1520
Supreme Court of the United States

Ralph BAZE and Thomas C. Bowling, Petitioners,
v.
John D. REES, Commissioner, Kentucky Department of Corrections, et al.

No. 07–5439.
|
Argued Jan. 7, 2008.
|
Decided April 16, 2008.

Synopsis
Background: State death row inmates brought declaratory judgment action against Commissioner of Kentucky Department of Corrections and others, alleging that state's three-drug lethal injection method of capital punishment posed unacceptable risk of significant pain and was cruel and unusual under Eighth Amendment. The Franklin Circuit Court, Roger Crittenden, J., denied relief. The Supreme Court of Kentucky, 217 S.W.3d 207, affirmed. Certiorari was granted.

Holdings: The United States Supreme Court, Chief Justice Roberts, held that:

[1] risk of improper administration of initial drug did not render three-drug protocol cruel and unusual, and

[2] state's failure to adopt proposed, allegedly more humane alternatives to three-drug protocol did not constitute cruel and unusual punishment.

Affirmed.

Justice Alito filed concurring opinion.

Justice Stevens filed opinion concurring in the judgment.

Justice Scalia filed opinion concurring in the judgment, joined by Justice Thomas.

Justice Thomas filed opinion concurring in the judgment, joined by Justice Scalia.

Justice Breyer filed opinion concurring in the judgment.

Justice Ginsburg filed dissenting opinion, joined by Justice Souter.

West Headnotes (4)

[1] Sentencing and Punishment
Death penalty as cruel or unusual punishment

Capital punishment is constitutional, i.e. does not violate Eighth Amendment's prohibition of cruel and unusual punishments. U.S.C.A. Const.Amend. 8.

110 Cases that cite this headnote

[2] Sentencing and Punishment
Mode of execution

Eighth Amendment's prohibition of cruel and unusual punishments does not demand avoidance of all risk of pain in carrying out executions. U.S.C.A. Const.Amend. 8.

256 Cases that cite this headnote

[3] Sentencing and Punishment
Mode of execution

Risk of improper administration of sodium thiopental, the initial anesthetizing drug in state's three-drug lethal injection protocol that also included pancuronium bromide and potassium chloride, did not render protocol cruel and unusual in violation of Eighth Amendment; protocol incorporated several safeguards including minimum level of professional experience for individuals who inserted intravenous (IV) catheters, requirement for practice sessions, establishment of backup IV lines and other redundancies, and warden's presence in execution chamber. (Per Chief Justice

Roberts, with two Justices concurring and four Justices concurring in the judgment.) U.S.C.A. Const.Amend. 8; KRS 431.220(1)(a).

377 Cases that cite this headnote

[4] Sentencing and Punishment
Mode of execution

State's failure to adopt proposed, allegedly more humane, alternatives to its three-drug lethal injection protocol, which comprised injections of sodium thiopental, pancuronium bromide and potassium chloride, did not constitute cruel and unusual punishment in violation of Eighth Amendment. (Per Chief Justice Roberts, with two Justices concurring and four Justices concurring in the judgment.) U.S.C.A. Const.Amend. 8; KRS 431.220(1)(a).

498 Cases that cite this headnote

West Codenotes

Recognized as Unconstitutional
Neb.Rev.St. § 29–2532McKinney's CPL § 400.27, subd. 10

****1521** *Syllabus* *

Lethal injection is used for capital punishment by the Federal Government ****1522** and 36 States, at least 30 of which (including Kentucky) use the same combination of three drugs: The first, sodium thiopental, induces unconsciousness when given in the specified amounts and thereby ensures that the prisoner does not experience any pain associated with the paralysis and cardiac arrest caused by the second and third drugs, pancuronium bromide and potassium chloride. Among other things, Kentucky's lethal injection protocol reserves to qualified personnel having at least one year's professional experience the responsibility for inserting the intravenous (IV) catheters into the prisoner, leaving it to others to mix the drugs and load them into syringes; specifies that the warden and deputy warden will remain in the execution chamber to observe the prisoner and watch for any IV problems while the execution team administers the drugs from another room; and mandates that if, as determined by the warden and deputy, the prisoner is not unconscious within 60 seconds after the sodium thiopental's delivery, a new dose will be given at a secondary injection site before the second and third drugs are administered.

Petitioners, convicted murderers sentenced to death in Kentucky state court, filed suit asserting that the Commonwealth's lethal injection protocol violates the Eighth Amendment's ban on "cruel and unusual punishments." The state trial court held extensive hearings and entered detailed factfindings and conclusions of law, ruling that there was minimal risk of various of petitioners' claims of improper administration of the protocol, and upholding it as constitutional. The Kentucky Supreme Court affirmed, holding that the protocol does not violate the Eighth Amendment because it does not create a substantial risk of wanton and unnecessary infliction of pain, torture, or lingering death.

Held: The judgment is affirmed.

217 S.W.3d 207, affirmed.

Chief Justice ROBERTS, joined by Justice KENNEDY and Justice ALITO, concluded that Kentucky's lethal injection protocol satisfies the Eighth Amendment. Pp. 1529 – 1538.

1. To constitute cruel and unusual punishment, an execution method must present a "substantial" or "objectively intolerable" risk of serious harm. A State's refusal to adopt proffered alternative procedures may violate the Eighth Amendment only where the alternative procedure is feasible, readily implemented, and in fact significantly reduces a substantial risk of severe pain. Pp. 1529 – 1532.

(a) This Court has upheld capital punishment as constitutional. See *Gregg v. Georgia,* 428 U.S. 153, 177, 96 S.Ct. 2909, 49 L.Ed.2d 859. Because some risk of pain is inherent in even the most humane execution method, if only from the prospect of error in following the required procedure, the Constitution does not demand the avoidance of all risk of pain. Petitioners contend that the Eighth Amendment prohibits procedures that create an "unnecessary risk" of pain, while Kentucky urges the

Court to approve the " 'substantial risk' " test used below. Pp. 1529 – 1530.

(b) This Court has held that the Eighth Amendment forbids "punishments of torture, ... and all others in the same line of unnecessary cruelty," *Wilkerson v. Utah,* 99 U.S. 130, 136, 25 L.Ed. 345, such as disemboweling, beheading, quartering, dissecting, and burning alive, all of which share the deliberate infliction of pain for the sake of pain, *id.,* at 135. Observing also that "[p]unishments are cruel when they involve torture or a lingering death[,] ... something inhuman and barbarous [and] ... more than the mere extinguishment of life," the Court has emphasized **1523 that an electrocution statute it was upholding "was passed in the effort to devise a more humane method of reaching the result." *In re Kemmler,* 136 U.S. 436, 447, 10 S.Ct. 930, 34 L.Ed. 519. P. 1530.

(c) Although conceding that an execution under Kentucky's procedures would be humane and constitutional if performed properly, petitioners claim that there is a significant risk that the procedures will *not* be properly followed—particularly, that the sodium thiopental will not be properly administered to achieve its intended effect—resulting in severe pain when the other chemicals are administered. Subjecting individuals to a substantial risk of future harm can be cruel and unusual punishment if the conditions presenting the risk are "sure or very likely to cause serious illness and needless suffering" and give rise to "sufficiently imminent dangers." *Helling v. McKinney,* 509 U.S. 25, 33, 34–35, 113 S.Ct. 2475, 125 L.Ed.2d 22. To prevail, such a claim must present a "substantial risk of serious harm," an "objectively intolerable risk of harm." *Farmer v. Brennan,* 511 U.S. 825, 842, 846, and n. 9, 114 S.Ct. 1970, 128 L.Ed.2d 811. For example, the Court has held that an isolated mishap alone does not violate the Eighth Amendment, *Louisiana ex rel. Francis v. Resweber,* 329 U.S. 459, 463–464, 67 S.Ct. 374, 91 L.Ed. 422, because such an event, while regrettable, does not suggest cruelty or a "substantial risk of serious harm." Pp. 1530 – 1531.

(d) Petitioners' primary contention is that the risks they have identified can be eliminated by adopting certain alternative procedures. Because allowing a condemned prisoner to challenge a State's execution method merely by showing a slightly or marginally safer alternative finds no support in this Court's cases, would embroil the courts in ongoing scientific controversies beyond their expertise, and would substantially intrude on the role of state legislatures in implementing execution procedures, petitioners' proposed "unnecessary risk" standard is rejected in favor of *Farmer*'s "substantial risk of serious harm" test. To effectively address such a substantial risk, a proffered alternative procedure must be feasible, readily implemented, and in fact significantly reduce a substantial risk of severe pain. A State's refusal to adopt such an alternative in the face of these documented advantages, without a legitimate penological justification for its current execution method, can be viewed as "cruel and unusual." Pp. 1531 – 1532.

2. Petitioners have not carried their burden of showing that the risk of pain from maladministration of a concededly humane lethal injection protocol, and the failure to adopt untried and untested alternatives, constitute cruel and unusual punishment. Pp. 1532– 1538.

(a) It is uncontested that failing a proper dose of sodium thiopental to render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and of pain from potassium chloride. It is, however, difficult to regard a practice as "objectively intolerable" when it is in fact widely tolerated. Probative but not conclusive in this regard is the consensus among the Federal Government and the States that have adopted lethal injection and the specific three-drug combination Kentucky uses. Pp. 1533 – 1534.

(b) In light of the safeguards Kentucky's protocol puts in place, the risks of administering an inadequate sodium thiopental dose identified by petitioners are not so substantial or imminent as to amount to an Eighth Amendment violation. The charge that Kentucky employs **1524 untrained personnel unqualified to calculate and mix an adequate dose was answered by the state trial court's finding, substantiated by expert testimony, that there would be minimal risk of improper mixing if the manufacturers' thiopental package insert instructions were followed. Likewise, the IV line problems alleged by petitioners do not establish a sufficiently substantial risk because IV team members must have at least one year of relevant professional experience, and the presence of the warden and deputy warden in the execution chamber allows them to watch for IV problems. If an insufficient dose is initially administered through the primary IV site,

an additional dose can be given through the secondary site before the last two drugs are injected. Pp. 1533 – 1534.

(c) Nor does Kentucky's failure to adopt petitioners' proposed alternatives demonstrate that the state execution procedure is cruel and unusual. Kentucky's continued use of the three-drug protocol cannot be viewed as posing an "objectively intolerable risk" when no other State has adopted the one-drug method and petitioners have proffered no study showing that it is an equally effective manner of imposing a death sentence. Petitioners contend that Kentucky should omit pancuronium bromide because it serves no therapeutic purpose while suppressing muscle movements that could reveal an inadequate administration of sodium thiopental. The state trial court specifically found that pancuronium bromide serves two purposes: (1) preventing involuntary convulsions or seizures during unconsciousness, thereby preserving the procedure's dignity, and (2) hastening death. Petitioners assert that their barbiturate-only protocol is used routinely by veterinarians for putting animals to sleep and that 23 States bar veterinarians from using a neuromuscular paralytic agent like pancuronium bromide. These arguments overlook the States' legitimate interest in providing for a quick, certain death, and in any event, veterinary practice for animals is not an appropriate guide for humane practices for humans. Petitioners charge that Kentucky's protocol lacks a systematic mechanism, such as a Bispectral Index monitor, blood pressure cuff, or electrocardiogram, for monitoring the prisoner's "anesthetic depth." But expert testimony shows both that a proper thiopental dose obviates the concern that a prisoner will not be sufficiently sedated, and that each of the proposed alternatives presents its own concerns. Pp. 1533 – 1534.

Justice STEVENS concluded that instead of ending the controversy, this case will generate debate not only about the constitutionality of the three-drug protocol, and specifically about the justification for the use of pancuronium bromide, but also about the justification for the death penalty itself. States wishing to decrease the risk that future litigation will delay executions or invalidate their protocol would do well to reconsider their continued use of pancuronium bromide. Moreover, although experience demonstrates that imposing that penalty constitutes the pointless and needless extinction of life with only negligible social or public returns, this conclusion does not justify a refusal to respect this Court's precedents upholding the death penalty and establishing a framework for evaluating the constitutionality of particular execution methods, under which petitioners' evidence fails to prove that Kentucky's protocol violates the Eighth Amendment. Pp. 1542 – 1552.

Justice THOMAS, joined by Justice SCALIA, concluded that the plurality's formulation of the governing standard finds no support in the original understanding of the Cruel and Unusual Punishments Clause or in this Court's previous method-of-execution cases; casts constitutional **1525 doubt on long-accepted methods of execution; and injects the Court into matters it has no institutional capacity to resolve. The historical practices leading to the Clause's inclusion in the Bill of Rights, the views of early commentators on the Constitution, and this Court's cases, see, *e.g., Wilkerson v. Utah,* 99 U.S. 130, 135–136, 25 L.Ed. 345, all demonstrate that an execution method violates the Eighth Amendment only if it is deliberately designed to inflict pain. Judged under that standard, this is an easy case: Because it is undisputed that Kentucky adopted its lethal injection protocol in an effort to make capital punishment more humane, not to add elements of terror, pain, or disgrace to the death penalty, petitioners' challenge must fail. Pp. 1556 – 1563.

Justice BREYER concluded that there cannot be found, either in the record or in the readily available literature, sufficient grounds to believe that Kentucky's lethal injection method creates a significant risk of unnecessary suffering. Although the death penalty has serious risks —*e.g.,* that the wrong person may be executed, that unwarranted animus about the victims' race, for example, may play a role, and that those convicted will find themselves on death row for many years—the penalty's lawfulness is not before the Court. And petitioners' proof and evidence, while giving rise to legitimate concern, do not show that Kentucky's execution method amounts to "cruel and unusual punishmen[t]." Pp. 1563 – 1567.

ROBERTS, C. J., announced the judgment of the Court and delivered an opinion, in which KENNEDY and ALITO, JJ., joined. ALITO, J., filed a concurring opinion, *post*, pp. 1538 – 1542. STEVENS, J., filed an opinion concurring in the judgment, *post*, pp. 1542 – 1552. SCALIA, J., filed an opinion concurring in the judgment, in which THOMAS, J., joined, *post*, pp. 1552 – 1556. THOMAS, J., filed an opinion concurring in the judgment, in which SCALIA, J., joined, *post*, pp. 1556

– 1563. BREYER, J., filed an opinion concurring in the judgment, *post*, pp. 1563 – 1567. GINSBURG, J., filed a dissenting opinion, in which SOUTER, J., joined, *post*, pp. 1567 – 1572.

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Opinion

Chief Justice ROBERTS announced the judgment of the Court and delivered an opinion, in which Justice KENNEDY and Justice ALITO join.

***40** Like 35 other States and the Federal Government, Kentucky has chosen to impose capital punishment for certain crimes. As is true with respect to each of these States and the Federal Government, Kentucky has altered its method ***41** of execution over time to more humane means of carrying out the sentence. That progress has led to the use of lethal injection by every ****1526** jurisdiction that imposes the death penalty.

Petitioners in this case—each convicted of double homicide—acknowledge that the lethal injection procedure, if applied as intended, will result in a humane death. They nevertheless contend that the lethal injection protocol is unconstitutional under the Eighth Amendment's ban on "cruel and unusual punishments," because of the risk that the protocol's terms might not be properly followed, resulting in significant pain. They propose an alternative protocol, one that they concede has not been adopted by any State and has never been tried.

The trial court held extensive hearings and entered detailed findings of fact and conclusions of law. It recognized that "[t]here are no methods of legal execution that are satisfactory to those who oppose the death penalty on moral, religious, or societal grounds," but concluded that Kentucky's procedure "complies with the constitutional requirements against cruel and unusual punishment." App. 769. The State Supreme Court affirmed. We too agree that petitioners have not carried their burden of showing that the risk of pain from maladministration of a concededly humane lethal injection protocol, and the failure to adopt untried and untested alternatives, constitute cruel and unusual punishment. The judgment below is affirmed.

I

A

By the middle of the 19th century, "hanging was the 'nearly universal form of execution' in the United States." *Campbell v. Wood,* 511 U.S. 1119, 114 S.Ct. 2125, 128 L.Ed.2d 682 (1994) (Blackmun, J., dissenting from denial of certiorari) (quoting *State v. Frampton,* 95 Wash.2d 469, 492, 627 P.2d 922, 934 (1981)); Denno, ***42** Getting to Death: Are Executions Constitutional? 82 Iowa L.Rev. 319, 364 (1997) (counting 48 States and Territories that employed hanging as a method of execution). In 1888, following the recommendation of a commission empaneled by the Governor to find " 'the most humane and practical method known to modern science of carrying into effect the sentence of death,' " New York became the first State to authorize electrocution as a form of capital punishment. *Glass v. Louisiana,* 471 U.S. 1080, 1082, and n. 4, 105 S.Ct. 2159, 85 L.Ed.2d 514 (1985) (Brennan, J., dissenting from denial of certiorari); Denno, *supra,* at 373. By 1915, 11 other States had followed suit, motivated by the "well-grounded belief that electrocution is less painful and more humane than hanging." *Malloy v. South Carolina,* 237 U.S. 180, 185, 35 S.Ct. 507, 59 L.Ed. 905 (1915).

Electrocution remained the predominant mode of execution for nearly a century, although several methods, including hanging, firing squad, and lethal gas were in

use at one time. Brief for Fordham University School of Law, Louis Stein Center for Law and Ethics, as *Amicus Curiae* 5–9 (hereinafter Fordham Brief). Following the 9–year hiatus in executions that ended with our decision in *Gregg v. Georgia,* 428 U.S. 153, 96 S.Ct. 2909, 49 L.Ed.2d 859 (1976), however, state legislatures began responding to public calls to reexamine electrocution as a means of ensuring a humane death. See S. Banner, The Death Penalty: An American History 192–193, 296–297 (2002). In 1977, legislators in Oklahoma, after consulting with the head of the anesthesiology department at the University of Oklahoma College of Medicine, introduced the first bill proposing lethal injection as the State's method of execution. See Brief for Petitioners 4; Fordham Brief 21–22. A total of 36 States have now adopted lethal injection as the exclusive or primary means of implementing ****1527** the death penalty, making it by far the most prevalent method of execution in the United States. [1] It is also the method used by the ***43** Federal Government. See 18 U.S.C. § 3591 *et seq.* (2000 ed. and Supp. V); App. to Brief for United States as *Amicus Curiae* 1a–6a (lethal injection protocol used by the Federal Bureau of Prisons).

***44** Of these 36 States, at least 30 (including Kentucky) use the same combination of three drugs in their lethal injection protocols. See *Workman v. Bredesen,* 486 F.3d 896, 902 (C.A.6 2007). The first drug, sodium thiopental (also known as Pentothol), is a fast-acting barbiturate sedative that induces a deep, comalike unconsciousness when given in the amounts used for lethal injection. App. 762–763, 631–632. The second drug, pancuronium bromide (also known as Pavulon), is a paralytic agent that inhibits all muscular-skeletal movements and, by paralyzing the diaphragm, stops respiration. *Id.,* at 763. Potassium chloride, the third drug, interferes with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest. *Ibid.* The proper administration of the first drug ensures that the prisoner does not experience any pain associated with the paralysis and cardiac arrest caused by the second and third drugs. *Id.,* at 493–494, 541, 558–559.

B

Kentucky replaced electrocution with lethal injection in 1998. 1998 Ky. Acts ****1528** ch. 220, p. 777. The Kentucky statute does not specify the drugs or categories of drugs to be used during an execution, instead mandating that "every death sentence shall be executed by continuous intravenous injection of a substance or combination of substances sufficient to cause death." Ky.Rev.Stat. Ann. § 431.220(1)(a) (West 2006). Prisoners sentenced before 1998 have the option of electing either electrocution or lethal injection, but lethal injection is the default if—as is the case with petitioners—the prisoner refuses to make a choice at least 20 days before the scheduled execution. § 431.220(1)(b). If a court invalidates Kentucky's lethal injection method, Kentucky law provides that the method of execution will revert to electrocution. § 431.223.

Shortly after the adoption of lethal injection, officials working for the Kentucky Department of Corrections set ***45** about developing a written protocol to comply with the requirements of § 431.220(1)(a). Kentucky's protocol called for the injection of 2 grams of sodium thiopental, 50 milligrams of pancuronium bromide, and 240 milliequivalents of potassium chloride. In 2004, as a result of this litigation, the department chose to increase the amount of sodium thiopental from 2 grams to 3 grams. App. 762–763, 768. Between injections, members of the execution team flush the intravenous (IV) lines with 25 milligrams of saline to prevent clogging of the lines by precipitates that may form when residual sodium thiopental comes into contact with pancuronium bromide. *Id.,* at 761, 763–764. The protocol reserves responsibility for inserting the IV catheters to qualified personnel having at least one year of professional experience. *Id.,* at 984. Currently, Kentucky uses a certified phlebotomist and an emergency medical technician (EMT) to perform the venipunctures necessary for the catheters. *Id.,* at 761–762. They have up to one hour to establish both primary and secondary peripheral IV sites in the arm, hand, leg, or foot of the inmate. *Id.,* at 975–976. Other personnel are responsible for mixing the solutions containing the three drugs and loading them into syringes. *Id.,* at 761.

Kentucky's execution facilities consist of the execution chamber, a control room separated by a one-way window, and a witness room. *Id.,* at 203. The warden and deputy warden remain in the execution chamber with the prisoner, who is strapped to a gurney. The execution team administers the drugs remotely from the control room through five feet of IV tubing. *Id.,* at 286. If, as determined by the warden and deputy warden through visual inspection, the prisoner is not unconscious within

60 seconds following the delivery of the sodium thiopental to the primary IV site, a new 3–gram dose of thiopental is administered to the secondary site before injecting the pancuronium and potassium chloride. *Id.,* at 978–979. In addition to ensuring that the first dose of thiopental is successfully administered, the warden ***46** and deputy warden also watch for any problems with the IV catheters and tubing.

A physician is present to assist in any effort to revive the prisoner in the event of a last-minute stay of execution. *Id.,* at 764. By statute, however, the physician is prohibited from participating in the "conduct of an execution," except to certify the cause of death. Ky.Rev.Stat. Ann. § 431.220(3). An electrocardiogram (EKG) verifies the death of the prisoner. App. 764. Only one Kentucky prisoner, Eddie Lee Harper, has been executed since the Commonwealth adopted lethal injection. There were no reported problems at Harper's execution.

C

Petitioners Ralph Baze and Thomas C. Bowling were each convicted of two counts ****1529** of capital murder and sentenced to death. The Kentucky Supreme Court upheld their convictions and sentences on direct appeal. See *Baze v. Commonwealth,* 965 S.W.2d 817, 819–820, 826 (1997), cert. denied, 523 U.S. 1083, 118 S.Ct. 1536, 140 L.Ed.2d 685 (1998); *Bowling v. Commonwealth,* 873 S.W.2d 175, 176–177, 182 (1993), cert. denied, 513 U.S. 862, 115 S.Ct. 176, 130 L.Ed.2d 112 (1994).

After exhausting their state and federal collateral remedies, Baze and Bowling sued three state officials in the Franklin Circuit Court for the Commonwealth of Kentucky, seeking to have Kentucky's lethal injection protocol declared unconstitutional. After a 7–day bench trial during which the trial court received the testimony of approximately 20 witnesses, including numerous experts, the court upheld the protocol, finding there to be minimal risk of various claims of improper administration of the protocol. App. 765–769. On appeal, the Kentucky Supreme Court stated that a method of execution violates the Eighth Amendment when it "creates a substantial risk of wanton and unnecessary infliction of pain, torture or lingering death." 217 S.W.3d 207, 209 (2006). Applying that standard, the court affirmed. *Id.,* at 212.

***47** We granted certiorari to determine whether Kentucky's lethal injection protocol satisfies the Eighth Amendment. 551 U.S. 1192, 128 S.Ct. 34, 168 L.Ed.2d 809, amended, 552 U.S. 945, 128 S.Ct. 372, 169 L.Ed.2d 256 (2007). We hold that it does.

II

[1] **[2]** The Eighth Amendment to the Constitution, applicable to the States through the Due Process Clause of the Fourteenth Amendment, see *Robinson v. California,* 370 U.S. 660, 666, 82 S.Ct. 1417, 8 L.Ed.2d 758 (1962), provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." We begin with the principle, settled by *Gregg,* that capital punishment is constitutional. See 428 U.S., at 177, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and STEVENS, JJ.). It necessarily follows that there must be a means of carrying it out. Some risk of pain is inherent in any method of execution—no matter how humane—if only from the prospect of error in following the required procedure. It is clear, then, that the Constitution does not demand the avoidance of all risk of pain in carrying out executions.

Petitioners do not claim that it does. Rather, they contend that the Eighth Amendment prohibits procedures that create an "unnecessary risk" of pain. Brief for Petitioners 38. Specifically, they argue that courts must evaluate "(a) the severity of pain risked, (b) the likelihood of that pain occurring, and (c) the extent to which alternative means are feasible, either by modifying existing execution procedures or adopting alternative procedures." *Ibid.* Petitioners envision that the quantum of risk necessary to make out an Eighth Amendment claim will vary according to the severity of the pain and the availability of alternatives, Reply Brief for Petitioners 23–24, n. 9, but that the risk must be "significant" to trigger Eighth Amendment scrutiny, see Brief for Petitioners 39–40; Reply Brief for Petitioners 25–26.

Kentucky responds that this "unnecessary risk" standard is tantamount to a requirement that States adopt the " 'least risk' " alternative in carrying out an execution, a standard ***48** the Commonwealth contends will cast recurring constitutional doubt on any procedure adopted by the States. Brief for Respondents 29, 35. Instead,

Kentucky urges the Court to approve the " 'substantial risk' " test used by the courts below. *Id.,* at 34–35.

****1530** A

This Court has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment. In *Wilkerson v. Utah,* 99 U.S. 130, 25 L.Ed. 345 (1879), we upheld a sentence to death by firing squad imposed by a territorial court, rejecting the argument that such a sentence constituted cruel and unusual punishment. *Id.,* at 134–135. We noted there the difficulty of "defin[ing] with exactness the extent of the constitutional provision which provides that cruel and unusual punishments shall not be inflicted." *Id.,* at 135–136. Rather than undertake such an effort, the *Wilkerson* Court simply noted that "it is safe to affirm that punishments of torture, ... and all others in the same line of unnecessary cruelty, are forbidden" by the Eighth Amendment. *Id.,* at 136. By way of example, the Court cited cases from England in which "terror, pain, or disgrace were sometimes superadded" to the sentence, such as where the condemned was "embowelled alive, beheaded, and quartered," or instances of "public dissection in murder, and burning alive." *Id.,* at 135. In contrast, we observed that the firing squad was routinely used as a method of execution for military officers. *Id.,* at 134. What each of the forbidden punishments had in common was the deliberate infliction of pain for the sake of pain—"superadd [ing]" pain to the death sentence through torture and the like.

We carried these principles further in *In re Kemmler,* 136 U.S. 436, 10 S.Ct. 930, 34 L.Ed. 519 (1890). There we rejected an opportunity to incorporate the Eighth Amendment against the States in a challenge to the first execution by electrocution, to be carried ***49** out by the State of New York. *Id.,* at 449, 10 S.Ct. 930. In passing over that question, however, we observed: "Punishments are cruel when they involve torture or a lingering death; but the punishment of death is not cruel, within the meaning of that word as used in the Constitution. It implies there something inhuman and barbarous, something more than the mere extinguishment of life." *Id.,* at 447, 10 S.Ct. 930. We noted that the New York statute adopting electrocution as a method of execution "was passed in the effort to devise a more humane method of reaching the result." *Ibid.*

B

Petitioners do not claim that lethal injection or the proper administration of the particular protocol adopted by Kentucky by themselves constitute the cruel or wanton infliction of pain. Quite the contrary, they concede that "if performed properly," an execution carried out under Kentucky's procedures would be "humane and constitutional." Brief for Petitioners 31. That is because, as counsel for petitioners admitted at oral argument, proper administration of the first drug, sodium thiopental, eliminates any meaningful risk that a prisoner would experience pain from the subsequent injections of pancuronium and potassium chloride. See Tr. of Oral Arg. 5; App. 493–494 (testimony of petitioners' expert that, if sodium thiopental is "properly administered" under the protocol, "[i]n virtually every case, then that would be a humane death").

Instead, petitioners claim that there is a significant risk that the procedures will *not* be properly followed—in particular, that the sodium thiopental will not be properly administered to achieve its intended effect—resulting in severe pain when the other chemicals are administered. Our cases recognize that subjecting individuals to a risk of future harm—not simply actually inflicting pain—can qualify as cruel and unusual punishment. To establish that such exposure violates ***50** the Eighth Amendment, however, the conditions presenting ****1531** the risk must be "*sure or very likely* to cause serious illness and needless suffering," and give rise to "sufficiently *imminent* dangers." *Helling v. McKinney,* 509 U.S. 25, 33, 34–35, 113 S.Ct. 2475, 125 L.Ed.2d 22 (1993) (emphasis added). We have explained that to prevail on such a claim there must be a "substantial risk of serious harm," an "objectively intolerable risk of harm" that prevents prison officials from pleading that they were "subjectively blameless for purposes of the Eighth Amendment." *Farmer v. Brennan,* 511 U.S. 825, 842, 846, and n. 9, 114 S.Ct. 1970, 128 L.Ed.2d 811 (1994).

Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of "objectively intolerable risk of harm" that qualifies as cruel and unusual. In *Louisiana ex rel. Francis v. Resweber,* 329 U.S. 459, 67 S.Ct. 374, 91 L.Ed. 422 (1947), a plurality of the

Court upheld a second attempt at executing a prisoner by electrocution after a mechanical malfunction had interfered with the first attempt. The principal opinion noted that "[a]ccidents happen for which no man is to blame," *id.,* at 462, 67 S.Ct. 374, and concluded that such "an accident, with no suggestion of malevolence," *id.*, at 463, 67 S.Ct. 374, did not give rise to an Eighth Amendment violation, *id.,* at 463–464, 67 S.Ct. 374.

As Justice Frankfurter noted in a separate opinion based on the Due Process Clause, however, "a hypothetical situation" involving "a series of abortive attempts at electrocution" would present a different case. *Id.,* at 471, 67 S.Ct. 374 (concurring opinion). In terms of our present Eighth Amendment analysis, such a situation—unlike an "innocent misadventure," *id.*, at 470, 67 S.Ct. 374—would demonstrate an "objectively intolerable risk of harm" that officials may not ignore. See *Farmer,* 511 U.S., at 846, and n. 9, 114 S.Ct. 1970. In other words, an isolated mishap alone does not give rise to an Eighth Amendment violation, precisely because such an event, while regrettable, does not suggest cruelty, or that the procedure at issue gives rise to a "substantial risk of serious harm." *Id.,* at 842, 114 S.Ct. 1970.

***51** C

Much of petitioners' case rests on the contention that they have identified a significant risk of harm that can be eliminated by adopting alternative procedures, such as a one-drug protocol that dispenses with the use of pancuronium and potassium chloride, and additional monitoring by trained personnel to ensure that the first dose of sodium thiopental has been adequately delivered. Given what our cases have said about the nature of the risk of harm that is actionable under the Eighth Amendment, a condemned prisoner cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative.

Permitting an Eighth Amendment violation to be established on such a showing would threaten to transform courts into boards of inquiry charged with determining "best practices" for executions, with each ruling supplanted by another round of litigation touting a new and improved methodology. Such an approach finds no support in our cases, would embroil the courts in ongoing scientific controversies beyond their expertise, and would substantially intrude on the role of state legislatures in implementing their execution procedures—a role that by all accounts the States have fulfilled with an earnest desire to provide for a progressively more humane manner of death. See *Bell v. Wolfish,* 441 U.S. 520, 562, 99 S.Ct. 1861, 60 L.Ed.2d 447 (1979) ("The wide range of 'judgment calls' that meet constitutional and statutory requirements are confided to ****1532** officials outside of the Judicial Branch of Government"). Accordingly, we reject petitioners' proposed "unnecessary risk" standard, as well as the dissent's "untoward" risk variation. See *post,* at 1567, 1572 (opinion of GINSBURG, J.). [2]

***52** Instead, the proffered alternatives must effectively address a "substantial risk of serious harm." *Farmer, supra,* at 842, 114 S.Ct. 1970. To qualify, the alternative procedure must be feasible, readily implemented, and in fact significantly reduce a substantial risk of severe pain. If a State refuses to adopt such an alternative in the face of these documented advantages, without a legitimate penological justification for adhering to its current method of execution, then a State's refusal to change its method can be viewed as "cruel and unusual" under the Eighth Amendment. [3]

***53** III

In applying these standards to the facts of this case, we note at the outset that it is difficult to regard a practice as "objectively intolerable" when it is in fact widely tolerated. Thirty-six States that sanction capital punishment have adopted lethal injection as the preferred method of execution. The Federal Government uses lethal injection as well. See *supra,* at 1527, and n. 1. This broad consensus goes not just to the method of execution, but also to the specific three-drug combination used by Kentucky. Thirty States, as well as the Federal Government, use a series of sodium thiopental, pancuronium bromide, and potassium chloride, in varying amounts. See *supra,* at 1527. No State uses or has ever used the alternative one-drug protocol belatedly urged by petitioners. This ****1533** consensus is probative but not conclusive with respect to that aspect of the alternatives proposed by petitioners.

In order to meet their "heavy burden" of showing that Kentucky's procedure is "cruelly inhumane," *Gregg,* 428 U.S., at 175, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and STEVENS, JJ.), petitioners point

to numerous aspects of the protocol that they contend create opportunities for error. Their claim hinges on the improper administration of the first drug, sodium thiopental. It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride. See Tr. of Oral Arg. 27. We agree with the state trial court and State Supreme Court, however, that petitioners ***54** have not shown that the risk of an inadequate dose of the first drug is substantial. And we reject the argument that the Eighth Amendment requires Kentucky to adopt the untested alternative procedures petitioners have identified.

A

[3] Petitioners contend that there is a risk of improper administration of thiopental because the doses are difficult to mix into solution form and load into syringes; because the protocol fails to establish a rate of injection, which could lead to a failure of the IV; because it is possible that the IV catheters will infiltrate into surrounding tissue, causing an inadequate dose to be delivered to the vein; because of inadequate facilities and training; and because Kentucky has no reliable means of monitoring the anesthetic depth of the prisoner after the sodium thiopental has been administered. Brief for Petitioners 12–20.

As for the risk that the sodium thiopental would be improperly prepared, petitioners contend that Kentucky employs untrained personnel who are unqualified to calculate and mix an adequate dose, especially in light of the omission of volume and concentration amounts from the written protocol. *Id.,* at 45–46. The state trial court, however, specifically found that "[i]f the manufacturers' instructions for reconstitution of Sodium Thiopental are followed, ... there would be minimal risk of improper mixing, despite converse testimony that a layperson would have difficulty performing this task." App. 761. We cannot say that this finding is clearly erroneous, see *Hernandez v. New York,* 500 U.S. 352, 366, 111 S.Ct. 1859, 114 L.Ed.2d 395 (1991) (plurality opinion), particularly when that finding is substantiated by expert testimony describing the task of reconstituting powder sodium thiopental into solution form as "[n]ot difficult at all. ... You take a liquid, you inject it into a vial with the powder, then you shake it up until the powder dissolves and, you're done. The instructions are on the package insert." 5 Tr. 695 (Apr. 19, 2005).

***55** Likewise, the asserted problems related to the IV lines do not establish a sufficiently substantial risk of harm to meet the requirements of the Eighth Amendment. Kentucky has put in place several important safeguards to ensure that an adequate dose of sodium thiopental is delivered to the condemned prisoner. The most significant of these is the written protocol's requirement that members of the IV team must have at least one year of professional experience as a certified medical assistant, phlebotomist, EMT, paramedic, or military corpsman. App. 984. Kentucky currently uses a phlebotomist and an EMT, personnel who have daily experience establishing IV catheters for inmates in Kentucky's prison population. ****1534** *Id.,* at 273–274; Tr. of Oral Arg. 27–28. Moreover, these IV team members, along with the rest of the execution team, participate in at least 10 practice sessions per year. App. 984. These sessions, required by the written protocol, encompass a complete walk-through of the execution procedures, including the siting of IV catheters into volunteers. *Ibid.* In addition, the protocol calls for the IV team to establish both primary and backup lines and to prepare two sets of the lethal injection drugs before the execution commences. *Id.,* at 975. These redundant measures ensure that if an insufficient dose of sodium thiopental is initially administered through the primary line, an additional dose can be given through the backup line before the last two drugs are injected. *Id.,* at 279–280, 337–338, 978–979.

The IV team has one hour to establish both the primary and backup IVs, a length of time the trial court found to be "not excessive but rather necessary," *id.,* at 762, contrary to petitioners' claim that using an IV inserted after any "more than ten or fifteen minutes of unsuccessful attempts is dangerous because the IV is almost certain to be unreliable," Brief for Petitioners 47. And, in any event, merely because the protocol gives the IV team one hour to establish intravenous access does not mean that team members are required to spend the entire hour in a futile attempt to do so. The ***56** qualifications of the IV team also substantially reduce the risk of IV infiltration.

In addition, the presence of the warden and deputy warden in the execution chamber with the prisoner allows them

to watch for signs of IV problems, including infiltration. Three of the Commonwealth's medical experts testified that identifying signs of infiltration would be "very obvious," even to the average person, because of the swelling that would result. App. 385–386. See *id.,* at 353, 600–601. Kentucky's protocol specifically requires the warden to redirect the flow of chemicals to the backup IV site if the prisoner does not lose consciousness within 60 seconds. *Id.,* at 978–979. In light of these safeguards, we cannot say that the risks identified by petitioners are so substantial or imminent as to amount to an Eighth Amendment violation.

B

[4] Nor does Kentucky's failure to adopt petitioners' proposed alternatives demonstrate that the Commonwealth's execution procedure is cruel and unusual.

First, petitioners contend that Kentucky could switch from a three-drug protocol to a one-drug protocol by using a single dose of sodium thiopental or other barbiturate. Brief for Petitioners 51–57. That alternative was not proposed to the state courts below. [4] As a result, we are left without any findings on the effectiveness of petitioners' barbiturate-only ***57** protocol, despite scattered references in the trial testimony to the sole use of sodium thiopental or pentobarbital as a preferred method of ****1535** execution. See Reply Brief for Petitioners 18, n. 6.

In any event, the Commonwealth's continued use of the three-drug protocol cannot be viewed as posing an "objectively intolerable risk" when no other State has adopted the one-drug method and petitioners proffered no study showing that it is an equally effective manner of imposing a death sentence. See App. 760–761, n. 8 ("Plaintiffs have not presented any scientific study indicating a better method of execution by lethal injection"). Indeed, the State of Tennessee, after reviewing its execution procedures, rejected a proposal to adopt a one-drug protocol using sodium thiopental. The State concluded that the one-drug alternative would take longer than the three-drug method and that the "required dosage of sodium thiopental would be less predictable and more variable when it is used as the sole mechanism for producing death...." *Workman,* 486 F.3d, at 919 (Appendix A, ¶(A)(3)). We need not endorse the accuracy of those conclusions to note simply that the comparative efficacy of a one-drug method of execution is not so well established that Kentucky's failure to adopt it constitutes a violation of the Eighth Amendment.

Petitioners also contend that Kentucky should omit the second drug, pancuronium bromide, because it serves no therapeutic purpose while suppressing muscle movements that could reveal an inadequate administration of the first drug. The state trial court, however, specifically found that pancuronium serves two purposes. First, it prevents involuntary physical movements during unconsciousness that may accompany the injection of potassium chloride. App. 763. The Commonwealth has an interest in preserving the dignity of the procedure, especially where convulsions or seizures could be misperceived as signs of consciousness or distress. Second, pancuronium stops respiration, hastening death. ***58** *Ibid.* Kentucky's decision to include the drug does not offend the Eighth Amendment. [5]

Petitioners' barbiturate-only protocol, they contend, is not untested; it is used routinely by veterinarians in putting animals to sleep. Moreover, 23 States, including Kentucky, bar veterinarians from using a neuromuscular paralytic agent like pancuronium bromide, either expressly or, like Kentucky, by specifically directing the use of a drug like sodium pentobarbital. See Brief for Dr. Kevin Concannon et al. as *Amici Curiae* 18, n. 5. If pancuronium is too cruel for animals, the argument goes, then it must be too cruel for the condemned inmate. Whatever rhetorical force the argument carries, see *Workman, supra,* at 909 (describing the comparison to animal euthanasia as "more of a debater's point"), it overlooks the States' legitimate interest in providing for a quick, certain death. In the Netherlands, for example, where physician-assisted euthanasia is permitted, the Royal Dutch Society for the Advancement of Pharmacy recommends the use of a muscle relaxant (such as pancuronium dibromide) in addition to thiopental in order to prevent a prolonged, undignified death. See Kimsma, Euthanasia and Euthanizing Drugs in The Netherlands, reprinted in Drug Use in Assisted Suicide and Euthanasia 193, 200, 204 (M. Battin & A. Lipman eds.1996). That concern may be less compelling in the veterinary context, and in any event other methods approved by veterinarians ****1536** —such as stunning the animal or severing its spinal cord, see 6 Tr. 758–759

(Apr. 20, 2005)—make clear that veterinary practice for animals is not an appropriate guide to humane practices for humans.

Petitioners also fault the Kentucky protocol for lacking a systematic mechanism for monitoring the "anesthetic depth" ***59** of the prisoner. Under petitioners' scheme, qualified personnel would employ monitoring equipment, such as a Bispectral Index (BIS) monitor, blood pressure cuff, or EKG to verify that a prisoner has achieved sufficient unconsciousness before injecting the final two drugs. The visual inspection performed by the warden and deputy warden, they maintain, is an inadequate substitute for the more sophisticated procedures they envision. Brief for Petitioners 19, 58.

At the outset, it is important to reemphasize that a proper dose of thiopental obviates the concern that a prisoner will not be sufficiently sedated. All the experts who testified at trial agreed on this point. The risks of failing to adopt additional monitoring procedures are thus even more "remote" and attenuated than the risks posed by the alleged inadequacies of Kentucky's procedures designed to ensure the delivery of thiopental. See *Hamilton v. Jones,* 472 F.3d 814, 817 (C.A.10 2007) (*per curiam*); *Taylor v. Crawford,* 487 F.3d 1072, 1084 (C.A.8 2007).

But more than this, Kentucky's expert testified that a blood pressure cuff would have no utility in assessing the level of the prisoner's unconsciousness following the introduction of sodium thiopental, which depresses circulation. App. 578. Furthermore, the medical community has yet to endorse the use of a BIS monitor, which measures brain function, as an indication of anesthetic awareness. American Society of Anesthesiologists, Practice Advisory for Intraoperative Awareness and Brain Function Monitoring, 104 Anesthesiology 847, 855 (Apr.2006); see *Brown v. Beck,* 445 F.3d 752, 754–755 (C.A.4 2006) (Michael, J., dissenting). The asserted need for a professional anesthesiologist to interpret the BIS monitor readings is nothing more than an argument against the entire procedure, given that both Kentucky law, see Ky.Rev.Stat. Ann. § 431.220(3), and the American Society of Anesthesiologists' own ethical guidelines, see Brief for American Society of Anesthesiologists as *Amicus Curiae* 2–3, prohibit anesthesiologists from participating in capital ***60** punishment. Nor is it pertinent that the use of a blood pressure cuff and EKG is "the standard of care in surgery requiring anesthesia," as the dissent points out. *Post,* at 1570. Petitioners have not shown that these supplementary procedures, drawn from a different context, are necessary to avoid a substantial risk of suffering.

The dissent believes that rough-and-ready tests for checking consciousness—calling the inmate's name, brushing his eyelashes, or presenting him with strong, noxious odors—could materially decrease the risk of administering the second and third drugs before the sodium thiopental has taken effect. See *ibid.* Again, the risk at issue is already attenuated, given the steps Kentucky has taken to ensure the proper administration of the first drug. Moreover, the scenario the dissent posits involves a level of unconsciousness allegedly sufficient to avoid detection of improper administration of the anesthesia under Kentucky's procedure, but not sufficient to prevent pain. See *post,* at 1570 – 1571. There is no indication that the basic tests the dissent advocates can make such fine distinctions. If these tests are effective only in determining whether the sodium thiopental has entered the inmate's bloodstream, see *post,* at 1570, the record confirms ****1537** that the visual inspection of the IV site under Kentucky's procedure achieves that objective. See *supra,* at 1534. [6]

The dissent would continue the stay of these executions (and presumably the many others held in abeyance pending decision in this case) and send the case back to the lower courts to determine whether such added measures redress an "untoward" risk of pain. *Post,* at 1572. But an inmate ***61** cannot succeed on an Eighth Amendment claim simply by showing one more step the State could take as a failsafe for other, independently adequate measures. This approach would serve no meaningful purpose and would frustrate the State's legitimate interest in carrying out a sentence of death in a timely manner. See *Baze v. Parker,* 371 F.3d 310, 317 (C.A.6 2004) (petitioner Baze sentenced to death in 1994); *Bowling v. Parker,* 138 F.Supp.2d 821, 840 (E.D.Ky.2001) (petitioner Bowling sentenced to death in 1991).

Justice STEVENS suggests that our opinion leaves the disposition of other cases uncertain, see *post,* at 1542 – 1543, but the standard we set forth here resolves more challenges than he acknowledges. A stay of execution may not be granted on grounds such as those asserted here unless the condemned prisoner establishes that the State's

lethal injection protocol creates a demonstrated risk of severe pain. He must show that the risk is substantial when compared to the known and available alternatives. A State with a lethal injection protocol substantially similar to the protocol we uphold today would not create a risk that meets this standard.

* * *

Reasonable people of good faith disagree on the morality and efficacy of capital punishment, and for many who oppose it, no method of execution would ever be acceptable. But as Justice Frankfurter stressed in *Resweber,* "[o]ne must be on guard against finding in personal disapproval a reflection of more or less prevailing condemnation." 329 U.S., at 471, 67 S.Ct. 374 (concurring opinion). This Court has ruled that capital punishment is not prohibited under our Constitution, and that the States may enact laws specifying that sanction. "[T]he power of a State to pass laws means little if the State cannot enforce them." *McCleskey v. Zant,* 499 U.S. 467, 491, 111 S.Ct. 1454, 113 L.Ed.2d 517 (1991). State efforts to implement capital punishment must certainly comply with the Eighth Amendment, but what that Amendment prohibits is wanton exposure to "objectively intolerable ***62** risk," *Farmer,* 511 U.S., at 846, and n. 9, 114 S.Ct. 1970, not simply the possibility of pain.

Kentucky has adopted a method of execution believed to be the most humane available, one it shares with 35 other States. Petitioners agree that, if administered as intended, that procedure will result in a painless death. The risks of maladministration they have suggested—such as improper mixing of chemicals and improper setting of IVs by trained and experienced personnel—cannot remotely be characterized as "objectively intolerable." Kentucky's decision to adhere to its protocol despite these asserted risks, while adopting safeguards to protect against them, cannot be viewed as probative of the wanton infliction of pain under the Eighth ****1538** Amendment. Finally, the alternative that petitioners belatedly propose has problems of its own, and has never been tried by a single State.

Throughout our history, whenever a method of execution has been challenged in this Court as cruel and unusual, the Court has rejected the challenge. Our society has nonetheless steadily moved to more humane methods of carrying out capital punishment. The firing squad, hanging, the electric chair, and the gas chamber have each in turn given way to more humane methods, culminating in today's consensus on lethal injection. *Gomez v. United States Dist. Court for Northern Dist. of Cal.,* 503 U.S. 653, 657, 112 S.Ct. 1652, 118 L.Ed.2d 293 (1992) (STEVENS, J., dissenting); App. 755. The broad framework of the Eighth Amendment has accommodated this progress toward more humane methods of execution, and our approval of a particular method in the past has not precluded legislatures from taking the steps they deem appropriate, in light of new developments, to ensure humane capital punishment. There is no reason to suppose that today's decision will be any different. [7]

***63** The judgment below concluding that Kentucky's procedure is consistent with the Eighth Amendment is, accordingly, affirmed.

It is so ordered.

Justice ALITO, concurring.

I join the plurality opinion but write separately to explain my view of how the holding should be implemented. The opinion concludes that "a State's refusal to change its method [of execution] can be viewed as 'cruel and unusual' under the Eighth Amendment" if the State, "without a legitimate penological justification," rejects an alternative method that is "feasible" and "readily" available and that would "significantly reduce a substantial risk of severe pain." *Ante,* at 1532. Properly understood, this standard will not, as Justice THOMAS predicts, lead to litigation that enables "those seeking to abolish the death penalty ... to embroil the States in never-ending litigation concerning the adequacy of their execution procedures." *Post,* at 1562 (opinion concurring in judgment).

I

As the plurality opinion notes, the constitutionality of capital punishment is not before us in this case, and therefore we proceed on the assumption that the death penalty is constitutional. *Ante,* at 1530. From that assumption, it follows that there must be a constitutional means of carrying out a death sentence.

We also proceed in this case on the assumption that lethal injection is a constitutional means of execution. See *Gregg v. Georgia,* 428 U.S. 153, 175, 96 S.Ct. 2909, 49 L.Ed.2d 859 (1976) (joint opinion of Stewart, Powell, and STEVENS, JJ.) ("[I]n assessing a punishment selected by a democratically elected legislature against the ***64** constitutional measure, we presume its validity"). Lethal injection was adopted by the Federal Government and 36 States because it was thought to be the most humane method of execution, and petitioners here do not contend that lethal ****1539** injection should be abandoned in favor of any of the methods that it replaced—execution by electric chair, the gas chamber, hanging, or a firing squad. Since we assume for present purposes that lethal injection is constitutional, the use of that method by the Federal Government and the States must not be blocked by procedural requirements that cannot practicably be satisfied.

Prominent among the practical constraints that must be taken into account in considering the feasibility and availability of any suggested modification of a lethal injection protocol are the ethical restrictions applicable to medical professionals. The first step in the lethal injection protocols currently in use is the anesthetization of the prisoner. If this step is carried out properly, it is agreed, the prisoner will not experience pain during the remainder of the procedure. Every day, general anesthetics are administered to surgical patients in this country, and if the medical professionals who participate in these surgeries also participated in the anesthetization of prisoners facing execution by lethal injection, the risk of pain would be minimized. But the ethics rules of medical professionals—for reasons that I certainly do not question here—prohibit their participation in executions.

Guidelines issued by the American Medical Association (AMA) state that "[a]n individual's opinion on capital punishment is the personal moral decision of the individual," but that "[a] physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution." AMA, Code of Medical Ethics, Policy E–2.06 Capital Punishment (2000), online at http://www.ama-assn.org/ ama1/pub/upload/mm/369/e206capitalpunish.pdf (all Internet materials as visited ***65** Apr. 14, 2008, and available in Clerk of Court's case file). The guidelines explain:

> "Physician participation in an execution includes, but is not limited to, the following actions: prescribing or administering tranquilizers and other psychotropic agents and medications that are part of the execution procedure; monitoring vital signs on site or remotely (including monitoring electrocardiograms); attending or observing an execution as a physician; and rendering of technical advice regarding execution." *Ibid.*

The head of ethics at the AMA has reportedly opined that "[e]ven helping to design a more humane protocol would disregard the AMA code." Marris, Will Medics' Qualms Kill the Death Penalty? 441 Nature 8–9 (May 4, 2006).

The American Nurses Association (ANA) takes the position that participation in an execution "is a breach of the ethical traditions of nursing, and the *Code for Nurses*." ANA, Position Statement: Nurses' Participation in Capital Punishment (1994), online at http://nursingworld.org/ Main menu Categories/HealthcareandPolicyIssues/ ANAPositionStatements/EthicsandHuman Rights.aspx. This means, the ANA explains, that a nurse must not "take part in assessment, supervision or monitoring of the procedure or the prisoner; procuring, prescribing or preparing medications or solutions; inserting the intravenous catheter; injecting the lethal solution; and attending or witnessing the execution as a nurse." *Ibid.*

The National Association of Emergency Medical Technicians (NAEMT) holds that "[p]articipation in capital punishment is inconsistent with the ethical precepts and goals of the [Emergency Medical Services] profession." NAEMT, Position Statement on EMT and Paramedic Participation in Capital Punishment (June 9, 2006), online at http://www.naemt.org/aboutNAEMT/ ****1540** capital punishment.htm. The NAEMT's Position Statement advises that emergency medical ***66** technicians and paramedics should refrain from the same activities outlined in the ANA statement. *Ibid.*

Recent litigation in California has demonstrated the effect of such ethics rules. Michael Morales, who was convicted and sentenced to death for a 1981 murder, filed a federal civil rights action challenging California's lethal injection protocol, which, like Kentucky's, calls for the sequential administration of three drugs: sodium pentothal, pancuronium bromide, and potassium chloride. The District Court enjoined the State from

proceeding with the execution unless it either (1) used only sodium pentothal or another barbiturate or (2) ensured that an anesthesiologist was present to ensure that Morales remained unconscious throughout the process. *Morales v. Hickman,* 415 F.Supp.2d 1037, 1047 (N.D.Cal.2006). The Ninth Circuit affirmed the District Court's order, *Morales v. Hickman,* 438 F.3d 926, 931 (2006), and the State arranged for two anesthesiologists to be present for the execution. However, they subsequently concluded that "they could not proceed for reasons of medical ethics," *Morales v. Tilton,* 465 F.Supp.2d 972, 976 (N.D.Cal.2006), and neither Morales nor any other prisoner in California has since been executed, see Denno, The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty, 76 Ford. L.Rev. 49 (2007).

Objections to features of a lethal injection protocol must be considered against the backdrop of the ethics rules of medical professionals and related practical constraints. Assuming, as previously discussed, that lethal injection is not unconstitutional *per se,* it follows that a suggested modification of a lethal injection protocol cannot be regarded as "feasible" or "readily" available if the modification would require participation—either in carrying out the execution or in training those who carry out the execution—by persons whose professional ethics rules or traditions impede their participation.

***67** II

In order to show that a modification of a lethal injection protocol is required by the Eighth Amendment, a prisoner must demonstrate that the modification would "*significantly* reduce a *substantial* risk of *severe* pain." *Ante,* at 1532 (emphasis added). Showing merely that a modification would result in some reduction in risk is insufficient. Moreover, an inmate should be required to do more than simply offer the testimony of a few experts or a few studies. Instead, an inmate challenging a method of execution should point to a well-established scientific consensus. Only if a State refused to change its method in the face of such evidence would the State's conduct be comparable to circumstances that the Court has previously held to be in violation of the Eighth Amendment. See *Farmer v. Brennan,* 511 U.S. 825, 836, 114 S.Ct. 1970, 128 L.Ed.2d 811 (1994).

The present case well illustrates the need for this type of evidence. Although there has been a proliferation of litigation challenging current lethal injection protocols, evidence regarding alleged defects in these protocols and the supposed advantages of alternatives is strikingly haphazard and unreliable. As THE CHIEF JUSTICE and Justice BREYER both note, the much-discussed Lancet article, Koniaris, Zimmers, Lubarsky, & Sheldon, Inadequate Anaesthesia in Lethal Injection for Execution, 365 Lancet 1412 (Apr.2005), that prompted criticism of the three-drug protocol has now been questioned, see Groner, Inadequate Anaesthesia in Lethal Injection for Execution, 366 Lancet ****1541** 1073, 1073 (Sept.2005). And the lack of clear guidance in the currently available scientific literature is dramatically illustrated by the conclusions reached by petitioners and by Justice STEVENS regarding what they view as superior alternatives to the three-drug protocol.

Petitioners' chief argument is that Kentucky's procedure violates the Eighth Amendment because it does not employ ***68** a one-drug protocol involving a lethal dose of an anesthetic. By "relying ... on a lethal dose of an anesthetic," petitioners contend, Kentucky "would virtually eliminate the risk of pain." Brief for Petitioners 51. Petitioners point to expert testimony in the trial court that "a three-gram dose of thiopental would cause death within three minutes to fifteen minutes." *Id.*, at 54, n. 16.

The accuracy of that testimony is not universally accepted. Indeed, the medical authorities in the Netherlands, where assisted suicide is legal, have recommended against the use of a lethal dose of a barbiturate. An *amicus* supporting petitioners, Dr. Robert D. Truog, Professor of Medical Ethics and Anesthesiology at Harvard Medical School, has made the following comments about the use of a lethal dose of a barbiturate:

> "A number of experts have said that 2 or 3 or 5 g[rams] of pentothal is absolutely going to be lethal. The fact is that, at least in this country, none of us have any experience with this ....
>
> "If we go to Holland, where euthanasia is legal, and [we] look at a study from 2000 of 535 cases of euthanasia, in 69% of those cases, they used a paralytic agent. Now, what do they know that we haven't figured out yet? I think what they know is that it's actually very difficult to kill someone with just a big dose of a barbiturate. And, in fact, they report that in 6% of those cases, there were

problems with completion. And in I think five of those, the person actually woke up, came back out of coma." Perspective Roundtable: Physicians and Execution—Highlights from a Discussion of Lethal Injection, 358 New England J. Med. 448 (2008).

Justice STEVENS does not advocate a one-drug protocol but argues that "States wishing to decrease the risk that future litigation will delay executions or invalidate their protocols would do well to reconsider their continued use of ***69** pancuronium bromide" in the second step of the three-drug protocol. [*] *Post,* at 1546 (opinion concurring in judgment). But this very drug, pancuronium bromide, is recommended by the Royal Dutch Society for the Advancement of Pharmacy as the second of the two drugs to be used in cases of euthanasia. See Kimsma, Euthanasia and Euthanizing Drugs in The Netherlands, reprinted in Drug Use in Assisted Suicide and Euthanasia 193, 200, 204 (M. Battin & A. Lipman eds.1996).

My point in citing the Dutch study is not that a multidrug protocol is in fact better than a one-drug protocol or that it is advisable to use pancuronium bromide. Rather, my point is that public policy on the death penalty, an issue that stirs deep emotions, cannot be dictated by the testimony ****1542** of an expert or two or by judicial findings of fact based on such testimony.

III

The seemingly endless proceedings that have characterized capital litigation during the years following *Gregg* are well documented. In 1989, the Report of the Judicial Conference's Ad Hoc Committee on Federal Habeas Corpus in Capital Cases, chaired by Justice Powell, noted the lengthy delays produced by collateral litigation in death penalty cases. See Committee Report and Proposal 2–4. The Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA) was designed to address this problem. See, *e.g., Woodford v. Garceau,* 538 U.S. 202, 206, 123 S.Ct. 1398, 155 L.Ed.2d 363 (2003) ("Congress enacted AEDPA to reduce delays in the execution of ***70** state and federal criminal sentences, particularly in capital cases ... " (citing *Williams v. Taylor,* 529 U.S. 362, 386, 120 S.Ct. 1495, 146 L.Ed.2d 389 (2000) (opinion of STEVENS, J.))); H.R.Rep. No. 104–23, p. 8 (1995) (stating that AEDPA was "designed to curb the abuse of the habeas corpus process, and particularly to address the problem of delay and repetitive litigation in capital cases").

Misinterpretation of the standard set out in the plurality opinion or adoption of the standard favored by the dissent and Justice BREYER would create a grave danger of extended delay. The dissenters and Justice BREYER would hold that the protocol used in carrying out an execution by lethal injection violates the Eighth Amendment if it creates an "*untoward,* readily avoidable risk of inflicting severe and unnecessary pain." See *post,* at 1572 (GINSBURG, J., dissenting) (emphasis added); *post,* at 1563 (BREYER, J., concurring in judgment). Determining whether a risk is "untoward," we are told, requires a weighing of three factors—the severity of the pain that may occur, the likelihood of this pain, and the availability of alternative methods. *Post,* at 1568 (GINSBURG, J., dissenting). We are further informed that "[t]he three factors are interrelated; a strong showing on one reduces the importance of the others." *Ibid.*

An "untoward" risk is presumably a risk that is "unfortunate" or "marked by or causing trouble or unhappiness." Webster's Third New International Dictionary 2513 (1971); Random House Dictionary of the English Language 1567 (1967). This vague and malleable standard would open the gates for a flood of litigation that would go a long way toward bringing about the end of the death penalty as a practical matter. While I certainly do not suggest that this is the intent of the Justices who favor this test, the likely consequences are predictable.

The issue presented in this case—the constitutionality of a *method* of execution—should be kept separate from the controversial issue of the death penalty itself. If the Court wishes to reexamine the latter issue, it should do so directly, ***71** as Justice STEVENS now suggests. *Post,* at 1548 – 1549. The Court should not produce a *de facto* ban on capital punishment by adopting method-of-execution rules that lead to litigation gridlock.

Justice STEVENS, concurring in the judgment.

When we granted certiorari in this case, I assumed that our decision would bring the debate about lethal injection as a method of execution to a close. It now seems clear that it will not. The question whether a similar three-drug protocol may be used in other States remains open, and may well be answered differently in a future case on the basis of a more complete record.

Instead of ending the controversy, I am now convinced that this case will **1543 generate debate not only about the constitutionality of the three-drug protocol, and specifically about the justification for the use of the paralytic agent, pancuronium bromide, but also about the justification for the death penalty itself.

I

Because it masks any outward sign of distress, pancuronium bromide creates a risk that the inmate will suffer excruciating pain before death occurs. There is a general understanding among veterinarians that the risk of pain is sufficiently serious that the use of the drug should be proscribed when an animal's life is being terminated.[1] As a *72 result of this understanding among knowledgeable professionals, several States—including Kentucky—have enacted legislation prohibiting use of the drug in animal euthanasia. See 2 Ky. Admin. Regs., tit. 201, ch. 16:090, § 5(1) (2004).[2] It is unseemly—to say the least—that Kentucky may well kill *73 petitioners using a drug that it would not permit to be used on their pets.

Use of pancuronium bromide is particularly disturbing because—as the trial court specifically found in this case—it serves "no therapeutic purpose." App. 763. The **1544 drug's primary use is to prevent involuntary muscle movements, and its secondary use is to stop respiration. In my view, neither of these purposes is sufficient to justify the risk inherent in the use of the drug.

The plurality believes that preventing involuntary movement is a legitimate justification for using pancuronium bromide because "[t]he Commonwealth has an interest in preserving the dignity of the procedure, especially where convulsions or seizures could be misperceived as signs of consciousness or distress." *Ante,* at 1535. This is a woefully inadequate justification. Whatever minimal interest there may be in ensuring that a condemned inmate dies a dignified death, and that witnesses to the execution are not made uncomfortable by an incorrect belief (which could easily be corrected) that the inmate is in pain, is vastly outweighed by the risk that the inmate is actually experiencing excruciating pain that no one can detect.[3] Nor is there any necessity for pancuronium bromide to be included in the cocktail to inhibit respiration when it is immediately followed by potassium chloride, which causes death quickly by stopping the inmate's heart.

*74 Moreover, there is no nationwide endorsement of the use of pancuronium bromide that merits any special presumption of respect. While state legislatures have approved lethal injection as a humane method of execution, the majority have not enacted legislation specifically approving the use of pancuronium bromide, or any given combination of drugs.[4] And when the Colorado Legislature focused on the issue, it specified a one-drug protocol consisting solely of sodium thiopental. See Colo.Rev.Stat. Ann. § 18–1.3–1202 (2007).[5] **1545 In the majority of States that use the three-drug protocol, the drugs were selected by unelected department of correction *75 officials with no specialized medical knowledge and without the benefit of expert assistance or guidance. As such, their drug selections are not entitled to the kind of deference afforded legislative decisions.

Nor should the failure of other state legislatures, or of Congress, to outlaw the use of the drug on condemned prisoners be viewed as a nationwide endorsement of an unnecessarily dangerous practice. Even in those States where the legislature specifically approved the use of a paralytic agent, review of the decisions that led to the adoption of the three-drug protocol has persuaded me that they are the product of " 'administrative convenience' " and a "stereotyped reaction" to an issue, rather than a careful analysis of relevant considerations favoring or disfavoring a conclusion. See *Mathews v. Lucas,* 427 U.S. 495, 519, 520–521, 96 S.Ct. 2755, 49 L.Ed.2d 651 (1976) (STEVENS, J., dissenting). Indeed, the trial court found that "the various States simply fell in line" behind Oklahoma, adopting the protocol without any critical analysis of whether it was the best available alternative.[6] App. 756; see also *post,* at 1569 (GINSBURG, J., dissenting).

New Jersey's experience with the creation of a lethal injection protocol is illustrative. When New Jersey restored the death penalty in 1983, its legislature "fell in line" and enacted a statute that called for inmates to be executed by "continuous, intravenous administration until the person is dead of a lethal quantity of an ultrashort-acting barbiturate in combination with a chemical paralytic agent in a quantity sufficient to cause

death." N.J. Stat. Ann. § 2C:49–2 (West 2005). New Jersey Department of Corrections (DOC) officials, including doctors and administrators, immediately expressed ***76** concern. The capital sentencing unit's chief doctor, for example, warned the assistant commissioner that he had " 'concerns ... in regard to the chemical substance classes from which the lethal substances may be selected.' " Edwards, New Jersey's Long Waltz With Death, 170 N.J.L.J. 657, 673 (2002).[7] Based on these concerns, the former DOC Commissioner lobbied the legislature to amend the lethal injection statute to provide DOC with discretion to select more humane drugs: " '[We wanted] a generic statement, like 'drugs to be determined and identified by the commissioner, or the attorney general, or the Department of Health' .... 'Who knew what the future was going to bring?' " *Ibid.* And these concerns likely motivated the DOC's decision to adopt a protocol that omitted pancuronium bromide—despite the legislature's failure to act on the proposed ****1546** amendment. See Denno, When Legislatures Delegate Death: The Troubling Paradox Behind State Uses of Electrocution and Lethal Injection and What It Says About Us, 63 Ohio St. L.J. 63, 117–118, 233 (2002) (explaining that the New Jersey protocol in effect in 2002 called for use of a two-drug cocktail consisting of sodium thiopental and potassium chloride).

Indeed, DOC officials seemed to harbor the same concerns when they undertook to revise New Jersey's lethal injection protocol in 2005. At a public hearing on the proposed amendment, the DOC supervisor of legal and legislative affairs told attendees that the drugs to be used in the lethal injection protocol were undetermined:

> "Those substances have not been determined at this point because when and if an execution is scheduled the ***77** [DOC] will be doing research and determining the state-of-the-art drugs at that point in time .... We have not made a decision on which specific drugs because we will have several months once we know that somebody is going to be executed and it will give us the opportunity at that point to decide which would be the most humane.
>
> "And things change. We understand that the state-of-the-art is changing daily so to say we are going to use something today when something may be more humane becomes known later wouldn't make sense for us." Tr. of Public Hearing on Proposed Amendments to the New Jersey Lethal Injection Protocol 36 (Feb. 4, 2005).

It is striking that when this state agency—with some specialized medical knowledge and with the benefit of some expert assistance and guidance—focused on the issue, it disagreed with the legislature's "stereotyped reaction," *Mathews,* 427 U.S., at 520, 521, 96 S.Ct. 2755 (STEVENS, J., dissenting), and specified a two-drug protocol that omitted pancuronium bromide.[8]

In my view, therefore, States wishing to decrease the risk that future litigation will delay executions or invalidate their protocols would do well to reconsider their continued use of pancuronium bromide.[9]

***78** II

The thoughtful opinions written by THE CHIEF JUSTICE and by Justice GINSBURG have persuaded me that current decisions by state legislatures, by the Congress of the United States, and by this Court to retain the death penalty as a part of our law are the product of habit and inattention rather than an acceptable deliberative process that weighs the costs and risks of administering that penalty against its identifiable benefits, and rest in part on a faulty assumption about the retributive force of the death penalty.

In *Gregg v. Georgia,* 428 U.S. 153, 96 S.Ct. 2909, 49 L.Ed.2d 859 (1976), we explained ****1547** that unless a criminal sanction serves a legitimate penological function, it constitutes "gratuitous infliction of suffering" in violation of the Eighth Amendment. We then identified three societal purposes for death as a sanction: incapacitation, deterrence, and retribution. See *id.,* at 183, and n. 28, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and STEVENS, JJ.). In the past three decades, however, each of these rationales has been called into question.

While incapacitation may have been a legitimate rationale in 1976, the recent rise in statutes providing for life imprisonment without the possibility of parole demonstrates that incapacitation is neither a necessary nor a sufficient justification for the death penalty.[10] Moreover, a recent poll indicates that support for the death penalty drops significantly when life without the possibility of parole is presented as an ***79** alternative option.[11] And the available sociological

evidence suggests that juries are less likely to impose the death penalty when life without parole is available as a sentence. [12]

The legitimacy of deterrence as an acceptable justification for the death penalty is also questionable, at best. Despite 30 years of empirical research in the area, there remains no reliable statistical evidence that capital punishment in fact deters potential offenders. [13] In the absence of such evidence, deterrence cannot serve as a sufficient penological justification for this uniquely severe and irrevocable punishment.

We are left, then, with retribution as the primary rationale for imposing the death penalty. And indeed, it is the retribution rationale that animates much of the remaining enthusiasm ***80** for the death penalty. [14] As Lord Justice Denning argued in ****1548** 1950, " 'some crimes are so outrageous that society insists on adequate punishment, because the wrong-doer deserves it, irrespective of whether it is a deterrent or not.' " See *Gregg,* 428 U.S., at 184, n. 30, 96 S.Ct. 2909. Our Eighth Amendment jurisprudence has narrowed the class of offenders eligible for the death penalty to include only those who have committed outrageous crimes defined by specific aggravating factors. It is the cruel treatment of victims that provides the most persuasive arguments for prosecutors seeking the death penalty. A natural response to such heinous crimes is a thirst for vengeance. [15]

At the same time, however, as the thoughtful opinions by THE CHIEF JUSTICE and Justice GINSBURG make pellucidly clear, our society has moved away from public and painful retribution toward ever more humane forms of punishment. State-sanctioned killing is therefore becoming more and more anachronistic. In an attempt to bring executions in line with our evolving standards of decency, we have adopted increasingly less painful methods of execution, and then declared previous methods barbaric and archaic. But by requiring that an execution be relatively painless, we necessarily protect the inmate from enduring any punishment that is ***81** comparable to the suffering inflicted on his victim. [16] This trend, while appropriate and required by the Eighth Amendment's prohibition on cruel and unusual punishment, actually undermines the very premise on which public approval of the retribution rationale is based. See, *e.g.,* Kaufman–Osborn, Regulating Death: Capital Punishment and the Late Liberal State, 111 Yale L.J. 681, 704 (2001) (explaining that there is "a tension between our desire to realize the claims of retribution by killing those who kill, and ... a method [of execution] that, because it seems to do no harm other than killing, cannot satisfy the intuitive sense of equivalence that informs this conception of justice"); A. Sarat, When the State Kills: Capital Punishment and the American Condition 60–84 (2001).

Full recognition of the diminishing force of the principal rationales for retaining the death penalty should lead this Court and legislatures to reexamine the question recently posed by Professor Salinas, a former Texas prosecutor and judge: "Is it time to Kill the Death Penalty?" See Salinas, 34 Am. J.Crim. L. 39 (2006). The time for a dispassionate, impartial comparison of the enormous costs that death penalty litigation imposes on society with the ****1549** benefits that it produces has surely arrived. [17]

***82** III

"[A] penalty may be cruel and unusual because it is excessive and serves no valid legislative purpose." *Furman v. Georgia,* 408 U.S. 238, 331, 92 S.Ct. 2726, 33 L.Ed.2d 346 (1972) (Marshall, J., concurring); see also *id.,* at 332, 92 S.Ct. 2726 ("The entire thrust of the Eighth Amendment is, in short, against 'that which is excessive' "). Our cases holding that certain sanctions are "excessive," and therefore prohibited by the Eighth Amendment, have relied ***83** heavily on "objective criteria," such as legislative enactments. See, *e.g., Solem v. Helm,* 463 U.S. 277, 292, 103 S.Ct. 3001, 77 L.Ed.2d 637 (1983); *Harmelin v. Michigan,* 501 U.S. 957, 111 S.Ct. 2680, 115 L.Ed.2d 836 (1991); *United States v. Bajakajian,* 524 U.S. 321, 118 S.Ct. 2028, 141 L.Ed.2d 314 (1998). In our recent decision in *Atkins v. Virginia,* 536 U.S. 304, 122 S.Ct. 2242, 153 L.Ed.2d 335 (2002), holding that death is an excessive sanction for a mentally retarded defendant, we also relied heavily on opinions written by Justice White holding that the death penalty is an excessive punishment for the crime of raping a 16–year–old woman, *Coker v. Georgia,* 433 U.S. 584, 97 S.Ct. 2861, 53 L.Ed.2d 982 (1977), and for a murderer who did not intend to kill, *Enmund v. Florida,* 458 U.S. 782, 102 S.Ct. 3368, 73 L.Ed.2d 1140 (1982). In those opinions we acknowledged that "objective evidence, though of great importance, did not 'wholly determine' the controversy,

'for the Constitution contemplates that in the end our own judgment will be brought to bear on the question of the acceptability of the death **1550 penalty under the Eighth Amendment.' " *Atkins,* 536 U.S., at 312, 122 S.Ct. 2242 (quoting *Coker,* 433 U.S., at 597, 97 S.Ct. 2861 (plurality opinion)).

Justice White was exercising his own judgment in 1972 when he provided the decisive vote in *Furman,* the case that led to a nationwide reexamination of the death penalty. His conclusion that death amounted to "cruel and unusual punishment in the constitutional sense" as well as the "dictionary sense," rested on both an uncontroversial legal premise and on a factual premise that he admittedly could not "prove" on the basis of objective criteria. 408 U.S., at 312, 313, 92 S.Ct. 2726 (concurring opinion). As a matter of law, he correctly stated that the "needless extinction of life with only marginal contributions to any discernible social or public purposes ... would be patently excessive" and violative of the Eighth Amendment. *Id.,* at 312, 92 S.Ct. 2726. As a matter of fact, he stated, "like my Brethren, I must arrive at judgment; and I can do no more than state a conclusion based on 10 years of almost daily exposure to the facts and circumstances of hundreds and hundreds of federal and state criminal cases involving crimes for which death is the authorized penalty." *84 *Id.,* at 313, 92 S.Ct. 2726. I agree with Justice White that there are occasions when a Member of this Court has a duty to make judgments on the basis of data that falls short of absolute proof.

Our decisions in 1976 upholding the constitutionality of the death penalty relied heavily on our belief that adequate procedures were in place that would avoid the danger of discriminatory application identified by Justice Douglas' opinion in *Furman, id.,* at 240–257, 92 S.Ct. 2726 (concurring opinion), of arbitrary application identified by Justice Stewart, *id.,* at 306, 92 S.Ct. 2726 (same), and of excessiveness identified by Justices Brennan and Marshall. In subsequent years a number of our decisions relied on the premise that "death is different" from every other form of punishment to justify rules minimizing the risk of error in capital cases. See, *e.g., Gardner v. Florida,* 430 U.S. 349, 357–358, 97 S.Ct. 1197, 51 L.Ed.2d 393 (1977) (plurality opinion). Ironically, however, more recent cases have endorsed procedures that provide less protections to capital defendants than to ordinary offenders.

Of special concern to me are rules that deprive the defendant of a trial by jurors representing a fair cross section of the community. Litigation involving both challenges for cause and peremptory challenges has persuaded me that the process of obtaining a "death qualified jury" is really a procedure that has the purpose and effect of obtaining a jury that is biased in favor of conviction. The prosecutorial concern that death verdicts would rarely be returned by 12 randomly selected jurors should be viewed as objective evidence supporting the conclusion that the penalty is excessive. [18]

Another serious concern is that the risk of error in capital cases may be greater than in other cases because the facts are often so disturbing that the interest in making sure the *85 crime does not go unpunished may overcome residual doubt concerning the identity of the offender. Our former emphasis on the importance of ensuring that decisions in death cases be adequately supported by reason rather **1551 than emotion, *Gardner,* 430 U.S. 349, 97 S.Ct. 1197, 51 L.Ed.2d 393, has been undercut by more recent decisions placing a thumb on the prosecutor's side of the scales. Thus, in *Kansas v. Marsh,* 548 U.S. 163, 126 S.Ct. 2516, 165 L.Ed.2d 429 (2006), the Court upheld a state statute that requires imposition of the death penalty when the jury finds that the aggravating and mitigating factors are in equipoise. And in *Payne v. Tennessee,* 501 U.S. 808, 111 S.Ct. 2597, 115 L.Ed.2d 720 (1991), the Court overruled earlier cases and held that "victim impact" evidence relating to the personal characteristics of the victim and the emotional impact of the crime on the victim's family is admissible despite the fact that it sheds no light on the question of guilt or innocence or on the moral culpability of the defendant, and thus serves no purpose other than to encourage jurors to make life or death decisions on the basis of emotion rather than reason.

A third significant concern is the risk of discriminatory application of the death penalty. While that risk has been dramatically reduced, the Court has allowed it to continue to play an unacceptable role in capital cases. Thus, in *McCleskey v. Kemp,* 481 U.S. 279, 107 S.Ct. 1756, 95 L.Ed.2d 262 (1987), the Court upheld a death sentence despite the "strong probability that [the defendant's] sentencing jury ... was influenced by the fact that [he was] black and his victim was white." *Id.,* at 366, 107 S.Ct. 1756 (STEVENS, J., dissenting); see also *Evans v. State,* 396 Md. 256, 323, 914 A.2d 25, 64 (2006), cert.

denied, 552 U.S. 835, 128 S.Ct. 65, 169 L.Ed.2d 53 (2007) (affirming a death sentence despite the existence of a study showing that "the death penalty is *statistically* more likely to be pursued against a black person who murders a white victim than against a defendant in any other racial combination").

Finally, given the real risk of error in this class of cases, the irrevocable nature of the consequences is of decisive importance ***86** to me. Whether or not any innocent defendants have actually been executed, abundant evidence accumulated in recent years has resulted in the exoneration of an unacceptable number of defendants found guilty of capital offenses. See Garrett, Judging Innocence, 108 Colum. L.Rev. 55 (2008); Risinger, Innocents Convicted: An Empirically Justified Factual Wrongful Conviction Rate, 97 J.Crim. L. & C. 761 (2007). The risk of executing innocent defendants can be entirely eliminated by treating any penalty more severe than life imprisonment without the possibility of parole as constitutionally excessive.

In sum, just as Justice White ultimately based his conclusion in *Furman* on his extensive exposure to countless cases for which death is the authorized penalty, I have relied on my own experience in reaching the conclusion that the imposition of the death penalty represents "the pointless and needless extinction of life with only marginal contributions to any discernible social or public purposes. A penalty with such negligible returns to the State [is] patently excessive and cruel and unusual punishment violative of the Eighth Amendment." *Furman,* 408 U.S., at 312, 92 S.Ct. 2726 (White, J., concurring). [19]

****1552 *87** IV

The conclusion that I have reached with regard to the constitutionality of the death penalty itself makes my decision in this case particularly difficult. It does not, however, justify a refusal to respect precedents that remain a part of our law. This Court has held that the death penalty is constitutional, and has established a framework for evaluating the constitutionality of particular methods of execution. Under those precedents, whether as interpreted by THE CHIEF JUSTICE or Justice GINSBURG, I am persuaded that the evidence adduced by petitioners fails to prove that Kentucky's lethal injection protocol violates the Eighth Amendment. Accordingly, I join the Court's judgment.

Justice SCALIA, with whom Justice THOMAS joins, concurring in the judgment.

I join the opinion of Justice THOMAS concurring in the judgment. I write separately to provide what I think is needed response to Justice STEVENS' separate opinion.

I

Justice STEVENS concludes as follows: "[T]he imposition of the death penalty represents the pointless and needless extinction of life with only marginal contributions to any discernible social or public purposes. A penalty with such negligible returns to the State [is] patently excessive and cruel and unusual punishment violative of the Eighth Amendment." *Ante,* at 1551 (opinion concurring in judgment) (internal quotation marks omitted; second bracket in original).

This conclusion is insupportable as an interpretation of the Constitution, which generally leaves it to democratically elected legislatures rather than courts to decide what makes significant contribution to social or public purposes. Besides that more general proposition, the very text of the document recognizes that the death penalty is a permissible legislative choice. The Fifth Amendment expressly requires a ***88** presentment or indictment of a grand jury to hold a person to answer for "a capital, or otherwise infamous crime," and prohibits deprivation of "life" without due process of law. U.S. Const., Amdt. 5. The same Congress that proposed the Eighth Amendment also enacted the Act of April 30, 1790, which made several offenses punishable by death. 1 Stat. 112; see also *Gregg v. Georgia,* 428 U.S. 153, 176–178, 96 S.Ct. 2909, 49 L.Ed.2d 859 (1976) (joint opinion of Stewart, Powell, and STEVENS, JJ.). Writing in 1977, Professor Hugo Bedau—no friend of the death penalty himself—observed that "[u]ntil fifteen years ago, save for a few mavericks, no one gave any credence to the possibility of ending the death penalty by judicial interpretation of constitutional law." The Courts, the Constitution, and Capital Punishment 118 (1977). There is simply no legal authority for the proposition that the imposition of death as a criminal penalty is unconstitutional other than the opinions in *Furman v. Georgia,* 408 U.S. 238, 92

S.Ct. 2726, 33 L.Ed.2d 346 (1972), which established a nationwide moratorium on capital **1553 punishment that Justice STEVENS had a hand in ending four years later in *Gregg*.

II

What prompts Justice STEVENS to repudiate his prior view and to adopt the astounding position that a criminal sanction expressly mentioned in the Constitution violates the Constitution? His analysis begins with what he believes to be the "uncontroversial legal premise" that the " 'extinction of life with only marginal contributions to any discernible social or public purposes ... would be patently excessive' and violative of the Eighth Amendment." *Ante,* at 1550 (quoting in part *Furman, supra,* at 312, 92 S.Ct. 2726 (White, J., concurring)); see also *ante,* at 1546 – 1547 (citing *Gregg, supra,* at 183, and n. 28, 96 S.Ct. 2909). Even if that were uncontroversial in the abstract (and it is certainly not what occurs to me as the meaning of "cruel and unusual punishments"), it is assuredly controversial (indeed, flatout wrong) as applied to a mode of punishment that is explicitly sanctioned by the Constitution. As to that, *the* *89 *people* have determined whether there is adequate contribution to social or public purposes, and it is no business of unelected judges to set that judgment aside. But even if we grant Justice STEVENS his "uncontroversial premise," his application of that premise to the current practice of capital punishment does not meet the "heavy burden [that] rests on those who would attack the judgment of the representatives of the people." *Gregg, supra,* at 175, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and STEVENS, JJ.). That is to say, Justice STEVENS' policy analysis of the constitutionality of capital punishment fails on its own terms.

According to Justice STEVENS, the death penalty promotes none of the purposes of criminal punishment because it neither prevents more crimes than alternative measures nor serves a retributive purpose. *Ante,* at 1546 – 1547. He argues that "the recent rise in statutes providing for life imprisonment without the possibility of parole" means that States have a ready alternative to the death penalty. *Ibid.* Moreover, "[d]espite 30 years of empirical research in the area, there remains no reliable statistical evidence that capital punishment in fact deters potential offenders." *Ante,* at 1547. Taking the points together, Justice STEVENS concludes that the availability of alternatives, and what he describes as the unavailability of "reliable statistical evidence," renders capital punishment unconstitutional. In his view, the benefits of capital punishment—as compared to other forms of punishment such as life imprisonment—are outweighed by the costs.

These conclusions are not supported by the available data. Justice STEVENS' analysis barely acknowledges the "significant body of recent evidence that capital punishment may well have a deterrent effect, possibly a quite powerful one." Sunstein & Vermeule, Is Capital Punishment Morally Required? Acts, Omissions, and Life–Life Tradeoffs, 58 Stan. L.Rev. 703, 706 (2005); see also *id.,* at 706, n. 9 (listing the approximately half a dozen studies supporting this conclusion). *90 According to a "leading national study," "each execution prevents some eighteen murders, on average." *Id.,* at 706. "If the current evidence is even roughly correct ... then a refusal to impose capital punishment will effectively condemn numerous innocent people to death." *Ibid.*

Of course, it may well be that the empirical studies establishing that the death penalty has a powerful deterrent effect are incorrect, and some scholars have disputed its deterrent value. See *ante,* at 1547, n. **1554 13. But that is not the point. It is simply not our place to choose one set of responsible empirical studies over another in interpreting the Constitution. Nor is it our place to demand that state legislatures support their criminal sanctions with foolproof empirical studies, rather than commonsense predictions about human behavior. "The value of capital punishment as a deterrent of crime is a complex factual issue the resolution of which properly rests with the legislatures, which can evaluate the results of statistical studies in terms of their own local conditions and with a flexibility of approach that is not available to the courts." *Gregg, supra,* at 186, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and STEVENS, JJ.). Were Justice STEVENS' current view the constitutional test, even his own preferred criminal sanction—life imprisonment without the possibility of parole—may fail constitutional scrutiny, because it is entirely unclear that enough empirical evidence supports that sanction as compared to alternatives such as life with the possibility of parole.

But even if Justice STEVENS' assertion about the deterrent value of the death penalty were correct, the death

penalty would yet be constitutional (as he concedes) if it served the appropriate purpose of retribution. I would think it difficult indeed to prove that a criminal sanction fails to serve a retributive purpose—a judgment that strikes me as inherently subjective and insusceptible of judicial review. Justice STEVENS, however, concludes that, because the Eighth Amendment "protect[s] the inmate from enduring any punishment ***91** that is comparable to the suffering inflicted on his victim," capital punishment serves no retributive purpose at all. *Ante,* at 1548. The infliction of any pain, according to Justice STEVENS, violates the Eighth Amendment's prohibition against cruel and unusual punishments, but so too does the imposition of capital punishment *without pain* because a criminal penalty lacks a retributive purpose unless it inflicts pain commensurate with the pain that the criminal has caused. In other words, if a punishment is not retributive enough, it is not retributive at all. To state this proposition is to refute it, as Justice STEVENS once understood. "[T]he decision that capital punishment may be the appropriate sanction in extreme cases is an expression of the community's belief that certain crimes are themselves so grievous an affront to humanity that the only adequate response may be the penalty of death." *Gregg,* 428 U.S., at 184, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and STEVENS, JJ.).

Justice STEVENS' final refuge in his cost-benefit analysis is a familiar one: There is a risk that an innocent person might be convicted and sentenced to death—though not a risk that Justice STEVENS can quantify, because he lacks a single example of a person executed for a crime he did not commit in the current American system. See *ante,* at 1550 – 1551. His analysis of this risk is thus a series of sweeping condemnations that, if taken seriously, would prevent any punishment under any criminal justice system. According to him, "[t]he prosecutorial concern that death verdicts would rarely be returned by 12 randomly selected jurors should be viewed as objective evidence supporting the conclusion that the penalty is excessive." *Ante,* at 1550. But prosecutors undoubtedly have a similar concern that *any* unanimous conviction would rarely be returned by 12 randomly selected jurors. That is why they, like defense counsel, are permitted to use the challenges for cause and peremptory challenges that Justice STEVENS finds so troubling, in order to arrive at a jury that both sides believe will be more likely to do justice in a ***92** particular case. Justice ****1555** STEVENS' concern that prosecutors will be inclined to challenge jurors who will not find a person guilty supports not his conclusion, but the separate (and equally erroneous) conclusion that peremptory challenges and challenges for cause are unconstitutional. According to Justice STEVENS, "the risk of error in capital cases may be greater than in other cases because the facts are often so disturbing that the interest in making sure the crime does not go unpunished may overcome residual doubt concerning the identity of the offender." *Ibid.* That rationale, however, supports not Justice STEVENS' conclusion that the death penalty is unconstitutional, but the more sweeping proposition that any conviction in a case in which facts are disturbing is suspect—including, of course, convictions resulting in life without parole in those States that do not have capital punishment. The same is true of Justice STEVENS' claim that there is a risk of "discriminatory application of the death penalty." *Ante,* at 1551. The same could be said of any criminal penalty, including life without parole; there is no proof that in this regard the death penalty is distinctive.

But of all Justice STEVENS' criticisms of the death penalty, the hardest to take is his bemoaning of "the enormous costs that death penalty litigation imposes on society," including the "burden on the courts and the lack of finality for victim's families." *Ante,* at 1548, and n. 17. Those costs, those burdens, and that lack of finality are in large measure the creation of Justice STEVENS and other Justices opposed to the death penalty, who have "encumber[ed][it] ... with unwarranted restrictions neither contained in the text of the Constitution nor reflected in two centuries of practice under it"—the product of their policy views "not shared by the vast majority of the American people." *Kansas v. Marsh,* 548 U.S. 163, 186, 126 S.Ct. 2516, 165 L.Ed.2d 429 (2006) (SCALIA, J., concurring).

***93** III

But actually none of this really matters. As Justice STEVENS explains, " 'objective evidence, though of great importance, [does] not wholly determine the controversy, for the Constitution contemplates that in the end *our own judgment will be brought to bear on the question of the acceptability of the death penalty under the Eighth Amendment*.' " *Ante,* at 1549 (quoting *Atkins v. Virginia,* 536 U.S. 304, 312, 122 S.Ct. 2242, 153 L.Ed.2d 335 (2002); emphasis added; some internal quotation marks omitted). "I have relied *on my own experience* in reaching

the conclusion that the imposition of the death penalty" is unconstitutional. *Ante,* at 1551 (emphasis added).

Purer expression cannot be found of the principle of rule by judicial fiat. In the face of Justice STEVENS' experience, the experience of all others is, it appears, of little consequence. The experience of the state legislatures and the Congress—who retain the death penalty as a form of punishment—is dismissed as "the product of habit and inattention rather than an acceptable deliberative process." *Ante,* at 1546. The experience of social scientists whose studies indicate that the death penalty deters crime is relegated to a footnote. *Ante,* at 1548, n. 13. The experience of fellow citizens who support the death penalty is described, with only the most thinly veiled condemnation, as stemming from a "thirst for vengeance." *Ante,* at 1548. It is Justice STEVENS' experience that reigns over all.

* * *

I take no position on the desirability of the death penalty, except to say that its ****1556** value is eminently debatable and the subject of deeply, indeed passionately, held views —which means, to me, that it is preeminently not a matter to be resolved here. And especially not when it is explicitly permitted by the Constitution.

***94** Justice THOMAS, with whom Justice SCALIA joins, concurring in the judgment.

Although I agree that petitioners have failed to establish that Kentucky's lethal injection protocol violates the Eighth Amendment, I write separately because I cannot subscribe to the plurality opinion's formulation of the governing standard. As I understand it, that opinion would hold that a method of execution violates the Eighth Amendment if it poses a substantial risk of severe pain that could be significantly reduced by adopting readily available alternative procedures. *Ante,* at 1532. This standard—along with petitioners' proposed "unnecessary risk" standard and the dissent's "untoward risk" standard, *post,* at 1567 (opinion of Ginsburg, J.) —finds no support in the original understanding of the Cruel and Unusual Punishments Clause or in our previous method-of-execution cases; casts constitutional doubt on long-accepted methods of execution; and injects the Court into matters it has no institutional capacity to resolve. Because, in my view, a method of execution violates the Eighth Amendment only if it is deliberately designed to inflict pain, I concur only in the judgment.

I

The Eighth Amendment's prohibition on the "inflict[ion]" of "cruel and unusual punishments" must be understood in light of the historical practices that led the Framers to include it in the Bill of Rights. Justice STEVENS' ruminations notwithstanding, see *ante,* at 1546 – 1552 (opinion concurring in judgment), it is clear that the Eighth Amendment does not prohibit the death penalty. That is evident both from the ubiquity of the death penalty in the founding era, see S. Banner, The Death Penalty: An American History 23 (2002) (hereinafter Banner) (noting that, in the late 18th century, the death penalty was "the standard penalty for all serious crimes"), and from the Constitution's express provision for capital punishment, see, *e.g.,* Amdt. 5 (requiring an indictment ***95** or presentment of a grand jury to hold a person for "a capital, or otherwise infamous crime," and prohibiting deprivation of "life" without due process of law).

That the Constitution permits capital punishment in principle does not, of course, mean that all methods of execution are constitutional. In English and early colonial practice, the death penalty was not a uniform punishment, but rather a range of punishments, some of which the Framers likely regarded as cruel and unusual. Death by hanging was the most common mode of execution both before and after 1791, and there is no doubt that it remained a permissible punishment after enactment of the Eighth Amendment. "An ordinary death by hanging was not, however, the harshest penalty at the disposal of the seventeenth- and eighteenth-century state." Banner 70. In addition to hanging, which was intended to, and often did, result in a quick and painless death, "[o]fficials also wielded a set of tools capable of *intensifying* a death sentence," that is, "ways of producing a punishment worse than death." *Id.*, at 54.

One such "tool" was burning at the stake. Because burning, unlike hanging, was always painful and destroyed the body, it was considered "a form of super-capital punishment, worse than death itself." *Id.,* at 71. Reserved for offenders whose crimes were thought to pose an ****1557** especially grave threat to the social order

—such as slaves who killed their masters and women who killed their husbands—burning a person alive was so dreadful a punishment that sheriffs sometimes hanged the offender first "as an act of charity." *Id.*, at 72.

Other methods of intensifying a death sentence included "gibbeting," or hanging the condemned in an iron cage so that his body would decompose in public view, see *id.,* at 72–74, and "public dissection," a punishment Blackstone associated with murder, 4 W. Blackstone, Commentaries 376 (W. Lewis ed. 1897) (hereinafter Blackstone). But none of these was the worst fate a criminal could meet. That was ***96** reserved for the most dangerous and reprobate offenders—traitors. "The punishment of high treason," Blackstone wrote, was "very solemn and terrible," *id.*, at 92, and involved "embowelling alive, beheading, and quartering," *id.*, at 376. Thus, the following death sentence could be pronounced on seven men convicted of high treason in England:

> " 'That you and each of you, be taken to the place from whence you came, and from thence be drawn on a hurdle to the place of execution, where you shall be hanged by the necks, not till you are dead; that you be severally taken down, while yet alive, and your bowels be taken out and burnt before your faces—that your heads be then cut off, and your bodies cut in four quarters, to be at the King's disposal. And God Almighty have mercy on your souls.' " G. Scott, History of Capital Punishment 179 (1950). [*]

The principal object of these aggravated forms of capital punishment was to terrorize the criminal, and thereby more effectively deter the crime. Their defining characteristic was that they were purposely designed to inflict pain and suffering beyond that necessary to cause death. As Blackstone put it, "in very atrocious crimes, other circumstances of terror, pain, or disgrace [were] superadded." 4 Blackstone 376. These "superadded" circumstances "were carefully ***97** handed out to apply terror where it was thought to be most needed," and were designed "to ensure that death would be slow and painful, and thus all the more frightening to contemplate." Banner 70.

Although the Eighth Amendment was not the subject of extensive discussion during the debates on the Bill of Rights, there is good reason to believe that the Framers viewed such enhancements to the death penalty as falling within the prohibition of the Cruel and Unusual Punishments Clause. By the late 18th century, the more violent modes of execution had "dwindled away," *id.,* at 76, and would for that reason have been "unusual" in the sense that they were no longer "regularly or customarily employed," *Harmelin v. Michigan,* 501 U.S. 957, 976, 111 S.Ct. 2680, 115 L.Ed.2d 836 (1991) (opinion of SCALIA, J.); see also *Weems v. United States,* 217 U.S. 349, 395, 30 S.Ct. 544, 54 L.Ed. 793 (1910) (White, J., dissenting) ****1558** (noting that, "prior to the formation of the Constitution, the necessity for the protection afforded by the cruel and unusual punishment guarantee of the English bill of rights had ceased to be a matter of concern, because as a rule the cruel bodily punishments of former times were no longer imposed"). Embellishments upon the death penalty designed to inflict pain for pain's sake also would have fallen comfortably within the ordinary meaning of the word "cruel." See 1 S. Johnson, A Dictionary of the English Language 459 (1773) (defining "cruel" to mean "[p]leased with hurting others; inhuman; hard-hearted; void of pity; wanting compassion; savage; barbarous; unrelenting"); 1 N. Webster, An American Dictionary of the English Language 52 (1828) (defining "cruel" as "[d]isposed to give pain to others, in body or mind; willing or pleased to torment, vex or afflict; inhuman; destitute of pity, compassion or kindness").

Moreover, the evidence we do have from the debates on the Constitution confirms that the Eighth Amendment was intended to disable Congress from imposing torturous punishments. It was the absence of such a restriction on Congress' power in the Constitution as drafted in Philadelphia ***98** in 1787 that led one delegate at the Massachusetts ratifying convention to complain that Congress was "nowhere restrained from inventing the most cruel and unheard-of punishments, and annexing them to crimes; and there is no constitutional check on them, but that *racks* and *gibbets* may be amongst the most mild instruments of their discipline." 2 J. Elliot, The Debates in the Several State Conventions on the Adoption of the Federal Constitution 111 (2d ed. 1891). Similarly, during the ratification debate in Virginia, Patrick Henry objected to the lack of a Bill of Rights, in part because there was nothing to prevent Congress from inflicting "tortures, or cruel and barbarous punishment[s]." 3 *id.,* at 447–448.

Early commentators on the Constitution likewise interpreted the Cruel and Unusual Punishments Clause

as referring to torturous punishments. One commentator viewed the Eighth Amendment as prohibiting "horrid modes of torture":

> "The prohibition of cruel and unusual punishments, marks the improved spirit of the age, which would not tolerate the use of the rack or the stake, or any of those horrid modes of torture, devised by human ingenuity for the gratification of fiendish passion." J. Bayard, A Brief Exposition of the Constitution of the United States 154 (2d ed. 1840).

Similarly, another commentator found "sufficient reasons" for the Eighth Amendment in the "barbarous and cruel punishments" inflicted in less enlightened countries:

> "Under the [Eighth] amendment the infliction of cruel and unusual punishments, is also prohibited. The various barbarous and cruel punishments inflicted under the laws of some other countries, and which profess not to be behind the most enlightened nations on earth in civilization and refinement, furnish sufficient reasons for this express prohibition. Breaking on the wheel, flaying ***99** alive, rending asunder with horses, various species of horrible tortures inflicted in the inquisition, maiming, mutilating and scourging to death, are wholly alien to the spirit of our humane general constitution." B. Oliver, The Rights of An American Citizen 186 (1832) (reprint 1970).

So barbaric were the punishments prohibited by the Eighth Amendment that Joseph Story thought the provision "wholly unnecessary in a free government, since it is scarcely possible, that any department of such a government should authorize, or ****1559** justify such atrocious conduct." 3 J. Story, Commentaries on the Constitution of the United States 750 (1833).

II

Consistent with the original understanding of the Cruel and Unusual Punishments Clause, this Court's cases have repeatedly taken the view that the Framers intended to prohibit torturous modes of punishment akin to those that formed the historical backdrop of the Eighth Amendment. See, *e.g., Estelle v. Gamble,* 429 U.S. 97, 102, 97 S.Ct. 285, 50 L.Ed.2d 251 (1976) ("[T]he primary concern of the drafters was to proscribe 'torture[s]' and other 'barbar [ous]' methods of punishment"); *Weems, supra*, at 390, 30 S.Ct. 544 (White, J., dissenting) ("[I]t may not be doubted, and indeed is not questioned by any one, that the cruel punishments against which the bill of rights provided were the atrocious, sanguinary and inhuman punishments which had been inflicted in the past upon the persons of criminals"). That view has permeated our method-of-execution cases. Thrice the Court has considered a challenge to a modern method of execution, and thrice it has rejected the challenge, each time emphasizing that the Eighth Amendment is aimed at methods of execution purposely designed to inflict pain.

In the first case, *Wilkerson v. Utah,* 99 U.S. 130, 25 L.Ed. 345 (1879), the Court rejected the contention that death by firing squad was cruel and unusual. In so doing, it reviewed the various ***100** modes of execution catalogued by Blackstone, repeating his observation that "in very atrocious crimes other circumstances of terror, pain, or disgrace were sometimes superadded." *Id.*, at 135. The Court found it "safe to affirm that punishments of torture, such as those mentioned by [Blackstone], and all others in the same line of unnecessary cruelty, are forbidden by [the Eighth Amendment]." *Id.*, at 136. The unanimous Court had no difficulty concluding that death by firing squad did not "fal[l] within that category." *Ibid.*

Similarly, when the Court in *In re Kemmler,* 136 U.S. 436, 446, 10 S.Ct. 930, 34 L.Ed. 519 (1890), unanimously rejected a challenge to electrocution, it interpreted the Eighth Amendment to prohibit punishments that "were manifestly cruel and unusual, as burning at the stake, crucifixion, breaking on the wheel, or the like":

> "Punishments are cruel when they involve torture or a lingering death; but the punishment of death is not cruel, within the meaning of that word as used in the Constitution. It implies there something inhuman and barbarous, something more than the mere extinguishment of life." *Id.*, at 447, 10 S.Ct. 930.

Finally, in *Louisiana ex rel. Francis v. Resweber,* 329 U.S. 459, 67 S.Ct. 374, 91 L.Ed. 422 (1947), the Court rejected the petitioner's contention that the Eighth Amendment prohibited Louisiana from subjecting him to a second attempt at electrocution, the first attempt having failed when "[t]he executioner threw the switch but, presumably because of some mechanical difficulty, death did not result." *Id.*, at 460, 67 S.Ct. 374 (plurality opinion). Characterizing the abortive attempt as "an accident, with

no suggestion of malevolence," *id.*, at 463, 67 S.Ct. 374, the plurality opinion concluded that "the fact that petitioner ha[d] already been subjected to a current of electricity [did] not make his subsequent execution any more cruel in the constitutional sense than any other execution":

> "The cruelty against which the Constitution protects a convicted man is cruelty inherent in the method of punishment, ***101** not the necessary suffering involved in any method employed to extinguish life ****1560** humanely. The fact that an unforeseeable accident prevented the prompt consummation of the sentence cannot, it seems to us, add an element of cruelty to a subsequent execution. There is no purpose to inflict unnecessary pain nor any unnecessary pain involved in the proposed execution." *Id.*, at 464, 67 S.Ct. 374.

III

In light of this consistent understanding of the Cruel and Unusual Punishments Clause as forbidding purposely torturous punishments, it is not surprising that even an ardent abolitionist was constrained to acknowledge in 1977 that "[a]n unbroken line of interpreters has held that it was the original understanding and intent of the framers of the Eighth Amendment ... to proscribe as 'cruel and unusual' *only* such modes of execution as compound the simple infliction of death with added cruelties or indignities." H. Bedau, The Courts, the Constitution, and Capital Punishment 35. What is surprising is the plurality's willingness to discard this unbroken line of authority in favor of a standard that finds no support in the original understanding of the Eighth Amendment or in our method-of-execution cases and that, disclaimers notwithstanding, "threaten[s] to transform courts into boards of inquiry charged with determining 'best practices' for executions, with each ruling supplanted by another round of litigation touting a new and improved methodology." *Ante,* at 1531.

We have never suggested that a method of execution is "cruel and unusual" within the meaning of the Eighth Amendment simply because it involves a risk of pain—whether "substantial," "unnecessary," or "untoward"—that could be reduced by adopting alternative procedures. And for good reason. It strains credulity to suggest that the defining characteristic of burning at the stake, disemboweling, drawing and quartering, beheading, and the like was that ***102** they involved risks of pain that could be eliminated by using alternative methods of execution. Quite plainly, what defined these punishments was that they were *designed* to inflict torture as a way of enhancing a death sentence; they were *intended* to produce a penalty worse than death, to accomplish something "more than the mere extinguishment of life." *Kemmler, supra,* at 447, 10 S.Ct. 930. The evil the Eighth Amendment targets is intentional infliction of gratuitous pain, and that is the standard our method-of-execution cases have explicitly or implicitly invoked.

Thus, the Court did not find it necessary in *Wilkerson* to conduct a comparative analysis of death by firing squad as opposed to hanging or some other method of execution. Nor did the Court inquire into the precise procedures used to execute an individual by firing squad in order to determine whether they involved risks of pain that could be alleviated by adopting different procedures. It was enough that death by firing squad was well established in military practice, 99 U.S., at 134–135, and plainly did not fall within the "same line of unnecessary cruelty" as the punishments described by Blackstone, *id.*, at 136.

The same was true in *Kemmler*. One searches the opinion in vain for a comparative analysis of electrocution versus other methods of execution. The Court observed that the New York Legislature had adopted electrocution in order to replace hanging with " 'the most humane and practical method known to modern science of carrying into effect the sentence of death in capital cases.' " 136 U.S., at 444, 10 S.Ct. 930. But there is no suggestion that the Court thought it necessary to sift through the "voluminous mass of evidence ... taken [in the courts below] as to the effect of electricity as an agent of death," ****1561** id., at 442, 10 S.Ct. 930, in order to confirm that electrocution in fact involved less substantial risks of pain or lingering death than hanging. The court below had rejected the challenge because the "act was passed in the effort to devise a more ***103** humane method of reaching the result," and "courts were bound to presume that the legislature was possessed of the facts upon which it took action." *Id.*, at 447, 10 S.Ct. 930. Treating the lower court's decision "as involving an adjudication that the statute was not repugnant to the Federal Constitution," *ibid.,* the Court found that conclusion "so plainly right," *ibid.*, that it had "no hesitation" in denying the writ of error, *id.*, at 449, 10 S.Ct. 930.

Likewise in *Resweber,* the Court was confronted in dramatic fashion with the reality that the electric chair involved risks of error or malfunction that could result in excruciating pain. See 329 U.S., at 480, n. 2, 67 S.Ct. 374 (Burton, J., dissenting) (quoting affidavits from the petitioner's brief recounting that during the unsuccessful first attempt at electrocution, the petitioner's " 'lips puffed out and his body squirmed and tensed and he jumped so that the chair rocked on the floor' "). But absent "malevolence" or a "purpose to inflict unnecessary pain," the Court concluded that the Constitution did not prohibit Louisiana from subjecting the petitioner to those very risks a second time in order to carry out his death sentence. *Id.*, at 463, 464, 67 S.Ct. 374 (plurality opinion); *id.*, at 471, 67 S.Ct. 374 (Frankfurter, J., concurring); see also *Furman v. Georgia,* 408 U.S. 238, 326–327, 92 S.Ct. 2726, 33 L.Ed.2d 346 (1972) (Marshall, J., concurring) (describing *Resweber* as holding "that the legislature adopted electrocution for a humane purpose, and that its will should not be thwarted because, in its desire to reduce pain and suffering in most cases, it may have inadvertently increased suffering in one particular case"). No one suggested that Louisiana was required to implement additional safeguards or alternative procedures in order to reduce the risk of a second malfunction. And it was the *dissenters* in *Resweber* who insisted that the absence of an intent to inflict pain was irrelevant. 329 U.S., at 477, 67 S.Ct. 374 (Burton, J., dissenting) ("The intent of the executioner cannot lessen the torture or excuse the result").

***104** IV

Aside from lacking support in history or precedent, the various risk-based standards proposed in this case suffer from other flaws, not the least of which is that they cast substantial doubt on every method of execution other than lethal injection. It may well be that other methods of execution such as hanging, the firing squad, electrocution, and lethal gas involve risks of pain that could be eliminated by switching to lethal injection. Indeed, they have been attacked as unconstitutional for that very reason. See, *e.g., Gomez v. United States Dist. Court for Northern Dist. of Cal.,* 503 U.S. 653, 654, 656–657, 112 S.Ct. 1652, 118 L.Ed.2d 293 (1992) (STEVENS, J., dissenting) (arguing that lethal gas violates the Eighth Amendment because of "the availability of more humane and less violent methods of execution," namely, lethal injection); *Glass v. Louisiana,* 471 U.S. 1080, 1093, 105 S.Ct. 2159, 85 L.Ed.2d 514 (1985) (Brennan, J., dissenting from denial of certiorari) (arguing that electrocution violates the Eighth Amendment because it poses risks of pain that could be alleviated by "other currently available means of execution," such as lethal injection); *Campbell v. Wood,* 18 F.3d 662, 715 (C.A.9 1994) (Reinhardt, J., concurring and dissenting) (arguing that hanging violates the Eighth Amendment because it involves risks of pain and mutilation not presented by lethal injection). But the notion that ****1562** the Eighth Amendment permits only one mode of execution, or that it requires an anesthetized death, cannot be squared with the history of the Constitution.

It is not a little ironic—and telling—that lethal injection, hailed just a few years ago as *the* humane alternative in light of which every other method of execution was deemed an unconstitutional relic of the past, is the subject of today's challenge. It appears the Constitution is "evolving" even faster than I suspected. And it is obvious that, for some who oppose capital punishment on policy grounds, the only acceptable end point of the evolution is for this Court, in an exercise of raw judicial power unsupported by the text or ***105** history of the Constitution, or even by a contemporary moral consensus, to strike down the death penalty as cruel and unusual in all circumstances. In the meantime, though, the next best option for those seeking to abolish the death penalty is to embroil the States in never-ending litigation concerning the adequacy of their execution procedures. But far from putting an end to abusive litigation in this area, and thereby vindicating in some small measure the States' "significant interest in meting out a sentence of death in a timely fashion," *Nelson v. Campbell,* 541 U.S. 637, 644, 124 S.Ct. 2117, 158 L.Ed.2d 924 (2004), today's decision is sure to engender more litigation. At what point does a risk become "substantial"? Which alternative procedures are "feasible" and "readily implemented"? When is a reduction in risk "significant"? What penological justifications are "legitimate"? Such are the questions the lower courts will have to grapple with in the wake of today's decision. Needless to say, we have left the States with nothing resembling a bright-line rule.

Which brings me to yet a further problem with comparative-risk standards: They require courts to resolve medical and scientific controversies that are largely beyond judicial ken. Little need be said here, other than

to refer to the various opinions filed by my colleagues today. Under the competing risk standards advanced by the plurality opinion and the dissent, for example, the difference between a lethal injection procedure that satisfies the Eighth Amendment and one that does not may well come down to one's judgment with respect to something as hairsplitting as whether an eyelash stroke is necessary to ensure that the inmate is unconscious, or whether instead other measures have already provided sufficient assurance of unconsciousness. Compare *post,* at 1569 – 1570 (GINSBURG, J., dissenting) (criticizing Kentucky's protocol because "[n]o one calls the inmate's name, shakes him, brushes his eyelashes to test for a reflex, or applies a noxious stimulus to gauge his response"), with *ante,* at 1537 (rejecting the dissent's criticisms because ***106** "an inmate cannot succeed on an Eighth Amendment claim simply by showing one more step the State could take as a failsafe for other, independently adequate measures"). We have neither the authority nor the expertise to micromanage the States' administration of the death penalty in this manner. There is simply no reason to believe that "unelected" judges without scientific, medical, or penological training are any better suited to resolve the delicate issues surrounding the administration of the death penalty than are state administrative personnel specifically charged with the task. Cf. *ante,* at 1545 (STEVENS, J., concurring in judgment) (criticizing the States' use of the three-drug protocol because "[i]n the majority of States that use the three-drug protocol, the drugs were selected by unelected department of correction officials with no specialized medical knowledge and without the benefit of expert assistance or guidance").

****1563** In short, I reject as both unprecedented and unworkable any standard that would require the courts to weigh the relative advantages and disadvantages of different methods of execution or of different procedures for implementing a given method of execution. To the extent that there is any comparative element to the inquiry, it should be limited to whether the challenged method inherently inflicts significantly more pain than traditional modes of execution such as hanging and the firing squad. See, *e.g., Gray v. Lucas,* 463 U.S. 1237, 1239–1240, 104 S.Ct. 211, 77 L.Ed.2d 1453 (1983) (Burger, C. J., concurring in denial of certiorari) (rejecting an Eighth Amendment challenge to lethal gas because the petitioner had not shown that " 'the pain and terror resulting from death by cyanide gas is so different in degree or nature from that resulting from other traditional modes of execution as to implicate the eighth amendment right' " (quoting *Gray v. Lucas,* 710 F.2d 1048, 1061 (C.A.5 1983))); *Hernandez v. State,* 43 Ariz. 424, 441, 32 P.2d 18, 25 (1934) ("The fact that [lethal gas] is less painful and more humane than hanging is all that is required to refute completely the charge that it constitutes cruel and unusual ***107** punishment within the meaning of this expression as used in [the Eighth Amendment]").

V

Judged under the proper standard, this is an easy case. It is undisputed that Kentucky adopted its lethal injection protocol in an effort to make capital punishment more humane, not to add elements of terror, pain, or disgrace to the death penalty. And it is undisputed that, if administered properly, Kentucky's lethal injection protocol will result in a swift and painless death. As the Sixth Circuit observed in rejecting a similar challenge to Tennessee's lethal injection protocol, we "do not have a situation where the State has any intent (or anything approaching intent) to inflict unnecessary pain; the complaint is that the State's *pain-avoidance procedure* may fail because the executioners may make a mistake in implementing it." *Workman v. Bredesen,* 486 F.3d 896, 907 (2007). But "[t]he risk of negligence in implementing a death-penalty procedure ... does not establish a cognizable Eighth Amendment claim." *Id.,* at 907–908. Because Kentucky's lethal injection protocol is designed to eliminate pain rather than to inflict it, petitioners' challenge must fail. I accordingly concur in the Court's judgment affirming the decision below.

Justice BREYER, concurring in the judgment.

Assuming the lawfulness of the death penalty itself, petitioners argue that Kentucky's method of execution, lethal injection, nonetheless constitutes a constitutionally forbidden, "cruel and unusual punishmen[t]." U.S. Const., Amdt. 8. In respect to *how* a court should review such a claim, I agree with Justice GINSBURG. She highlights the relevant question, whether the method creates an untoward, readily avoidable risk of inflicting severe and unnecessary suffering. *Post,* at 1572 (dissenting opinion). I agree that the relevant factors—the "degree of risk," the "magnitude of pain," and ***108** the "availability of alternatives"—are interrelated and each

must be considered. *Post,* at 1568. At the same time, I believe that the legal merits of the kind of claim presented must inevitably turn not so much upon the wording of an intermediate standard of review as upon facts and evidence. And I cannot find, either in the record in this case or in the literature on the subject, sufficient evidence that Kentucky's execution method poses the "significant and unnecessary risk of inflicting severe ****1564** pain" that petitioners assert. Brief for Petitioners 28.

In respect to the literature, I have examined the periodical article that seems first to have brought widespread legal attention to the claim that lethal injection might bring about unnecessary suffering. See *ante,* at 1532, n. 2 (plurality opinion); Denno, The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty, 76 Ford. L.Rev. 49, 105, n. 366 (2007) (collecting cases in which condemned inmates cited the Lancet study). The article, by Dr. Leonidas G. Koniaris, Teresa A. Zimmers (of the University of Miami School of Medicine), and others, appeared in the April 16, 2005, issue of the Lancet, an eminent, peer-reviewed medical journal. See Koniaris, Zimmers, Lubarsky, & Sheldon, Inadequate Anaesthesia in Lethal Injection for Execution, 365 Lancet 1412 (hereinafter Lancet Study). The authors examined "autopsy toxicology results from 49 executions in Arizona, Georgia, North Carolina, and South Carolina." *Id.*, at 1412–1413. The study noted that lethal injection usually consists of sequential administration of a barbiturate (sodium thiopental), followed by injection of a paralyzing agent (pancuronium bromide) and a heart-attack-inducing drug (potassium chloride). The study focused on the effectiveness of the first drug in anesthetizing the inmate. See *id.*, at 1412. It noted that the four States used 2 grams of thiopental. *Id.*, at 1413. (Kentucky follows a similar system but currently uses 3 grams of sodium thiopental. See *ante,* at 1528 (plurality opinion).) Although the sodium thiopental ***109** dose (of, say, 2 grams) was several times the dose used in ordinary surgical operations, the authors found that the level of barbiturate present in the bloodstream several hours (or more) after death was *lower* than the level one might expect to find during an operation. Lancet Study 1413–1414. With certain qualifications, they state that "21 (43%)" of the examined instances "had [thiopental] concentrations consistent with consciousness,"*Id.*, at 1413—a fact that should create considerable concern given the related likelihood of unexpressed suffering. The authors suggest that, among other things, inadequate training may help explain the results. *Id.*, at 1414.

The Lancet Study, however, may be seriously flawed. In its September 24, 2005, issue, the Lancet published three responses. The first, by one of the initial referees, Jonathan I. Groner of Children's Hospital, Columbus, Ohio, claimed that a low level of thiopental in the bloodstream does not necessarily mean that an inadequate dose was given, for, under circumstances likely common to lethal injections, thiopental can simply diffuse from the bloodstream into surrounding tissues. See Inadequate Anaesthesia in Lethal Injection for Execution, 366 Lancet 1073. And a long pause between death and measurement means that this kind of diffusion likely occurred. See *ibid.* For this reason and others, Groner, who said he had initially "expressed strong support for the article," had become "concerned" that its key finding "may be erroneous because of a lack of equipoise in the study." *Ibid.*

The second correspondents, Mark J.S. Heath (petitioners' expert in their trial below), Donald R. Stanski, and Derrick J. Pounder, respectively of the Department of Anesthesiology, Columbia University, of Stanford University School of Medicine, and the University of Dundee, United Kingdom, concluded that "Koniaris and colleagues do not present scientifically convincing data to justify their conclusion that so large a proportion of inmates have experienced awareness ***110** during lethal injection." *Ibid.* These researchers noted that because the blood samples were taken "several hours to days after" the inmates' ****1565** deaths, the postmortem concentrations of thiopental—a lipophilic drug that diffuses from blood into tissue—could not be relied on as accurate indicators for concentrations in the bloodstream during life. *Ibid.* See also *ante,* at 1532, n. 2 (plurality opinion).

The third correspondents, Robyn S. Weisman, Jeffrey N. Bernstein, and Richard S. Weisman, of the University of Miami, School of Medicine, and Florida Poison Information Center, said that "[p]ost-mortem drug concentrations are extremely difficult to interpret and there is substantial variability in results depending on timing, anatomical origin of the specimen, and physical and chemical properties of the drug." 366 Lancet, at 1074. They believed that the original finding "requires further assessment." *Ibid.*

The authors of the original study replied, defending the accuracy of their findings. See *id.*, at 1074–1076. Yet, neither the petition for certiorari nor any of the briefs filed in this Court (including seven *amici curiae* briefs supporting petitioners) make any mention of the Lancet Study, which was published during petitioners' trial. In light of that fact, and the responses to the original study, a judge, nonexpert in these matters, cannot give the Lancet Study significant weight.

The literature also contains a detailed article on the subject, which appeared in 2002 in the Ohio State Law Journal. The author, Professor Deborah W. Denno, examined executions by lethal injection in the 36 States where thiopental is used. See When Legislatures Delegate Death: The Troubling Paradox Behind State Uses of Electrocution and Lethal Injection and What It Says About Us, 63 Ohio St. L.J. 63. In Table 9, the author lists 31 "Botched Lethal Injection Executions" in the time from our decision in *Gregg v. Georgia,* 429 U.S. 1301, 96 S.Ct. 3235, 50 L.Ed.2d 30 (1976), through 2001. See Denno, 63 Ohio St. L. J., at 139–141. Of these, 19 involved a problem ***111** of locating a suitable vein to administer the chemicals. *Ibid.* Eleven of the remaining twelve apparently involved strong, readily apparent physical reactions. *Ibid.* One, taking place in Illinois in 1990, is described as involving "some indication that, while appearing calm on the outside due to the paralyzing drugs, [the inmate] suffered excruciating pain." *Id.*, at 139. The author adds that "[t]here were reports of faulty equipment and inexperienced personnel." *Ibid.* This article, about which Professor Denno testified at petitioners' trial and on which petitioners rely in this Court, may well provide cause for concern about the administration of the lethal injection. But it cannot materially aid petitioners here. That is because, as far as the record here reveals, and as the Kentucky courts found, Kentucky's use of trained phlebotomists and the presence of observers should prevent the kind of "botched" executions that Denno's Table 9 documents.

The literature also casts a shadow of uncertainty upon the ready availability of some of the alternatives to lethal execution methods. Petitioners argued to the trial court, for example, that Kentucky should eliminate the use of a paralytic agent, such as pancuronium bromide, which could, by preventing any outcry, mask suffering an inmate might be experiencing because of inadequate administration of the anesthetic. See Brief for Petitioners 51–57; Reply Brief for Petitioners 18, and n. 6. And they point out that use of pancuronium bromide to euthanize animals is contrary to veterinary standards. See *id.*, at 20 (citing Brief for Dr. Kevin Concannon et al. as *Amici Curiae* 17–18). See also *id.,* at 4, 18, n. 5 (noting that Kentucky, like 22 other States, prohibits the use of neuromuscular blocking agents in euthanizing animals). ****1566** In the Netherlands, however, the use of pancuronium bromide is recommended for purposes of lawful assisted suicide. See *ante,* at 1535 – 1536 (plurality opinion) (discussing the Royal Dutch Society for the Advancement of Pharmacy's recommendation of the use of a muscle relaxant ***112** such as pancuronium in addition to thiopental). See also Kimsma, Euthanasia and Euthanizing Drugs in The Netherlands, reprinted in Drug Use in Assisted Suicide and Euthanasia 193, 199–202 (M. Battin & A. Lipman eds.1996) (discussing use of neuromuscular relaxants). Why, one might ask, if the use of pancuronium bromide is undesirable, would those in the Netherlands, interested in practices designed to bring about a humane death, recommend the use of that, or similar, drugs? Petitioners pointed out that in the Netherlands, physicians trained in anesthesiology are involved in assisted suicide, while that is not the case in Kentucky. See Tr. of Oral Arg. 55. While important, that difference does not resolve the apparently conflicting views about the inherent propriety or impropriety of use of this drug to extinguish human life humanely.

Similarly, petitioners argue for better trained personnel. But it is clear that both the American Medical Association (AMA) and the American Nursing Association (ANA) have rules of ethics that strongly oppose their members' participation in executions. See Brief for American Society of Anesthesiologists as *Amicus Curiae* 2–3 (citing AMA, Code of Medical Ethics, Policy E–2.06 Capital Punishment (2000), online at http://www.ama-assn.org/ama1/pub/upload/mm/369/e206capitalpunish.pdf (all Internet materials as visited Apr. 10, 2008, and available in Clerk of Court's case file)); ANA, Position Statement: Nurses' Participation in Capital Punishment (1994), online at http://nursingworld.org/MainMenuCategories/HealthcareandPolicyIssues/ANA PositionStatements/EthicsandHumanRights.aspx (noting that nurses' participation in executions "is viewed as contrary to the fundamental goals and ethical traditions of the profession"). Cf. Ky.Rev.Stat. Ann. § 431.220(3) (West 2006) (Kentucky prohibiting a physician from participating in the "conduct of an execution," except to

certify the cause of death). And these facts suggest that finding better trained personnel may be more difficult than might, at first blush, appear.

***113** Nor can I find in the record in this case any stronger evidence in petitioners' favor than the literature itself provides of an untoward, readily avoidable risk of severe pain. Indeed, Justice GINSBURG has accepted what I believe is petitioners' strongest claim, namely, Kentucky should require more thorough testing as to unconsciousness. See *post,* at 1569 – 1572. In respect to this matter, however, I must agree with the plurality and Justice STEVENS. The record provides too little reason to believe that such measures, if adopted in Kentucky, would make a significant difference.

The upshot is that I cannot find, either in the record or in the readily available literature that I have seen, sufficient grounds to believe that Kentucky's method of lethal injection creates a significant risk of unnecessary suffering. The death penalty itself, of course, brings with it serious risks, for example, risks of executing the wrong person, see, *e.g.*, *ante,* at 1551 (STEVENS, J., concurring in judgment), risks that unwarranted animus (in respect, *e.g.*, to the race of victims) may play a role, see, *e.g.*, *ante,* at 1551, risks that those convicted will find themselves on death row for many years, perhaps decades, to come, see *Smith v. Arizona,* 552 U.S. 1551, 128 S.Ct. 466, 169 L.Ed.2d 326 (2007) (BREYER, J., dissenting from denial of certiorari). These risks in part explain ****1567** why that penalty is so controversial. But the lawfulness of the death penalty is not before us. And petitioners' proof and evidence, while giving rise to legitimate concern, do not show that Kentucky's method of applying the death penalty amounts to "cruel and unusual punishmen[t]."

For these reasons, I concur in the judgment.

Justice GINSBURG, with whom Justice SOUTER joins, dissenting.

It is undisputed that the second and third drugs used in Kentucky's three-drug lethal injection protocol, pancuronium bromide and potassium chloride, would cause a conscious inmate to suffer excruciating pain. Pancuronium bromide ***114** paralyzes the lung muscles and results in slow asphyxiation. App. 435, 437, 625. Potassium chloride causes burning and intense pain as it circulates throughout the body. *Id.,* at 348, 427, 444, 600, 626. Use of pancuronium bromide and potassium chloride on a conscious inmate, the plurality recognizes, would be "constitutionally unacceptable." *Ante,* at 1533.

The constitutionality of Kentucky's protocol therefore turns on whether inmates are adequately anesthetized by the first drug in the protocol, sodium thiopental. Kentucky's system is constitutional, the plurality states, because "petitioners have not shown that the risk of an inadequate dose of the first drug is substantial." *Ante,* at 1533. I would not dispose of the case so swiftly given the character of the risk at stake. Kentucky's protocol lacks basic safeguards used by other States to confirm that an inmate is unconscious before injection of the second and third drugs. I would vacate and remand with instructions to consider whether Kentucky's omission of those safeguards poses an untoward, readily avoidable risk of inflicting severe and unnecessary pain.

I

The Court has considered the constitutionality of a specific method of execution on only three prior occasions. Those cases, and other decisions cited by the parties and *amici,* provide little guidance on the standard that should govern petitioners' challenge to Kentucky's lethal injection protocol.

In *Wilkerson v. Utah,* 99 U.S. 130, 25 L.Ed. 345 (1879), the Court held that death by firing squad did not rank among the "cruel and unusual punishments" banned by the Eighth Amendment. In so ruling, the Court did not endeavor "to define with exactness the extent of the constitutional provision which provides that cruel and unusual punishments shall not be inflicted." *Id.,* at 135–136. But it was "safe to affirm," the Court stated, that "punishments of torture ..., and all others in the same line of unnecessary cruelty, are forbidden." *Id.,* at 136.

***115** Next, in *In re Kemmler,* 136 U.S. 436, 10 S.Ct. 930, 34 L.Ed. 519 (1890), death by electrocution was the assailed method of execution. [1] The Court reiterated that the Eighth Amendment prohibits "torture" and "lingering death." *Id.,* at 447, 10 S.Ct. 930. The word "cruel," the Court further observed, "implies ... something inhuman ... something more than the mere extinguishment of life." *Ibid.* Those statements, however, were made *en passant*. ****1568** *Kemmler*'s actual holding was that the Eighth

Amendment does not apply to the States, *id.,* at 448–449, 10 S.Ct. 930, [2] a proposition we have since repudiated, see, *e.g., Robinson v. California,* 370 U.S. 660, 82 S.Ct. 1417, 8 L.Ed.2d 758 (1962).

Finally, in *Louisiana ex rel. Francis v. Resweber,* 329 U.S. 459, 67 S.Ct. 374, 91 L.Ed. 422 (1947), the Court rejected Eighth and Fourteenth Amendment challenges to a reelectrocution following an earlier attempt that failed to cause death. The plurality opinion in that case first stated: "The traditional humanity of modern Anglo–American law forbids the infliction of unnecessary pain in the execution of the death sentence." *Id.,* at 463, 67 S.Ct. 374. But the very next sentence varied the formulation; it referred to the "[p]rohibition against the wanton infliction of pain." *Ibid.*

No clear standard for determining the constitutionality of a method of execution emerges from these decisions. Moreover, the age of the opinions limits their utility as an aid to resolution of the present controversy. The Eighth Amendment, we have held, " 'must draw its meaning from the evolving standards of decency that mark the progress of a ***116** maturing society.' " *Atkins v. Virginia,* 536 U.S. 304, 311–312, 122 S.Ct. 2242, 153 L.Ed.2d 335 (2002) (quoting *Trop v. Dulles,* 356 U.S. 86, 101, 78 S.Ct. 590, 2 L.Ed.2d 630 (1958) (plurality opinion)). *Wilkerson* was decided 129 years ago, *Kemmler* 118 years ago, and *Resweber* 61 years ago. Whatever little light our prior method-of-execution cases might shed is thus dimmed by the passage of time.

Further phrases and tests can be drawn from more recent decisions, for example, *Gregg v. Georgia,* 428 U.S. 153, 96 S.Ct. 2909, 49 L.Ed.2d 859 (1976). Speaking of capital punishment in the abstract, the lead opinion said that the Eighth Amendment prohibits "the unnecessary and wanton infliction of pain," *id.,* at 173, 96 S.Ct. 2909 (joint opinion of Stewart, Powell, and STEVENS, JJ.); the same opinion also cautioned that a death sentence cannot "be imposed under sentencing procedures that creat[e] a substantial risk that it would be inflicted in an arbitrary and capricious manner," *id.,* at 188, 96 S.Ct. 2909.

Relying on *Gregg* and our earlier decisions, the Kentucky Supreme Court stated that an execution procedure violates the Eighth Amendment if it "creates a substantial risk of wanton and unnecessary infliction of pain, torture or lingering death." 217 S.W.3d 207, 209, 210 (2006). Petitioners respond that courts should consider "(a) the severity of pain risked, (b) the likelihood of that pain occurring, *and* (c) the extent to which alternative means are feasible." Brief for Petitioners 38 (emphasis added). The plurality settles somewhere in between, requiring a "substantial risk of serious harm" and considering whether a "feasible, readily implemented" alternative can "significantly reduce" that risk. *Ante,* at 1532 (internal quotation marks omitted).

I agree with petitioners and the plurality that the degree of risk, magnitude of pain, and availability of alternatives must be considered. I part ways with the plurality, however, to the extent its "substantial risk" test sets a fixed threshold for the first factor. The three factors are interrelated; a strong showing on one reduces the importance of the others.

****1569** ***117** Lethal injection as a mode of execution can be expected, in most instances, to result in painless death. Rare though errors may be, the consequences of a mistake about the condemned inmate's consciousness are horrendous and effectively undetectable after injection of the second drug. Given the opposing tugs of the degree of risk and magnitude of pain, the critical question here, as I see it, is whether a feasible alternative exists. Proof of "a slightly or marginally safer alternative" is, as the plurality notes, insufficient. *Ante,* at 1532. But if readily available measures can materially increase the likelihood that the protocol will cause no pain, a State fails to adhere to contemporary standards of decency if it declines to employ those measures.

II

Kentucky's Legislature adopted lethal injection as a method of execution in 1998. See 1998 Ky. Acts ch. 220, p. 777, Ky.Rev.Stat. Ann. § 431.220(1)(a) (West 2006). Lawmakers left the development of the lethal injection protocol to officials in the Department of Corrections. Those officials, the trial court found, were "given the task without the benefit of scientific aid or policy oversight." App. 768. "Kentucky's protocol," that court observed, "was copied from other states and accepted without challenge." *Ibid.* Kentucky "did not conduct any independent scientific or medical studies or consult any medical professionals concerning the drugs and dosage amounts to be injected into the condemned." *Id.,* at 760,

¶3. Instead, the trial court noted, Kentucky followed the path taken in other States that "simply fell in line" behind the three-drug protocol first developed by Oklahoma in 1977. *Id.,* at 756. See also *ante,* at 1532, n. 1 (plurality opinion).

Kentucky's protocol begins with a careful measure: Only medical professionals may perform the venipunctures and establish intravenous (IV) access. Members of the IV team must have at least one year's experience as a certified medical ***118** assistant, phlebotomist, emergency medical technician (EMT), paramedic, or military corpsman. App. 984; *ante,* at 1534 (plurality opinion). Kentucky's IV team currently has two members: a phlebotomist with 8 years' experience and an EMT with 20 years' experience. App. 273–274. Both members practice siting catheters at ten lethal injection training sessions held annually. *Id.,* at 984.

Other than using qualified and trained personnel to establish IV access, however, Kentucky does little to ensure that the inmate receives an effective dose of sodium thiopental. After siting the catheters, the IV team leaves the execution chamber. *Id.,* at 977. From that point forward, only the warden and deputy warden remain with the inmate. *Id.,* at 276. Neither the warden nor the deputy warden has any medical training.

The warden relies on visual observation to determine whether the inmate "appears" unconscious. *Id.,* at 978. In Kentucky's only previous execution by lethal injection, the warden's position allowed him to see the inmate best from the waist down, with only a peripheral view of the inmate's face. See *id.,* at 213–214. No other check for consciousness occurs before injection of pancuronium bromide. Kentucky's protocol does not include an automatic pause in the "rapid flow" of the drugs, *id.,* at 978, or any of the most basic tests to determine whether the sodium thiopental has worked. No one calls the inmate's name, shakes him, brushes his eyelashes to test for a reflex, or applies a noxious stimulus to gauge his response.

****1570** Nor does Kentucky monitor the effectiveness of the sodium thiopental using readily available equipment, even though the inmate is already connected to an electrocardiogram (EKG), *id.,* at 976. A drop in blood pressure or heart rate after injection of sodium thiopental would not prove that the inmate is unconscious, see *id.,* at 579–580; *ante,* at 1533 (plurality opinion), but would signal that the drug has ***119** entered the inmate's bloodstream, see App. 424, 498, 578, 580; 8 Tr. 1099 (May 2, 2005). Kentucky's own expert testified that the sodium thiopental should "cause the inmate's blood pressure to become very, very low," App. 578, and that a precipitous drop in blood pressure would "confir[m]" that the drug was having its expected effect, *id.,* at 580. Use of a blood pressure cuff and EKG, the record shows, is the standard of care in surgery requiring anesthesia. *Id.,* at 539. [3]

A consciousness check supplementing the warden's visual observation before injection of the second drug is easily implemented and can reduce a risk of dreadful pain. Pancuronium bromide is a powerful paralytic that prevents all voluntary muscle movement. Once it is injected, further monitoring of the inmate's consciousness becomes impractical without sophisticated equipment and training. Even if the inmate were conscious and in excruciating pain, there would be no visible indication. [4]

Recognizing the importance of a window between the first and second drugs, other States have adopted safeguards not contained in Kentucky's protocol. See Brief for Criminal ***120** Justice Legal Foundation as *Amicus Curiae* 19–23. [5] Florida pauses between injection of the first and second drugs so the warden can "determine, after consultation, that the inmate is indeed unconscious." *Lightbourne v. McCollum,* 969 So.2d 326, 346 (Fla.2007) *(per curiam)* (internal quotation marks omitted). The warden does so by touching the inmate's eyelashes, calling his name, and shaking him. *Id.*, at 347. [6] If the inmate's consciousness ****1571** remains in doubt in Florida, "the medical team members will come out from the chemical room and consult in the assessment of the inmate." *Ibid.* During the entire execution, the person who inserted the IV line monitors the IV access point and the inmate's face on closed-circuit television. *Ibid.*

In Missouri, "medical personnel must examine the prisoner physically to confirm that he is unconscious using standard clinical techniques and must inspect the catheter site again." *Taylor v. Crawford,* 487 F.3d 1072, 1083 (C.A.8 2007). "The second and third chemicals are injected only after confirmation that the prisoner is unconscious and after a period of at least three minutes has elapsed from the first injection of thiopental." *Ibid.*

In California, a member of the IV team brushes the inmate's eyelashes, speaks to him, and shakes him at the halfway ***121** point and, again, at the completion of the sodium thiopental injection. See State of California, San Quentin Operational Procedure No. 0–770, Execution by Lethal Injection, § V(S)(4)(e) (2007), online at http:// www.cdcr.ca.gov/News/docs/RevisedProtocol. pdf.

In Alabama, a member of the execution team "begin[s] by saying the condemned inmate's name. If there is no response, the team member will gently stroke the condemned inmate's eyelashes. If there is no response, the team member will then pinch the condemned inmate's arm." Respondents' Opposition to Callahan's Application for a Stay of Execution in *Callahan v. Allen,* O.T.2007, No. 07A630, p. 3 (internal quotation marks omitted).

In Indiana, officials inspect the injection site after administration of sodium thiopental, say the inmate's name, touch him, and use ammonia tablets to test his response to a noxious nasal stimulus. See Tr. of Preliminary Injunction Hearing in 1:06–cv–1859 (SD Ind.), pp. 199–200, online at http:// www.law.berkeley.edu/clinics/dpclinic/ LethalInjection/Public/MoralesTaylor Amicus/20.pdf (hereinafter Timberlake Hearing). [7]

These checks provide a degree of assurance—missing from Kentucky's protocol—that the first drug has been properly administered. They are simple and essentially costless to employ, yet work to lower the risk that the inmate will be subjected to the agony of conscious suffocation caused by pancuronium bromide and the searing pain caused by potassium chloride. The record contains no explanation why Kentucky does not take any of these elementary measures.

The risk that an error administering sodium thiopental would go undetected is minimal, Kentucky urges, because if the drug was mistakenly injected into the inmate's tissue, not a vein, he "would be awake and screaming." Tr. of Oral Arg. 30–31. See also Brief for Respondents 42; Brief for ***122** State of Texas et al. as *Amici Curiae* 26–27. That argument ignores aspects of Kentucky's protocol that render passive reliance on obvious signs of consciousness, such as screaming, inadequate to determine whether the inmate is experiencing pain.

First, Kentucky's use of pancuronium bromide to paralyze the inmate means he will not be able to scream after the second drug is injected, no matter how much pain he is experiencing. Kentucky's argument, therefore, appears to rest on the assertion that sodium thiopental is itself painful ****1572** when injected into tissue rather than a vein. See App. 601. The trial court made no finding on that point, and Kentucky cites no supporting evidence from executions in which it is known that sodium thiopental was injected into the inmate's soft tissue. See, *e.g., Lightbourne,* 969 So.2d, at 344 (describing execution of Angel Diaz).

Second, the inmate may receive enough sodium thiopental to mask the most obvious signs of consciousness without receiving a dose sufficient to achieve a surgical plane of anesthesia. See 7 Tr. 976 (Apr. 21, 2005). If the drug is injected too quickly, the increase in blood pressure can cause the inmate's veins to burst after a small amount of sodium thiopental has been administered. Cf.App. 217 (describing risk of "blowout"). Kentucky's protocol does not specify the rate at which sodium thiopental should be injected. The executioner, who does not have any medical training, pushes the drug "by feel" through five feet of tubing. *Id.,* at 284, 286–287. [8] In practice sessions, unlike in an actual execution, there is no resistance on the catheter, see *id.,* at 285; thus the executioner's training may lead him to push the drugs too fast.

***123** "The easiest and most obvious way to ensure that an inmate is unconscious during an execution," petitioners argued to the Kentucky Supreme Court, "is to check for consciousness prior to injecting pancuronium [bromide]." Brief for Appellants in No.2005–SC–00543, p. 41. See also App. 30, ¶105(j) (Complaint) (alleging Kentucky's protocol does not "require the execution team to determine that the condemned inmate is unconscious prior to administering the second and third chemicals"). The court did not address petitioners' argument. I would therefore remand with instructions to consider whether the failure to include readily available safeguards to confirm that the inmate is unconscious after injection of sodium thiopental, in combination with the other elements of Kentucky's protocol, creates an untoward, readily avoidable risk of inflicting severe and unnecessary pain.

All Citations

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Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.,* 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

1 Twenty-seven of the thirty-six States that currently provide for capital punishment require execution by lethal injection as the sole method. See Ariz.Rev.Stat. Ann. § 13–704 (West 2001); Ark.Code Ann. § 5–4–617 (2006); Colo.Rev.Stat. Ann. § 18–1.3–1202 (2007); Conn. Gen.Stat. § 54–100 (2007); Del.Code Ann., Tit. 11, § 4209 (2006 Supp.); Ga.Code Ann. § 17–10–38 (2004); Ill. Comp. Stat., ch. 725, § 5/119–5 (West 2006); Ind.Code § 35–38–6–1 (West 2004); Kan. Stat. Ann. § 22–4001 (2006 Cum.Supp.); Ky.Rev.Stat. Ann. § 431.220 (West 2006); La. Stat. Ann. § 15:569 (West 2005); Md.Crim. Law Code Ann. § 2–303 (Lexis Supp.2007); Miss.Code Ann. § 99–19–51 (2007); Mont.Code Ann. § 46–19–103 (2007); Nev.Rev.Stat. § 176.355 (2007); N.M. Stat. Ann. § 31–14–11 (2000); N.Y. Correc. Law Ann. § 658 (West 2003) (held unconstitutional in *People v. LaValle,* 3 N.Y.3d 88, 130–131, 783 N.Y.S.2d 485, 817 N.E.2d 341, 367 (2004)); N.C. Gen.Stat. Ann. § 15–187 (Lexis 2007); Ohio Rev.Code Ann. § 2949.22 (Lexis 2006); Okla. Stat., Tit. 22, § 1014 (West 2001); Ore.Rev.Stat. § 137.473 (2003); Pa. Stat. Ann., Tit. 61, § 3004 (Purdon 1999); S.D. Codified Laws § 23A–27A–32 (Supp.2007); Tenn.Code Ann. § 40–23–114 (2006); Tex.Code Crim. Proc. Ann., Art. 43.14 (Vernon 2006 Supp. Pamphlet); Utah Code Ann. § 77–18–5.5 (Lexis Supp.2007); Wyo. Stat. Ann. § 7–13–904 (2007). Nine States allow for lethal injection in addition to an alternative method, such as electrocution, see Ala.Code §§ 15–18–82 to 82.1 (Supp.2007); Fla. Stat. § 922.105 (2006); S.C.Code Ann. § 24–3–530 (2007); Va.Code Ann. § 53.1–234 (Lexis Supp.2007), hanging, see N.H.Rev.Stat. Ann. § 630:5 (2007); Wash. Rev.Code § 10.95.180 (2006), lethal gas, see Cal.Penal Code Ann. § 3604 (West 2000); Mo.Rev.Stat. § 546.720 (2007 Cum.Supp.), or firing squad, see Idaho Code § 19–2716 (Lexis 2004). Nebraska is the only State whose statutes specify electrocution as the sole method of execution, see Neb.Rev.Stat. § 29–2532 (1995), but the Nebraska Supreme Court recently struck down that method under the Nebraska Constitution, see *State v. Mata,* 275 Neb. 1, 745 N.W.2d 229, 278 (2008).

Although it is undisputed that the States using lethal injection adopted the protocol first developed by Oklahoma without significant independent review of the procedure, it is equally undisputed that, in moving to lethal injection, the States were motivated by a desire to find a more humane alternative to then-existing methods. See Fordham Brief 2–3. In this regard, Kentucky was no different. See *id.,* at 29–30 (quoting statement by the State Representative who sponsored the bill to replace electrocution with lethal injection in Kentucky: "[I]f we are going to do capital punishment, it needs to be done in the most humane manner" (internal quotation marks omitted)).

2 The difficulties inherent in such approaches are exemplified by the controversy surrounding the study of lethal injection published in the April 2005 edition of the British medical journal the Lancet. After examining thiopental concentrations in toxicology reports based on blood samples drawn from 49 executed inmates, the study concluded that "most of the executed inmates had concentrations that would not be expected to produce a surgical plane of anaesthesia, and 21(43%) had concentrations consistent with consciousness." Koniaris, Zimmers, Lubarsky, & Sheldon, Inadequate Anaesthesia in Lethal Injection for Execution, 365 Lancet 1412, 1412–1413. The study was widely cited around the country in motions to stay executions and briefs on the merits. See, *e.g.,* Denno, The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty, 76 Ford. L.Rev. 49, 105, n. 366 (2007) (collecting cases in which claimants cited the Lancet study). But shortly after the Lancet study appeared, peer responses by seven medical researchers criticized the methodology supporting the original conclusions. See Groner, Inadequate Anaesthesia in Lethal Injection for Execution, 366 Lancet 1073–1074 (Sept.2005). These researchers noted that because the blood samples were taken "several hours to days after" the inmates' deaths, the postmortem concentrations of thiopental—a fat-soluble compound that passively diffuses from blood into tissue—could not be relied on as accurate indicators for concentrations during life. *Id.,* at 1073. The authors of the original study responded to defend their methodology. *Id.,* at 1074–1076. See also *post,* at 1564 – 1565 (BREYER, J., concurring in judgment).

We do not purport to take sides in this dispute. We cite it only to confirm that a "best practices" approach, calling for the weighing of relative risks without some measure of deference to a State's choice of execution procedures, would involve the courts in debatable matters far exceeding their expertise.

3 Justice THOMAS agrees that courts have neither the authority nor the expertise to function as boards of inquiry determining best practices for executions, see *post,* at 1560 (opinion concurring in judgment) (quoting this opinion); *post,* at 1562, but contends that the standard we adopt inevitably poses such concerns. In our view, those concerns are effectively addressed by the threshold requirement reflected in our cases of a " 'substantial risk of serious harm' " or an " 'objectively intolerable risk of harm,' " see *supra,* at 1561, and by the substantive requirements in the articulated standard.

4 Petitioners did allude to an "alternative chemical or combination of chemicals" that could replace Kentucky's three-drug protocol in their post-trial brief, see App. 684, but based on the arguments presented there, it is clear they intended to refer only to other, allegedly less painful drugs that could substitute for potassium chloride as a heart-stopping agent, see *id.,* at 701. Likewise, the only alternatives to the three-drug protocol presented to the Kentucky Supreme Court were those that replaced potassium chloride with other drugs for inducing cardiac arrest, or that omitted pancuronium bromide, or that added an analgesic to relieve pain. See Brief for Appellants in No.2005–SC–00543, pp. 38, 39, 40.

5 Justice STEVENS's conclusion that the risk addressed by pancuronium bromide is "vastly outweighed" by the risk of pain at issue here, see *post,* at 1544 (opinion concurring in judgment), depends, of course, on the magnitude of the risk of such pain. As explained, that risk is insignificant in light of the safeguards Kentucky has adopted.

6 Resisting this point, the dissent rejects the expert testimony that problems with the IV administration of sodium thiopental would be obvious, see *post,* at 1571 – 1572, testimony based not only on the pain that would result from injecting the first drug into tissue rather than the vein, see App. 600–601, but also on the swelling that would occur, see *id.,* at 353. See also *id.,* at 385–386. Neither of these expert conclusions was disputed below.

7 We do not agree with Justice STEVENS that anything in our opinion undermines or remotely addresses the validity of capital punishment. See *post,* at 1538. The fact that society has moved to progressively more humane methods of execution does not suggest that capital punishment itself no longer serves valid purposes; we would not have supposed that the case for capital punishment was stronger when it was imposed predominantly by hanging or electrocution.

* In making this recommendation, he states that "[t]here is a general understanding among veterinarians that the risk of pain is sufficiently serious that the use of [this] drug should be proscribed when an animal's life is being terminated." *Post,* at 1543. But the American Veterinary Medical Association (AVMA) guidelines take pains to point out that they should not be interpreted as commenting on the execution of humans by lethal injection. AVMA, Guidelines on Euthanasia (June 2007), online at http://avma.org/issues/ animal_welfare/euthanasia.pdf.

1 The 2000 Report of the American Veterinary Medical Association (AVMA) Panel on Euthanasia stated that a "combination of pentobarbital with a neuromuscular blocking agent is not an acceptable euthanasia agent." 218 J. Am. Veterinary Med. Assn. 669, 680 (2001). In a 2006 supplemental statement, however, the AVMA clarified that this statement was intended as a recommendation against mixing a barbiturate and neuromuscular blocking agent in the same syringe, since such practice creates the possibility that the paralytic will take effect before the barbiturate, rendering the animal paralyzed while still conscious. The 2007 AVMA Guidelines on Euthanasia plainly state that the application of a barbiturate, paralyzing agent, and potassium chloride delivered in separate syringes or stages is not discussed in the report. Several veterinarians, however, have filed an *amici* brief in this case arguing that the three-drug cocktail fails to measure up to veterinary standards and that the use of pancuronium bromide should be prohibited. See Brief for Dr. Kevin Concannon et al. as *Amici Curiae* 16–18. The Humane Society has also declared "inhumane" the use of "any combination of sodium pentobarbital with a neuromuscular blocking agent." R. Rhoades, The Humane Society of the United States, Euthanasia Training Manual 133 (2002); see also Alper, Anesthetizing the Public Conscience: Lethal Injection and Animal Euthanasia, 35 Ford. Urb. L.J. 817, 840 (2008) (concluding, based on a comprehensive study of animal euthanasia laws and regulations, that "the field of animal euthanasia has reached a unanimous consensus that neuromuscular blocking agents like pancuronium have no legitimate place in the execution process"), online at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1109258 (all Internet materials as visited Apr. 10, 2008, and available in Clerk of Court's case file).

2 See also, *e.g.,* Fla. Stat. § 828.058(3) (2006) ("[A]ny substance which acts as a neuromuscular blocking agent ... may not be used on a dog or cat for any purpose"); N.J. Stat. Ann. § 4:22–19.3 (West 1998) ("Whenever any dog, cat, or any other domestic animal is to be destroyed, the use of succinylcholine chloride, curare, curariform drugs, or any other substance which acts as a neuromuscular blocking agent is prohibited"); N.Y. Agric. & Mkts. Law Ann. § 374(2–b) (West 2004) ("No person shall euthanize any dog or cat with T–61, curare, any curariform drug, any neuro-muscular blocking agent or any other paralyzing drug"); Tenn.Code Ann. § 44–17–303(c) (2007) ("Succinylcholine chloride, curare, curariform mixtures ...

or any substance that acts as a neuromuscular blocking agent ... may not be used on any non-livestock animal for the purpose of euthanasia"). According to a recent study, not a single State sanctions the use of a paralytic agent in the administration of animal euthanasia, 9 States explicitly ban the use of such drugs, 13 others ban it by implication—*i.e.,* by mandating the use of nonparalytic drugs, 12 arguably ban it by reference to the AVMA guidelines, and 8 others express a strong preference for use of nonparalytic drugs. Alper, *supra,* at 841 – 842, and App. I to Alper, *supra*, at 853.

3 Indeed, the decision by prison administrators to use the drug on humans for aesthetic reasons is not supported by any consensus of medical professionals. To the contrary, the medical community has considered—and rejected—this aesthetic rationale for administering neuromuscular blocking agents in end-of-life care for terminally ill patients whose families may be disturbed by involuntary movements that are misperceived as signs of pain or discomfort. As explained in an *amici curiae* brief submitted by critical care providers and clinical ethicists, the medical and medical ethics communities have rejected this rationale because there is a danger that such drugs will mask signs that the patient is actually in pain. See Brief for Critical Care Providers et al. as *Amici Curiae*.

4 Of the 35 state statutes providing for execution by lethal injection, only approximately one-third specifically approve the use of a chemical paralytic agent. See Ark.Code Ann. § 5–4–617 (2006); Idaho Code § 19–2716 (Lexis 2004); Ill. Comp. Stat., ch. 725, § 5/119–5 (West 2006); Md.Crim. Law Code Ann. § 2–303 (Lexis Supp.2007); Miss.Code Ann. § 99–19–51 (2007); Mont.Code Ann. § 46–19–103 (2007); N.H.Rev.Stat. Ann. § 630:5 (2007); N.M. Stat. Ann. § 31–14–11 (2000); N.C. Gen.Stat. Ann. § 15–187 (Lexis 2007); Okla. Stat., Tit. 22, § 1014 (West 2001); Ore.Rev.Stat. § 137.473 (2003); Pa. Stat. Ann., Tit. 61, § 3004 (Purdon 1999); Wyo. Stat. Ann. § 7–13–904 (2007). Twenty of the remaining States do not specify any particular drugs. See Ariz.Rev.Stat. Ann. § 13–704 (West 2001); Cal.Penal Code Ann. § 3604 (West 2000); Conn. Gen.Stat. § 54–100 (2007); Del.Code Ann., Tit. 11, § 4209 (2006 Supp.); Fla. Stat. § 922.105 (2006); Ga.Code Ann. § 17–10–38 (2004); Ind.Code § 35–38–6–1 (West 2004); Kan. Stat. Ann. § 22–4001 (2006 Cum.Supp.); Ky.Rev.Stat. Ann. § 431.220 (West 2006); La. Stat. Ann. § 15:569 (West 2005); Mo.Rev.Stat. § 546.720 (2007 Cum.Supp.); Nev.Rev.Stat. § 176.355 (2007); Ohio Rev.Code Ann. § 2949.22 (Lexis 2006); S.C.Code Ann. § 24–3–530 (2007); S.D. Codified Laws § 23A–27A–32 (Supp.2007); Tenn.Code Ann. § 40–23–114 (2006); Tex.Code Crim. Proc. Ann., Art. 43.14 (Vernon 2006 Supp. Pamphlet); Utah Code Ann. § 77–18–5.5 (Lexis Supp.2007); Va.Code Ann. § 53.1–234 (Lexis Supp.2007); Wash. Rev.Code § 10.95.180 (2006).

5 Colorado's statute provides for "a continuous intravenous injection of a lethal quantity of sodium thiopental or other equally or more effective substance sufficient to cause death." § 18–1.3–1202. Despite the fact that the statute specifies only sodium thiopental, it appears that Colorado uses the same three drugs as other States. See Denno, The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty, 76 Ford. L.Rev. 49, 97, and n. 322 (2007).

6 Notably, the Oklahoma medical examiner who devised the protocol has disavowed the use of pancuronium bromide. When asked in a recent interview why he included it in his formula, he responded: " 'It's a good question. If I were doing it now, I would probably eliminate it.' " E. Cohen, Lethal injection creator: Maybe it's time to change formula, online at http://www.cnn.com/2007/HEALTH/04/30/lethal.injection/ index.html.

7 Officials of the DOC had before them an advisory paper submitted by a group of New York doctors recommending sodium thiopental " 'without the addition of other drugs,' " and the supervisor of the health services unit was informed in a memo from a colleague that pancuronium bromide " 'will cause paralysis of the vocal chords and stop breathing, and hence could cause death by asphyxiation.' " Edwards, 170 N.J.L. J., at 673.

8 Further, concerns about this issue may have played a role in New Jersey's subsequent decisions to create a New Jersey Death Penalty Study Commission in 2006, and ultimately to abolish the death penalty in 2007.

9 For similar reasons, States may also be well advised to reconsider the sufficiency of their procedures for checking the inmate's consciousness. See *post,* at 1569 (GINSBURG, J., dissenting).

Justice ALITO correctly points out that the Royal Dutch Society for the Advancement of Pharmacy recommends pancuronium bromide "as the second of the two drugs to be used in cases of euthanasia." *Ante,* at 1541 (concurring opinion). In the Netherlands, however, physicians with training in anesthesiology are involved in assisted suicide. For reasons Justice ALITO details, see *ante,* at 1539 – 1540, physicians have no similar role in American executions. When trained medical personnel administer anesthesia and monitor the individual's anesthetic depth, the serious risks that concern me are not presented.

10 Forty-eight States now have some form of life imprisonment without parole, with the majority of statutes enacted within the last two decades. See Note, A Matter of Life and Death: The Effect of Life–Without–Parole Statutes on Capital Punishment, 119 Harv. L.Rev. 1838, 1839, 1841–1844 (2006).

11 See R. Dieter, Sentencing for Life: Americans Embrace Alternatives to the Death Penalty (Apr.1993), online at http:// www.death penaltyinfo. org/article.php?scid=45 & did=481.

12 In one study, potential capital jurors in Virginia stated that knowing about the existence of statutes providing for life without the possibility of parole would significantly influence their sentencing decision. In another study, a significant majority of potential capital jurors in Georgia said they would be more likely to select a life sentence over a death sentence if they knew that the defendant would be ineligible for parole for at least 25 years. See Note, 119 Harv. L.Rev., at 1845. Indeed, this insight drove our decision in *Simmons v. South Carolina,* 512 U.S. 154, 114 S.Ct. 2187, 129 L.Ed.2d 133 (1994), that capital defendants have a due process right to require that their sentencing juries be informed of their ineligibility for parole.

13 Admittedly, there has been a recent surge in scholarship asserting the deterrent effect of the death penalty, see, *e.g.,* Mocan & Gittings, Getting Off Death Row: Commuted Sentences and the Deterrent Effect of Capital Punishment, 46 J. Law & Econ. 453 (2003); Adler & Summers, Capital Punishment Works, Wall Street Journal, Nov. 2, 2007, p. A13, but there has been an equal, if not greater, amount of scholarship criticizing the methodologies of those studies and questioning the results, see, *e.g.,* Fagan, Death and Deterrence Redux: Science, Law and Causal Reasoning on Capital Punishment, 4 Ohio St. J.Crim. L. 255 (2006); Donohue & Wolfers, Uses and Abuses of Empirical Evidence in the Death Penalty Debate, 58 Stan. L.Rev. 791 (2005).

14 Retribution is the most common basis of support for the death penalty. A recent study found that 37% of death penalty supporters cited "[a]n eye for an eye/they took a life/fits the crime" as their reason for supporting capital punishment. Another 13% cited "They deserve it." The next most common reasons—"[s]av[ing] taxpayers money/cost associated with prison" and deterrence—were each cited by 11% of supporters. See Dept. of Justice, Bureau of Justice Statistics, Sourcebook of Criminal Justice Statistics 147 (2003) (Table 2.55), online at http://www.albany. edu/sourcebook/pdf/t255.pdf.

15 For example, family members of victims of the Oklahoma City bombing called for the Government to " 'put [Timothy McVeigh] inside a bomb and blow it up.' " Walsh, One Arraigned, Two Undergo Questioning, Washington Post, Apr. 22, 1995, pp. A1, A13. Commentators at the time noted that an overwhelming percentage of Americans felt that executing McVeigh was not enough. Lindner, A Political Verdict: McVeigh: When Death Is Not Enough, L.A. Times, June 8, 1997, p. M1.

16 For example, one survivor of the Oklahoma City bombing expressed a belief that " 'death by [lethal] injection [was] "too good" for McVeigh.' " A. Sarat, When the State Kills: Capital Punishment and the American Condition 64 (2001). Similarly, one mother, when told that her child's killer would die by lethal injection, asked: "Do they feel anything? Do they hurt? Is there any pain? Very humane compared to what they've done to our children. The torture they've put our kids through. I think sometimes it's too easy. They ought to feel something. If it's fire burning all the way through their body or whatever. There ought to be some little sense of pain to it." *Id.,* at 60 (emphasis deleted).

17 For a discussion of the financial costs as well as some of the less tangible costs of the death penalty, see Kozinski & Gallagher, Death: The Ultimate Run–On Sentence, 46 Case W. Res. L.Rev. 1 (1995) (discussing, *inter alia,* the burden on the courts and the lack of finality for victim's families). Although a lack of finality in death cases may seem counterintuitive, Kozinski and Gallagher explain:

> "Death cases raise many more issues, and more complex issues, than other criminal cases, and they are attacked with more gusto and reviewed with more vigor in the courts. This means there is a strong possibility that the conviction or sentence will be reconsidered—seriously reconsidered—five, ten, twenty years after the trial. ... One has to wonder and worry about the effect this has on the families of the victims, who have to live with the possibility—and often the reality—of retrials, evidentiary hearings, and last-minute stays of execution for decades after the crime." *Id.,* at 17–18 (footnotes omitted).
>
> Thus, they conclude that "we are left in limbo, with machinery that is immensely expensive, that chokes our legal institutions so they are impeded from doing all the other things a society expects from its courts, [and] that visits repeated trauma on victims' families ... ." *Id.,* at 27–28; see also Block, A Slow Death, N.Y. Times, Mar. 15, 2007, p. A27 (discussing the "enormous costs and burdens to the judicial system" resulting from the death penalty).
>
> Some argue that these costs are the consequence of judicial insistence on unnecessarily elaborate and lengthy appellate procedures. To the contrary, they result "in large part from the States' failure to apply constitutionally sufficient procedures at the time of initial [conviction or] sentencing." *Knight v. Florida,* 528 U.S. 990, 998, 120 S.Ct. 459, 145 L.Ed.2d 370 (1999) (BREYER, J., dissenting from denial of certiorari). They may also result from a general reluctance by States to put large numbers of defendants to death, even after a sentence of death is imposed. Cf. Tempest, Death Row Often Means a Long Life; California Condemns Many Murderers, but Few Are Ever Executed, L.A. Times, Mar. 6, 2005, p. B1 (noting that California death row inmates account for about 20% of the Nation's total death row population, but that the State accounts for only 1% of the Nation's executions). In any event, they are most certainly not the fault of

judges who do nothing more than ensure compliance with constitutional guarantees prior to imposing the irrevocable punishment of death.

18 See *Uttecht v. Brown,* 551 U.S. 1, 35, 127 S.Ct. 2218, 2238–2239, 167 L.Ed.2d 1014 (2007) (STEVENS, J., dissenting) (explaining that "[m]illions of Americans oppose the death penalty," and that "[a] cross section of virtually every community in the country includes citizens who firmly believe the death penalty is unjust but who nevertheless are qualified to serve as jurors in capital cases").

19 Not a single Justice in *Furman* concluded that the mention of deprivation of "life" in the Fifth and Fourteenth Amendments insulated the death penalty from constitutional challenge. The five Justices who concurred in the judgment necessarily rejected this argument, and even the four dissenters, who explicitly acknowledged that the death penalty was not considered impermissibly cruel at the time of the framing, proceeded to evaluate whether anything had changed in the intervening 181 years that nevertheless rendered capital punishment unconstitutional. *Furman,* 408 U.S., at 380–384, 92 S.Ct. 2726 (Burger, C.J., joined by Blackmun, Powell, and Rehnquist, JJ., dissenting); see also *id.,* at 420, 92 S.Ct. 2726 (Powell, J., joined by Burger, C.J., and Blackmun and Rehnquist, JJ., dissenting). ("Nor are 'cruel and unusual punishments' and 'due process of law' static concepts whose meaning and scope were sealed at the time of their writing"). And indeed, the guarantees of procedural fairness contained in the Fifth and Fourteenth Amendments do not resolve the substantive questions relating to the separate limitations imposed by the Eighth Amendment.

* As gruesome as these methods of execution were, they were not the worst punishments the Framers would have been acquainted with. After surveying the various "superadd[itions]" to the death penalty in English law, as well as lesser punishments such as "mutilation or dismembering, by cutting off the hand or ears" and stigmatizing the offender "by slitting the nostrils, or branding in the hand or cheek," Blackstone was able to congratulate his countrymen on their refinement, in contrast to the barbarism on the Continent: "Disgusting as this catalogue may seem, it will afford pleasure to an English reader, and do honor to the English law, to compare it with that shocking apparatus of death and torment to be met with in the criminal codes of almost every other nation in Europe." 4 Blackstone 377.

1 Hanging was the State's prior mode of execution. Electrocution, considered "less barbarous," indeed "the most humane" way to administer the death penalty, was believed at the time to "result in instantaneous, and consequently in painless, death." *In re Kemmler,* 136 U.S. 436, 443–444, 10 S.Ct. 930, 34 L.Ed. 519 (1890) (internal quotation marks omitted).

2 The Court also ruled in *Kemmler* that the State's election to carry out the death penalty by electrocution in lieu of hanging encountered no Fourteenth Amendment shoal: No privilege or immunity of United States citizenship was entailed, nor did the Court discern any deprivation of due process. *Id.,* at 448–449, 10 S.Ct. 930.

3 The plurality deems medical standards irrelevant in part because "drawn from a different context." *Ante,* at 1536. Medical professionals monitor blood pressure and heart rate, however, not just to save lives, but also to reduce the risk of consciousness during otherwise painful procedures. Considering that the constitutionality of Kentucky's protocol depends on guarding against the same risk, see *supra,* at 1526; *ante,* at 1533 (plurality opinion), the plurality's reluctance to consider medical practice is puzzling. No one is advocating the wholesale incorporation of medical standards into the Eighth Amendment. But Kentucky could easily monitor the inmate's blood pressure and heart rate without physician involvement. That medical professionals consider such monitoring important enough to make it the standard of care in medical practice, I remain persuaded, is highly instructive.

4 Petitioners' expert testified that a layperson could not tell from visual observation if a paralyzed inmate was conscious and that doing so would be difficult even for a professional. App. 418. Kentucky's warden candidly admitted: "I honestly don't know what you'd look for." *Id.,* at 283.

5 Because most death penalty States keep their protocols secret, a comprehensive survey of other States' practices is not available. See Brief for American Civil Liberties Union et al. as *Amici Curiae* 6–12.

6 Florida's expert in *Lightbourne v. McCollum,* 969 So.2d 326 (Fla.2007) *(per curiam),* who also served as Kentucky's expert in this case, testified that the eyelash test is "probably the most common first assessment that we use in the operating room to determine ... when a patient might have crossed the line from being conscious to unconscious." 4 Tr. in *State v. Lightbourne,* No. 81–170–CF (Fla. Cir. Ct., Marion Cty.), p. 511, online at http://www.cjlf.org/files/ LightbourneRecord.pdf (all Internet materials as visited Apr. 14, 2008, and in Clerk of Court's case file). "A conscious person, if you touch their eyelashes very lightly, will blink; an unconscious person typically will not." *Ibid*. The shaking and name-calling tests, he further testified, are similar to those taught in basic life support courses. See *id*., at 512.

7 In Indiana, a physician also examines the inmate after injection of the first drug. Timberlake Hearing 199.

8 The length of the tubing contributes to the risk that the inmate will receive an inadequate dose of sodium thiopental. The warden and deputy warden watch for obvious leaks in the execution chamber, see *ante,* at 1528 – 1530 (plurality opinion), but the line also snakes into the neighboring control room through a small hole in the wall, App. 280.

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777 F.3d 286
United States Court of Appeals,
Fifth Circuit.

Robert Charles LADD, Plaintiff–Appellant
v.
Brad LIVINGSTON, Executive Director, Texas Department of Criminal Justice; William Stephens, Director, Texas Department of Criminal Justice, Correctional Institutions Division; James Jones, Senior Warden, Huntsville Unit Huntsville, Texas; Unknown Executioners, Defendants–Appellees.

No. 15–70004.
|
Jan. 28, 2015.

Synopsis

Background: State inmate who was convicted of capital murder and sentenced to death, 3 S.W.3d 547, filed § 1983 action alleging that Texas's method of **execution** would violate his constitutional rights. The United States District Court for the Southern District of Texas, John D. Rainey, J., denied inmate's motion for preliminary injunction or temporary restraining order, and he appealed.

[Holding:] The Court of Appeals, Patrick E. Higginbotham, Circuit Judge, held that inmate filed to establish likelihood that **execution** protocol violated Eighth Amendment.

Affirmed.

West Headnotes (4)

[1] Federal Courts
Preliminary injunction;temporary restraining order

Court of Appeals reviews denial of motion for preliminary injunctive relief for abuse of discretion.

2 Cases that cite this headnote

[2] Injunction
Grounds in general;multiple factors

To be entitled to preliminary injunction, movant must establish (1) likelihood of success on merits; (2) substantial threat of irreparable injury; (3) that threatened injury if injunction is denied outweighs any harm that will result if injunction is granted; and (4) that grant of injunction will not disserve public interest.

5 Cases that cite this headnote

[3] Sentencing and Punishment
Mode of **execution**

Plaintiff challenging state's method of **execution** can succeed on Eighth Amendment claim only if he can establish both that state's **execution** protocol creates demonstrated risk of severe pain and that that risk is substantial when compared to known and available alternatives. U.S.C.A. Const.Amend. 8.

2 Cases that cite this headnote

[4] Civil Rights
Criminal law enforcement;prisons

Death row inmate failed to establish likelihood that Texas's **execution** protocol, which involved **pentobarbital**, would cause him severe pain, in violation of Eighth Amendment, and thus was not entitled to preliminary injunction in his § 1983 action challenging protocol, despite inmate's contentions that compounded drugs were unregulated and subject to quality and efficacy problems, and that **executions** conducted in other states caused or appeared to cause prisoner severe pain, where state put forward evidence that **pentobarbital** that would be used was not contaminated, and other states used multi-drug protocols. U.S.C.A. Const.Amend. 8; 42 U.S.C.A. § 1983.

3 Cases that cite this headnote

Attorneys and Law Firms

***287** Maurie Levin, Philadelphia, PA, Patrick F. McCann, Law Offices of Patrick F. McCann, Houston, TX, for Plaintiff–Appellant.

Fredericka Searle Sargent, Assistant Attorney General, Office of the Attorney General, Austin, TX, for Defendants–Appellees.

Appeal from the United States District Court for the Southern District of Texas.

Before HIGGINBOTHAM, DAVIS, and HAYNES, Circuit Judges.

Opinion

PATRICK E. HIGGINBOTHAM, Circuit Judge:

Robert Charles Ladd was convicted of capital murder and sentenced to death. He is scheduled to be **executed** by the State of Texas on January 29, 2015. On January 27, 2015, after the Supreme Court granted certiorari in *Glossip v. Gross,* Ladd filed a section 1983 lawsuit alleging that the state's method of **execution** would violate his Eighth and Fourteenth Amendment rights. The district court denied his motion for a preliminary injunction or temporary restraining order. Compelled by our court's precedent, we AFFIRM.

I.

This case has a complex factual and procedural background, which we laid out in detail in our earlier opinion affirming the district court's denial of habeas relief. [1] We briefly summarize here.

On August 23, 1997, Ladd was convicted of capital murder for the rape and murder of Vicki Ann Garner. A Texas state jury imposed the death penalty four days later. The Texas Court of Criminal Appeals affirmed Ladd's sentence and conviction on direct appeal in October 1999. [2] After unsuccessfully seeking state habeas relief, he filed his first application for federal habeas relief on January 18, 2001, raising a claim that he received ineffective assistance of counsel because his attorney had not raised evidence of Ladd's intellectual disability during the punishment phase of the trial. [3] The district court denied habeas relief and we affirmed. [4]

In 2002, the Supreme Court, in *Atkins v. Virginia*, altered the capital punishment landscape by holding that individuals who are intellectually disabled are categorically ineligible for the death penalty. [5] Following this decision, Ladd filed a second petition for state habeas relief, which was denied without an evidentiary hearing or an opportunity for him to develop his *Atkins* claim. [6] We authorized the filing of a second habeas petition in the district court. After holding an evidentiary hearing, the district court denied Ladd's petition, concluding that he had failed to establish by a preponderance of the evidence that he was intellectually disabled. [7] We affirmed. [8] ***288** The Supreme Court denied Ladd's petition for a writ of certiorari on October 6, 2014. [9]

On January 23, 2015, the Supreme Court granted certiorari in *Glossip v. Gross,* [10] a Tenth Circuit case that upheld the constitutionality of Oklahoma's **execution** process, which involves a three-drug protocol: midazolam hydrochloride, pancuronium bromide, and potassium chloride. [11] Four days later, on January 27, 2015, Ladd filed a complaint in federal district court [12] under 42 U.S.C. § 1983, alleging that the method of his **execution** violated his rights under the Eighth and Fourteenth Amendments. [13] He sought a temporary or preliminary injunction to stay his **execution**. The district court denied the motion for injunctive relief on January 27, 2015. [14] Ladd appeals. [15]

II.

A.

[1] **[2]** We review the denial of a motion for preliminary injunctive relief for abuse of discretion. [16]

> To be entitled to a preliminary injunction, a movant must establish (1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and

(4) that the grant of an injunction will not disserve the public interest. [17]

We are also mindful of the Supreme Court's admonition that "[f]iling an action that can proceed under [section] 1983 does not entitle the complainant to an order staying the **execution** as a matter of course." [18] Rather, "equity must be sensitive to the State's strong interest in enforcing its criminal judgments without undue interference from the federal courts." [19]

***289** B.

[3] **[4]** Following the Supreme Court's decision in *Baze v. Rees,* [20] our court held that: "[a] plaintiff can ... succeed on an Eighth Amendment claim in this context only if he can establish both that the state's [**execution**] protocol creates a demonstrated risk of severe pain and that that risk is substantial when compared to the known and available alternatives." [21] Ladd argues that he is likely to succeed on his claim that there is a substantial risk that Texas's **execution** protocol will cause him severe pain, in violation of the Eighth Amendment. In light of our court's binding precedent, we cannot agree.

We have repeatedly upheld against Eighth Amendment challenge Texas's **Execution** Procedure of July 9, 2012, which involves the use of a single drug, **pentobarbital**. [22] The **execution** protocol at issue in those cases is essentially the same as that the State plans to use here: they involve the use of an unexpired 5 gram dose of **pentobarbital** obtained from a licensed compounding pharmacy, which has been tested by an independent laboratory and found to have a potency of greater than 100% and to be free of contaminants. [23] Under our circuit's rule of orderliness, these decisions, involving the application of essentially the same facts to the same law, control our own, and require us to deny the motion for injunctive relief. [24]

In an attempt to distinguish this precedent, Ladd raises two arguments. First, he argues that compounded drugs are unregulated and subject to quality and efficacy problems. This argument, however, is essentially speculative, and the Supreme Court has held that "speculation cannot substitute for evidence that the use of the drug is '*sure or very likely* to cause serious illness and needless suffering.' " [25] Rather, to succeed, our precedent requires Ladd to "offer some proof that the state's own process—that its choice of pharmacy, that its lab results, that the training of its executioners, and so forth, are suspect." [26] "[H]ypothetical possibilities that the process was defective" are not enough for a stay, [27] and here, Ladd puts forth only hypotheticals. Second, Ladd points to a series of **executions** conducted in other states, using multi-drug protocols not at issue here, which caused or appeared to cause the prisoner severe pain. We do not diminish the gravity of these incidents—as Justice Sotomayor, dissenting from the denial of a stay of **execution** earlier this month, wrote, "the Eighth Amendment guarantees that no one should be subject to an **execution** that causes searing, unnecessary ***290** pain before death." [28] None of these **executions** have apparently used a single-drug **pentobarbital** injection from a compounded pharmacy which, as the State points out in its brief, appears to have been used without significant incident for the last fourteen **executions** carried out by the State. [29] Ladd does point to the fact that **pentobarbital** was used as part of a three-drug cocktail in at least one of the out-of-state **executions** that appeared to cause the prisoner pain, and that an expert stated that the prisoner's adverse reaction was "consistent with contaminated **pentobarbital** sodium injection." Given the different protocols in use, as well as the fact that the State has put forward evidence indicating that the **pentobarbital** that will be used is not contaminated, this evidence is not sufficient to demonstrate that "the use of the drug is '*sure or very likely* to cause serious illness and needless suffering.' " [30]

III.

Against this backdrop, Ladd nonetheless argues that we should stay his **execution** because of the Supreme Court's grant of certiorari in *Glossip.* That case addresses an Eighth Amendment challenge to Oklahoma's three-drug protocol. None of the three questions presented in that petition are directly on point with this case, however. The first question looks to whether a three-drug **execution** protocol is constitutionally permissible, an issue not relevant when the state uses a one-drug protocol. The second question asks whether the *Baze* standard applies when states are not using a protocol "substantially similar" to the one that the Supreme Court considered in *Baze.* Our court has already held that the Texas **execution** protocol is substantially similar to

the *Baze* standard.[31] Finally, the third question asks whether "a prisoner [must] establish the availability of an alternative drug formula even if the state's lethal-injection protocol, as properly administered, will violate the Eighth Amendment."[32] We have previously held, however, that the proper administration of the Texas procedure comports with the Eighth Amendment.[33]

In any event, whatever our speculation about how the Supreme Court may alter the law in the future, we are bound to follow our precedent as it exists today.[34] This request for a stay is best made to the Supreme Court, the body most aware of *Glossip* 's potential.

IV.

We AFFIRM the district court's order denying the motion for temporary injunctive ***291** relief. We DENY Ladd's motion for stay of **execution**. We GRANT Ladd's motion to proceed in forma pauperis.

All Citations

777 F.3d 286

Footnotes

1 *Ladd v. Stephens,* 748 F.3d 637 (5th Cir.2014).
2 *Id.* at 640. The United States Supreme Court denied Ladd's petition for a writ of certiorari on April 17, 2000. *Id.*
3 *See id.* Following the Supreme Court's recent opinion in *Hall v. Florida,* —— U.S. ——, 134 S.Ct. 1986, 1990, 188 L.Ed.2d 1007 (2014), we use the term "intellectual disability" where "mental retardation" had previously been used.
4 *Ladd,* 748 F.3d at 640.
5 536 U.S. 304, 321, 122 S.Ct. 2242, 153 L.Ed.2d 335 (2002).
6 *Ladd,* 748 F.3d at 641.
7 *Id.* at 644. While the evidentiary hearing was held in 2005, the district court did not issue its ruling until 2013.
8 *Id.* at 647.
9 *Ladd v. Stephens,* —— U.S. ——, 135 S.Ct. 192, 190 L.Ed.2d 150 (2014) (mem.).
10 Nos. 14–7955, 14–A761, —— U.S. ——, 135 S.Ct. 1173, 190 L.Ed.2d 929, 2015 WL 302647 (U.S. Jan. 23, 2015).
11 *Warner v. Gross,* No. 14–6244, 776 F.3d 721, 723-25, 2015 WL 137627, at *1–2 (10th Cir. Jan. 12, 2015).
12 Ladd's complaint was jointly filed with Garcia Glen White, who was originally scheduled to be **executed** on January 28, 2015. On January 27, 2015, the Texas Court of Criminal Appeals stayed White's **execution** pending further order. That cause, which raises identical issues to those addressed in this case, is being adjudicated by a separate panel of this court.
13 In *Hill v. McDonough,* 547 U.S. 573, 580–81, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006), the Supreme Court held that section 1983 was a proper vehicle for bringing a challenge to the specific manner of **execution** employed by the state. This is in contrast to a challenge to the sentence of death, which can only be brought through a habeas petition. *See id.* at 579–80, 126 S.Ct. 2096.
14 *See* Mem. & Order, Docket No. 4:15–cv–00233, ECF No. 9. Also on January 27, 2015, the Texas Court of Criminal Appeals dismissed Ladd's second application for a writ of habeas corpus and denied his motion for a stay of **execution**.
15 Concurrent with his appeal, Ladd moves in this court for a stay of **execution** and for permission to proceed in forma pauperis.
16 *Trottie v. Livingston,* 766 F.3d 450, 451 (5th Cir.2014).
17 *Id.* at 452 (citing *Sells v. Livingston,* 750 F.3d 478, 480 (5th Cir.2014)). This standard is essentially the same as the framework for deciding whether to grant a stay of **execution**. *See Adams v. Thaler,* 679 F.3d 312, 318 (5th Cir.2012).
18 *Hill,* 547 U.S. at 583–84, 126 S.Ct. 2096.
19 *Id.*
20 553 U.S. 35, 61, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality op.).
21 *Whitaker v. Livingston,* 732 F.3d 465, 468 (5th Cir.2013).
22 *See, e.g., Trottie v. Livingston,* 766 F.3d 450, 452–53 (5th Cir.2014); *Campbell v. Livingston,* 567 Fed.Appx. 287, 289 (5th Cir.2014) (unpublished); *Sells v. Livingston,* 750 F.3d 478, 480–81 (5th Cir.2014); *Sells v. Livingston,* 561 Fed.Appx. 342, 344–45 (5th Cir.2014) (unpublished); *Thorson v. Epps,* 701 F.3d 444, 447 n. 3 (5th Cir.2012) (holding, in a decision addressing Mississippi's **execution** process, that Texas's one-drug protocol is acceptable under *Baze*).

23 *See Trottie,* 766 F.3d at 452; Def.s' Opp'n Temporary Injunctive Relief & Mot. TRO Seeking Stay **Execution** ("Defs' Opp'n"), at 2.

24 *See United States v. Traxler,* 764 F.3d 486, 489 (5th Cir.2014).

25 *Brewer v. Landrigan,* —— U.S. ——, 131 S.Ct. 445, 445, 178 L.Ed.2d 346 (2010) (mem.) (quoting *Baze,* 553 U.S. at 50, 128 S.Ct. 1520 (plurality op.)).

26 *Whitaker,* 732 F.3d at 468.

27 *Id.*

28 *Warner v. Gross,* —— U.S. ——, 135 S.Ct. 824, 190 L.Ed.2d 903 (2015) (mem.) (Sotomayor, J., dissenting from denial of stay of **execution**).

29 Press reports indicate that one prisoner said that "[i]t does kind of burn. Goodbye," as the **pentobarbital** took effect. The media report indicates that all movement stopped "[w]ithin seconds." Defs.' Opp'n at 20.

30 *Landrigan,* 131 S.Ct. at 445 (quoting *Baze,* 553 U.S. at 50, 128 S.Ct. 1520).

31 *See Raby v. Livingston,* 600 F.3d 552, 558–60 (5th Cir.2010); *see also Thorson v. Epps,* 701 F.3d 444, 447 & n. 3 (5th Cir.2012).

32 Pet. Writ Certiorari, at i., *Warner v. Gross,* No. 14–7955 (U.S.2015).

33 *See, e.g., Sells v. Livingston,* 750 F.3d 478, 480–81 (5th Cir.2014); *see also Raby,* 600 F.3d at 560 (concluded that plaintiff "has failed to establish that the Texas lethal injection protocol creates a demonstrated risk of severe pain").

34 *See Wicker v. McCotter,* 798 F.2d 155, 157–58 (5th Cir.1986) (holding that, notwithstanding the fact that the Supreme Court had granted a writ of certiorari in a related case, "we must follow our circuit's precedents and deny ... a stay of **execution**").

783 F.3d 1089
United States Court of Appeals,
Eighth Circuit.

David ZINK, Plaintiff–Appellant,
Michael S. Worthington; John E. Winfield, Plaintiffs
Leon Taylor; Walter T. Storey; Earl Ringo;
Roderick Nunley, Plaintiffs–Appellants,
John C. Middleton, Plaintiff,
Paul T. Goodwin; Andre Cole; Reginald Clemons;
Cecil Clayton; Mark Christeson; Russell
Bucklew; David Barnett, Plaintiffs–Appellants,
Richard Strong; Marcellus S. Williams, Intervenors,
v.
George A. LOMBARDI; David R. Dormire; Terry
Russell; John Does, 2–40, Defendants–Appellees.

No. 14–2220.
|
Submitted: Sept. 9, 2014.
|
Filed: March 6, 2015.

Synopsis

Background: Prisoners who had been sentenced to death commenced action to challenge lethal-injection protocol of the Missouri Department of Corrections. The United States District Court for the Western District of Missouri, Beth Phillips, J., dismissed the complaint. Prisoners appealed.

Holdings: The Court of Appeals held that:

[1] descriptions of hypothetical and speculative situations in which potential flaw in production of pentobarbital could cause pain were not sufficient to state claim that protocol violated Eighth Amendment;

[2] prisoners waived issue for consideration on appeal that use of central venous access rather than peripheral venous access violated Eighth Amendment;

[3] "concession" by state prisoners that other methods of lethal injection that state could choose to use would be constitutional was not sufficient to allege that other methods of lethal injection were feasible and could be readily implemented, or that they would significantly reduce substantial risk of severe pain allegedly caused by use of pentobarbital;

[4] prisoners could not state Eighth Amendment claim based on use of compounded pentobarbital in executions without plausible allegation of feasible alternative method of execution;

[5] prisoners did not state Eighth Amendment claim on allegations that they had serious medical need to be free from gratuitous pain during their executions, and that state officials acted with deliberate indifference to their need by using compounded pentobarbital as lethal drug in state's execution procedure;

[6] Ex Post Facto Clause was not implicated by changing execution protocol to provide for use of compounded pentobarbital;

[7] allegation that state prisoners were unable to obtain information regarding execution protocol, as potential Eighth Amendment violation, was not sufficient to state due process claim that state officials violated their right of access to courts; and

[8] prisoners could not employ Missouri Administrative Procedure Act to allege denial of private legal right under federal statutes when federal statutes themselves did not create such private legal right.

Affirmed.

Colloton, Circuit Judge, joined in all but Part II.A of the opinion.

Shepherd, Circuit Judge, joined in all but Part II.B of the opinion.

Bye, Circuit Judge, filed dissenting opinion, in which Murphy and Kelly, Circuit Judges, joined.

West Headnotes (31)

[1] **Sentencing and Punishment**
Mode of execution

Any allegation that all methods of execution are unconstitutional does not state a plausible claim under the Eighth Amendment. U.S.C.A. Const.Amend. 8.

9 Cases that cite this headnote

[2] **Federal Civil Procedure**
Insufficiency in general

Federal Civil Procedure
Matters deemed admitted;acceptance as true of allegations in complaint

Legal conclusions and threadbare recitations of the elements of a cause of action supported by mere conclusory statements are not entitled to a presumption of truth when considering the sufficiency of a complaint on a motion to dismiss for failure to state a claim upon which relief can be granted; a complaint must be plausible on its face and a claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. Fed.Rules Civ.Proc.Rule 12(b)(6), 28 U.S.C.A.

108 Cases that cite this headnote

[3] **Federal Civil Procedure**
Insufficiency in general

On a motion to dismiss for failure to state a claim upon which relief can be granted, making a plausibility determination is a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. Fed.Rules Civ.Proc.Rule 12(b)(6), 28 U.S.C.A.

15 Cases that cite this headnote

[4] **Sentencing and Punishment**
Mode of execution

Successfully pleading facts to demonstrate a substantial risk of severe pain, as required to state a plausible Eighth Amendment claim in the context of an attack upon a state's execution protocol, requires the prisoners to plead more than just a hypothetical possibility that an execution could go wrong, resulting in severe pain to a prisoner; the Eighth Amendment prohibits an objectively intolerable risk of pain, rather than simply the possibility of pain. U.S.C.A. Const.Amend. 8.

4 Cases that cite this headnote

[5] **Federal Civil Procedure**
Matters considered in general

When reviewing the sufficiency of a complaint on a motion to dismiss for failure to state a claim upon which relief can be granted, a court reviews the complaint itself and any exhibits attached to the complaint. Fed.Rules Civ.Proc.Rule 12(b)(6), 28 U.S.C.A.

37 Cases that cite this headnote

[6] **Sentencing and Punishment**
Mode of execution

Allegations of prisoners who had been sentenced to death that were limited to descriptions of hypothetical and speculative situations in which potential flaw in production of pentobarbital could cause pain were not sufficient to state claim that protocol violated Eighth Amendment prohibition against cruel and unusual punishment; prisoners did not make any specific factual allegations regarding production of pentobarbital that would have led to its contamination, potency problems, or improper pH, and instead relied on general risks associated with compounding pharmacies. U.S.C.A. Const.Amend. 8; Fed.Rules Civ.Proc.Rule 12(b)(6), 28 U.S.C.A.

1 Cases that cite this headnote

[7] **Federal Courts**
Failure to mention or inadequacy of treatment of error in appellate briefs

Prisoners who had been sentenced to death waived issue for consideration on appeal that use of central venous access rather than peripheral venous access carried higher risk of complication in following lethal-injection protocol, increased length of execution, and was more invasive and painful than peripheral venous access, and thus violated Eighth Amendment prohibition against cruel and unusual punishment, since prisoners did not make any mention of central vein issues in their briefing before Court of Appeals. U.S.C.A. Const.Amend. 8.

Cases that cite this headnote

[8] **Sentencing and Punishment**
Mode of execution

On a claim that a state's execution protocol violates the Eighth Amendment prohibition against cruel and unusual punishment, the prospect of an isolated incident that would result in severe pain does not satisfy the requirement for adequately pleading a substantial risk of severe pain to survive a motion to dismiss. U.S.C.A. Const.Amend. 8; Fed.Rules Civ.Proc.Rule 12(b)(6), 28 U.S.C.A.

4 Cases that cite this headnote

[9] **Sentencing and Punishment**
Mode of execution

To state a claim that an execution protocol violates the Eighth Amendment prohibition against cruel and unusual punishment, an inmate ultimately must prove that another execution procedure exists that is feasible and readily implemented, and that the alternative method will significantly reduce a substantial risk of severe pain; therefore, the existence of such an alternative method of execution is a necessary element of an Eighth Amendment claim, and this element, like any element of a claim, must be pleaded adequately. U.S.C.A. Const.Amend. 8; Fed.Rules Civ.Proc.Rules 8, 12(b)(6), 28 U.S.C.A.

9 Cases that cite this headnote

[10] **Sentencing and Punishment**
Mode of execution

"Concession" by state prisoners who had been sentenced to death that other methods of lethal injection that state could choose to use would be constitutional was not sufficient to allege that other methods of lethal injection were feasible and could be readily implemented, or that they would significantly reduce substantial risk of severe pain allegedly caused by use of pentobarbital, and thus prisoners did not state viable claim that pentobarbital execution protocol violated Eighth Amendment prohibition against cruel and unusual punishment, since prisoners did not include factual matter that even hinted at how state could modify its lethal-injection protocol to reduce significantly the alleged substantial risk of severe pain. U.S.C.A. Const.Amend. 8; Fed.Rules Civ.Proc.Rules 8, 12(b)(6), 28 U.S.C.A.

10 Cases that cite this headnote

[11] **Federal Civil Procedure**
Claim for relief in general

Discovery does not have to be made available to a plaintiff who cannot allege sufficient factual matter to plausibly suggest an entitlement to relief. Fed.Rules Civ.Proc.Rules 8, 12(b)(6), 28 U.S.C.A.

9 Cases that cite this headnote

[12] **Sentencing and Punishment**
Mode of execution

State prisoners who had been sentenced to death could not state Eighth Amendment claim based on use of compounded pentobarbital in executions without plausible allegation of feasible alternative method of execution that would significantly reduce substantial risk of serious pain, or purposeful

design by State to inflict unnecessary pain. U.S.C.A. Const.Amend. 8; Fed.Rules Civ.Proc.Rules 8, 12(b)(6), 28 U.S.C.A.

5 Cases that cite this headnote

[13] Sentencing and Punishment
Mode of execution

State prisoners who had been sentenced to death did not state Eighth Amendment claim on allegations that they had serious medical need to be free from gratuitous pain during their executions, and that state officials acted with deliberate indifference to their need by using compounded pentobarbital as lethal drug in state's execution procedure; even assuming that Eighth Amendment deliberate-indifference claim based on medical needs was not limited to cases involving medical procedures, prisoners did not adequately plead that state's lethal-injection protocol inflicted unnecessary pain. U.S.C.A. Const.Amend. 8; Fed.Rules Civ.Proc.Rules 8, 12(b)(6), 28 U.S.C.A.

1 Cases that cite this headnote

[14] Sentencing and Punishment
Cruelty and unnecessary infliction of pain

The Eighth Amendment protects against the unnecessary and wanton infliction of pain. U.S.C.A. Const.Amend. 8.

Cases that cite this headnote

[15] Sentencing and Punishment
Conditions of Confinement

To state a claim under the Eighth Amendment, a prisoner must allege both that a deprivation of rights is objectively, sufficiently serious, and that a state official is deliberately indifferent to inmate health or safety. U.S.C.A. Const.Amend. 8.

1 Cases that cite this headnote

[16] Constitutional Law
Sentencing and Imprisonment
Sentencing and Punishment
Mode of execution

Ex Post Facto Clause was not implicated by changing execution protocol to provide for use of compounded pentobarbital, since punishment remained the same and there was no super-added punishment or superior alternatives. U.S.C.A. Const. Art. 1, § 10, cl. 1.

1 Cases that cite this headnote

[17] Constitutional Law
Penal laws in general
Constitutional Law
Punishment in general

The Ex Post Facto Clause forbids enactment of a law that changes the punishment, and inflicts a greater punishment, than the law annexed to the crime, when committed. U.S.C.A. Const. Art. 1, § 10, cl. 1.

1 Cases that cite this headnote

[18] Constitutional Law
Purpose
Constitutional Law
Punishment in general

The Ex Post Facto Clause is concerned with lack of fair notice and governmental restraint when the legislature increases punishment beyond what was prescribed when the crime was consummated. U.S.C.A. Const. Art. 1, § 10, cl. 1.

1 Cases that cite this headnote

[19] Constitutional Law
Execution of sentence
Sentencing and Punishment
Mode of execution

Allegation that state prisoners who had been sentenced to death were unable to obtain information regarding execution protocol, as potential Eighth Amendment violation, was not sufficient to state due process claim that

state officials violated their right of access to courts. U.S.C.A. Const.Amends. 8, 14.

4 Cases that cite this headnote

[20] **Constitutional Law**
Access to courts

State prisoners have a Due Process right of access to the courts, but this right does not guarantee the ability to discover grievances, and to litigate effectively once in court; the right of access to the courts is satisfied if the prisoner has the capability of bringing contemplated challenges to sentences or conditions of confinement before the courts. U.S.C.A. Const.Amend. 14.

5 Cases that cite this headnote

[21] **Sentencing and Punishment**
Presentation and reservation in lower court of grounds of review

Prisoners who had been sentenced to death waived Due Process issue for consideration on appeal under *Mathews v. Eldridge* that their "life interest entitles them to notice of material information about the lethal drug with which they will be executed," since prisoners did not develop argument based on *Mathews* in the district court. U.S.C.A. Const.Amend. 14.

Cases that cite this headnote

[22] **Constitutional Law**
Capital Punishment;Death Penalty
Sentencing and Punishment
Proceedings
Sentencing and Punishment
Review of Proceedings to Impose Death Sentence

State prisoners who had been convicted and sentenced to death after trial in state court, and whose convictions and sentences were upheld on appeal, received due process for the deprivation of their life interests. U.S.C.A. Const.Amend. 14.

Cases that cite this headnote

[23] **Constitutional Law**
Execution of sentence
Sentencing and Punishment
Mode of execution

Prisoners who had been sentenced to death did not have a freestanding due process right to detailed disclosure about state's execution protocol; prisoners' assertion of necessity, i.e., that the state must disclose its protocol so they can challenge its conformity with the Eighth Amendment, did not substitute for the identification of a cognizable liberty interest. U.S.C.A. Const.Amends. 8, 14.

6 Cases that cite this headnote

[24] **Constitutional Law**
Capital punishment;death penalty
Sentencing and Punishment
Stay of execution

State prisoners who had been sentenced to death did not have fundamental right to avoid execution while no judicial stay was in effect even if legal activity was pending, and thus state's deviation from execution protocol by carrying out sentences while legal activity was pending did not violate equal protection, Eighth Amendment, or any other constitutional provision. U.S.C.A. Const.Amends. 8, 14.

Cases that cite this headnote

[25] **Constitutional Law**
Statutes and other written regulations and rules

If a legislative classification or distinction neither burdens a fundamental right nor targets a suspect class, it will be upheld under the Equal Protection Clause so long as it bears a rational relation to some legitimate end. U.S.C.A. Const.Amend. 14.

2 Cases that cite this headnote

[26] **Constitutional Law**
Sentencing and punishment
Sentencing and Punishment
Mode of execution

First Amendment did not grant right to state prisoner who had been sentenced to death to know where, how, and by whom lethal injection drugs would be manufactured. U.S.C.A. Const.Amend. 1; V.A.M.S. § 546.720(2).

3 Cases that cite this headnote

[27] **Constitutional Law**
Sentencing and punishment
Sentencing and Punishment
Mode of execution

Prisoners who had been sentenced to death did not state claim of qualified right of public access to information under First Amendment regarding source of compounded pentobarbital to be used in their executions, since they did not plausibly allege history of openness to general public, and complaint did not provide basis to conclude that public access to detailed information about execution protocols played significant positive role in functioning of process in question, given that practical effect of public disclosure likely would be frustration of state's ability to carry out lawful sentences. U.S.C.A. Const.Amend. 1; Fed.Rules Civ.Proc.Rules 8, 12(b)(6), 28 U.S.C.A.

6 Cases that cite this headnote

[28] **Constitutional Law**
Access to proceedings;closure

To determine whether a First Amendment public right of access attaches to a particular judicial proceeding, courts consider whether the place and process have historically been open to the press and general public and whether public access plays a significant positive role in the functioning of the particular process in question. U.S.C.A. Const.Amend. 1.

5 Cases that cite this headnote

[29] **Constitutional Law**
Sentencing and punishment

Missouri statute which provided that "identities of members of the execution team, as defined in the execution protocol of the department of corrections, shall be kept confidential" was not content-based restriction on access to information, and thus strict scrutiny was not warranted on First Amendment claim of public right of access, since statute did not limit dissemination of identities of execution team members based on identity of individual seeking that information and likely content of that individual's speech, and law did not limit use of any such information to certain types of speech. U.S.C.A. Const.Amend. 1; V.A.M.S. § 546.720(2).

1 Cases that cite this headnote

[30] **Sentencing and Punishment**
Mode of execution

State prisoners who had been sentenced to death could not employ Missouri Administrative Procedure Act to allege denial of private legal right under federal drug statutes with regard to use of compounded pentobarbital as lethal drug in executions when those federal statutes themselves did not create such a private legal right. Federal Food, Drug, and Cosmetic Act, § 1, 21 U.S.C.A. § 301; Comprehensive Drug Abuse Prevention and Control Act of 1970, § 101, 21 U.S.C.A. § 801; V.A.M.S. § 536.150.

3 Cases that cite this headnote

[31] **Administrative Law and Procedure**
Reviewability

Under Missouri law, to make a prima facie case for a court to review a decision of an administrative officer or body, an individual must plead facts that, if true, would show that he has been denied some legal right or

entitlement to a privilege; the plaintiff must thus identify a rule, statute, or other authority creating a legal right or entitlement. V.A.M.S. § 536.150.

Cases that cite this headnote

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Before RILEY, Chief Judge, WOLLMAN, LOKEN, MURPHY, BYE, SMITH, COLLOTON, GRUENDER, SHEPHERD, and KELLY, Circuit Judges, En Banc.

Opinion

PER CURIAM. [1]

Several prisoners sentenced to death in Missouri appeal the district court's [2] dismissal of their complaint challenging the lethal-injection protocol of the Missouri Department of Corrections. The prisoners sued state officials who are charged with planning, supervising, and carrying out executions, and two independent contractors who allegedly have prescribed, produced, or tested the compounded pentobarbital used in the State's current lethal-injection protocol. They sought a declaratory judgment that the lethal-injection protocol violates the Constitution of the United States, the Missouri Constitution, several provisions of state law, and Missouri common law, and an injunction ***1096** that prevents the defendants from executing them in accordance with the protocol.

I.

This litigation commenced in 2012 when the prisoners challenged what was then a new lethal-injection protocol. In prior years, Missouri's lethal-injection protocol involved the administration of three drugs: "[S]odium thiopental to anesthetize the prisoner and render him unconscious, pancuronium bromide to paralyze him and stop his breathing, and potassium chloride to stop the prisoner's heart." *Ringo v. Lombardi,* 677 F.3d 793, 795 (8th Cir.2012). In May 2012, after sodium thiopental

became unavailable, the State revised its protocol to use a single drug—propofol—as the lethal agent.

In June 2012, the prisoners sued in state court to challenge the new protocol. State officials removed the case to federal court and promptly moved to dismiss the petition for failure to state a claim. The district court denied the motion in part and granted it in part, ruling as relevant here that the plaintiffs had adequately pleaded that the protocol presented a risk of harm that violated the Eighth Amendment and that the prisoners were not required to plead a reasonable alternative method of execution to the use of propofol. The court also ruled that the allegedly higher risk of pain posed by the protocol, compared to the State's prior methods of execution, sufficed to state a claim of unconstitutional *ex post facto* punishment.

In October 2013, the State informed the district court that it had revised its protocol to use pentobarbital, rather than propofol, as the lethal agent. In late 2013, after a discovery dispute, the district court ordered the State to disclose to counsel for the prisoners the identities of the physician who prescribes the pentobarbital used in Missouri executions, the pharmacist who compounds it, and the laboratory that tests the compounded drug. *In re Lombardi,* 741 F.3d 888, 892 (8th Cir.) (en banc), *reh'g denied,* 741 F.3d 903 (8th Cir.), *cert. denied,* —— U.S. ——, 134 S.Ct. 1790, 188 L.Ed.2d 760 (2014). This court issued a writ of mandamus vacating the district court's order requiring disclosure. *Id.* at 897. We determined that the complaint then pending failed to state any claim to which the identities of those parties was relevant. *Id.* at 895–97.

In February 2014, the plaintiffs filed a second amended complaint. That complaint alleges ten separate claims, seven of which are at issue in this appeal: (1) that the State's use of compounded pentobarbital constitutes cruel and unusual punishment, in violation of the United States Constitution; (2) that the defendants are deliberately indifferent to the plaintiffs' medical need for their executions not to inflict gratuitous pain; (3) that the State's use of compounded pentobarbital creates a significant risk of increased punishment over previous methods and accordingly amounts to *ex post facto* punishment, in violation of the United States Constitution; (4) that the defendants have deprived them of due process under the United States Constitution by not providing timely and adequate notice of the lethal injection methods; (5) that the defendants have deprived them of equal protection under the United States Constitution by deviating from the execution protocol in certain instances; (6) that the defendants have violated their First Amendment rights under the United States Constitution by refusing to disclose the identities of the pharmacy that compounds the pentobarbital and its suppliers; and (7) that the defendants have violated a number of federal laws by soliciting and using the compounded pentobarbital in executions, all allegedly reviewable under ***1097** Missouri's Administrative Procedure Act, Mo.Rev.Stat. § 536.150.

In May 2014, the district court granted the State's motion to dismiss the complaint. The court dismissed all claims except for that alleging "cruel and unusual punishment" in violation of the Eighth Amendment and its Missouri constitutional analog. As for the remaining claim, the court ruled that the prisoners' concession that "other methods of lethal injection ... would be constitutional" did not suffice to state a claim under the Eighth Amendment. But the court allowed the prisoners seven days to amend the claim and address that deficiency by presenting "factual allegations permitting the Court to determine whether the alleged alternative method [of execution] is reasonably available and less likely to create a substantial risk of harm." The prisoners responded that they did not intend to plead an alternative method of execution, because they believed the law did not require them to do so. In light of that response, the district court dismissed the remaining claim and entered a final judgment. This appeal followed.

II.

[1] The prisoners' lead argument on appeal is that they stated a claim under the Eighth Amendment that Missouri's lethal-injection protocol violates the prohibition on cruel and unusual punishment.[3] As in *Lombardi*, our analysis must begin with a basic proposition: "[C]apital punishment is constitutional. It necessarily follows that there must be a means of carrying it out." *Baze v. Rees,* 553 U.S. 35, 47, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality opinion) (internal citation omitted). Any allegation that all methods of execution are unconstitutional, therefore, does not state a plausible claim under the Eighth Amendment. *Lombardi,* 741 F.3d at 895.

Baze addressed an Eighth Amendment challenge to a lethal-injection protocol, and our opinion in *Lombardi* summarized the rule of *Baze* as follows:

> Where, as here, there is no assertion that the State acts purposefully to inflict unnecessary pain in the execution process, the Supreme Court recognized only a limited right under the Eighth Amendment to require a State *to change* from one feasible method of execution to another. The controlling opinion of the Chief Justice in *Baze* provides that if a State refuses to adopt a readily available alternative method of execution that would significantly reduce a substantial risk of severe pain, then "a State's refusal *to change its method* can be viewed as 'cruel and unusual' under the Eighth Amendment." 553 U.S. at 52, 128 S.Ct. 1520 (plurality opinion) (emphasis added). In sum: "A stay of execution may not be granted on grounds such as those asserted here unless the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain. *He must show that the risk is substantial when compared to the known and available alternatives.*" *Id.* at 61, 128 S.Ct. 1520 (emphasis added).

741 F.3d at 895–96.

The district court, relying on *Lombardi*, concluded that the second amended complaint adequately alleged that the protocol creates a substantial risk of severe pain. The court ruled, however, that the prisoners failed to allege sufficiently the second essential element of an Eighth Amendment claim—*i.e.,* that there exists a feasible ***1098** alternative method of execution that would substantially reduce the risk of harm. Although the prisoners conceded in the second amended complaint that "other methods of lethal injection the Department could choose would be constitutional," the court reasoned that this "naked assertion" was insufficient to allege that an alternative method is reasonably available and less likely to create a substantial risk of harm.

To state a claim under the Federal Rules of Civil Procedure, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). A pleading need not include "detailed factual allegations," but it is not sufficient to tender "naked assertion[s]" that are "devoid of further factual enhancement." *Id.* (internal quotation marks omitted). A complaint must do more than allege "labels and conclusions" or "a formulaic recitation of the elements of a cause of action." *Id.*

A.

We first address whether the second amended complaint adequately alleges that Missouri's lethal-injection protocol creates a substantial risk of severe pain. We review a district court's grant of a motion to dismiss for failure to state a claim under Rule 12(b)(6) de novo. *United States ex rel. Raynor v. Nat'l Rural Utils. Coop. Fin., Corp.,* 690 F.3d 951, 955 (8th Cir.2012). We assume all facts in the complaint to be true, and draw all reasonable inferences in favor of the non-moving party. *Id.*

[2] **[3]** "[L]egal conclusions" and "threadbare recitations of the elements of a cause of action supported by mere conclusory statements" are not entitled to a presumption of truth when considering the sufficiency of a complaint. *Iqbal,* 556 U.S. at 678, 129 S.Ct. 1937. A complaint must be plausible on its face and " '[a] claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.' " *Magee v. Trustees of Hamline Univ., Minn.,* 747 F.3d 532, 535 (8th Cir.2014) (quoting *Iqbal,* 556 U.S. at 678, 129 S.Ct. 1937). Making a plausibility determination is a " 'context-specific task that requires the reviewing court to draw on its judicial experience and common sense.' " *Id.* (quoting *Iqbal,* 556 U.S. at 679, 129 S.Ct. 1937).

[4] Stating a plausible Eighth Amendment claim in the context of the prisoners' attack upon Missouri's execution protocol first requires the prisoners to plead sufficient facts indicating that the protocol creates a "substantial risk of serious harm." *See Baze,* 553 U.S. at 50, 128 S.Ct. 1520 ("We have explained that to prevail on such a claim there must be a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment.' " (quoting *Farmer v. Brennan,* 511 U.S. 825, 842, 846 & n. 9, 114 S.Ct. 1970, 128 L.Ed.2d 811

(1994))). Indeed, the prisoners allege the lethal-injection protocol creates a substantial risk of serious harm in that it inflicts a "substantial risk of severe pain." *See id.* at 52, 128 S.Ct. 1520. However, successfully pleading facts to demonstrate a substantial risk of severe pain requires the prisoners to plead more than just a hypothetical ***1099** possibility that an execution *could* go wrong, resulting in severe pain to a prisoner. The Eighth Amendment prohibits an " 'objectively intolerable risk' " of pain, rather than "simply the possibility of pain." *Id.* at 61–62, 128 S.Ct. 1520 (quoting *Farmer,* 511 U.S. at 846, 114 S.Ct. 1970). The plurality opinion in *Baze* acknowledged that the nature of executions necessarily involves the risk of pain: "Some risk of pain is inherent in any method of execution—no matter how humane—if only from the prospect of error in following the required procedure." *Id.* at 47, 128 S.Ct. 1520. But "the Constitution does not demand the avoidance of all risk of pain in carrying out executions." *Id.* Instead, the Eighth Amendment requires that the prisoners show the intended protocol is " '*sure or very likely* to cause serious illness and needless suffering.' " *Id.* at 50, 128 S.Ct. 1520 (quoting *Helling v. McKinney,* 509 U.S. 25, 33, 113 S.Ct. 2475, 125 L.Ed.2d 22 (1993)).

Relying on this court's decision in *Lombardi*, the district court found the prisoners' second amended complaint adequately alleged that the protocol created a substantial risk of severe pain:

> The Eighth Circuit specifically referenced the language used in Plaintiffs' previous complaints regarding the risk and level of pain necessary to plead an Eighth Amendment violation, and gave no indication such language was insufficient. Based on that fact and the case law cited by Plaintiffs, the Court concludes Plaintiffs sufficiently plead an Eighth Amendment claim regarding the risk and level of pain that the current execution protocol carries.

R. Doc. 437, at 8. Our decision in *Lombardi* addressed the pleading requirement of a feasible alternative to the current lethal-injection protocol. It did not address the sufficiency of the complaint regarding the allegation of a substantial risk of severe pain. Because the district court relied upon our decision in *Lombardi* as the basis for finding the prisoners had satisfied this pleading burden, a determination of the sufficiency of the prisoners' complaint regarding the allegation of a substantial risk of severe pain now requires a more thorough analysis.

[5] When reviewing the sufficiency of a complaint, we review the complaint itself and any exhibits attached to the complaint. *Meehan v. United Consumers Club Franchising Corp.,* 312 F.3d 909, 913 (8th Cir.2002) (" '[M]aterials attached to the complaint as exhibits may be considered in construing the sufficiency of the complaint.' " (quoting *Morton v. Becker,* 793 F.2d 185, 187 (8th Cir.1986))). The prisoners filed a second amended complaint with 32 exhibits attached, including declarations and affidavits from medical professionals.

1.

[6] In the second amended complaint the prisoners rely on analysis from a pharmacology expert and an anesthesiologist in alleging that the use of a compounding pharmacy to produce the execution drug creates an "objectively intolerable risk of pain." It is alleged that "[c]ompounding pharmacy products do not meet the requirements for identity, purity, efficacy, and safety that pharmaceuticals produced under FDA regulations must meet." R. Doc. 338, at 44. The prisoners identify four distinct potential risks which they believe could result from the State's use of compounded pentobarbital. First, they allege that the compounded pentobarbital could be sub- or super-potent. According to the second amended complaint, sub-potent pentobarbital could fail to cause the death of the prisoner, leaving him unconscious with a lower ***1100** rate of respiration, causing irreversible brain damage. R. Doc. 338, at Ex. 5. Super-potent pentobarbital could result in suffocation and difficulty breathing before losing consciousness. R. Doc. 338, at Ex. 5. Second, the prisoners allege that the pentobarbital could easily be contaminated with allergens, toxins, bacteria, or fungus. The prisoners allege that the injection of pentobarbital so contaminated could cause a painful allergic reaction in the blood. R. Doc. 338, at 45. Third, the prisoners allege that foreign particles could contaminate the compounded pentobarbital, creating the risk that a prisoner could experience serious pain upon injection or

could suffer from a pulmonary embolism. R. Doc. 338, at 45. Finally, the prisoners allege that the drug may not maintain the proper pH,[4] potentially resulting in numerous complications, most notably severe burning upon injection or a pulmonary embolism. R. Doc. 338, at 45. The prisoners also allege that improper storage of the pentobarbital and use beyond its expiration date could exacerbate the potential for these harms. R. Doc. 338, at 49–51.

Asserting that compounding pharmacies commonly lack oversight and regulation, it is alleged that the use of compounding pharmacies "often results in drugs which are contaminated, sub-potent or super-potent, or which do not have the strength, quality or purity" of FDA-regulated drugs. R. Doc. 338, at. Ex. 6. These compounding pharmacies are alleged to be an "emerging, substandard drug industry" that are responsible for the creation of "large quantities of unregulated, unpredictable and potentially unsafe drugs." R. Doc. 338, at Ex. 6. Noting that the lack of regulation allows compounding pharmacies to obtain ingredients from countries with little pharmaceutical oversight, it is alleged that it is impossible to trace the origin of the drugs, resulting in no guarantee that the drugs are what they purport to be. It is alleged that Missouri's current compounded pentobarbital lethal-injection protocol is "replete with flaws that present a substantial risk of causing severe and unacceptable levels of pain and suffering during the execution." R. Doc. 338, at Ex. 5.

[7] The prisoners also allege that the State might administer the execution drugs via central venous access rather than peripheral venous access.[5] R. Doc. 338, at 30. The prisoners allege that the use of a central line carries a higher risk of complication in following the lethal-injection protocol, increases the length of the execution, and is more invasive and painful than peripheral venous access. R. Doc. 338, at 32. Notably, the prisoners make no mention of the central vein issues in their briefing before this court, instead focusing on alleged issues relating to the use of compounded pentobarbital. Because the prisoners have failed to brief this issue before our court, we decline to consider it here. *See Neb. State Legislative* ***1101** *Bd., United Transp. Union v. Slater,* 245 F.3d 656, 658 n. 3 (8th Cir.2001) (explaining that claims not raised in an initial brief are waived).

2.

None of the alleged potentialities the prisoners identify in the second amended complaint relating to compounded pentobarbital rises to the level of "*sure or very likely* " to cause serious harm or severe pain. The prisoners' allegations are limited to descriptions of hypothetical situations in which a potential flaw in the production of the pentobarbital or in the lethal-injection protocol could cause pain. This speculation is insufficient to state an Eighth Amendment claim. *See Brewer v. Landrigan,* 562 U.S. 996, 131 S.Ct. 445, 445, 178 L.Ed.2d 346 (2010) ("[S]peculation cannot substitute for evidence that the use of the drug is *'sure or very likely* to cause serious illness and needless suffering.' " (quoting *Baze,* 553 U.S. at 50, 128 S.Ct. 1520)). By noting that the use of compounding pharmacies "often results" in "potentially unsafe drugs," the experts whose views have been incorporated into the second amended complaint underscore that the harms they have identified are hypothetical and not "*sure or very likely* " to occur. R. Doc. 338, at Ex. 6. The prisoners rely on allegations of generalized harms resulting from the use of a compounding pharmacy to produce the pentobarbital and have failed to provide anything more than speculation that the current protocol carries a substantial risk of severe pain.

[8] Even if one of the harms the prisoners identify were to occur, the prisoners offer nothing in their pleading to support the allegation that it would be more than an isolated incident. The prospect of an isolated incident does not satisfy the requirement that prisoners adequately plead a substantial risk of severe pain to survive a motion to dismiss their Eighth Amendment claim. *See Baze,* 553 U.S. at 50, 128 S.Ct. 1520 ("[A]n isolated mishap alone does not give rise to an Eighth Amendment violation, precisely because such an event, while regrettable, does not suggest cruelty, or that the procedure at issue gives rise to a 'substantial risk of serious harm.' " (quoting *Farmer,* 511 U.S. at 842, 114 S.Ct. 1970)). Accepting as true the *factual* matter alleged in the second amended complaint, if any of the hypothetical situations the prisoners identify came to pass, it would amount to an "isolated mishap" that, "while regrettable," would not result in an Eighth Amendment violation.

3.

Case law from other circuits also supports our conclusion that the prisoners' allegation of a substantial risk of severe pain is inadequate. At least one court has found that an Eighth Amendment challenge to an execution protocol was properly dismissed after the plaintiff-prisoner failed to sufficiently plead a plausible claim that the lethal-injection protocol was *sure or very likely* to create a substantial risk of severe pain. *See Cook v. Brewer,* 637 F.3d 1002, 1008 (9th Cir.2011). In *Cook,* the Ninth Circuit considered a challenge to Arizona's lethal-injection protocol, a three drug protocol involving the use of sodium thiopental. *Id.* The court found that the prisoner's "reliance on speculative and conclusory allegations [was] insufficient to state a facially plausible claim" when he alleged that the use of non-FDA approved sodium thiopental created a substantial risk of severe pain. *Id.* The prisoner alleged that the unregulated drug could be ineffective, contaminated, and could differ greatly in potency, quality, and formation from other FDA regulated drugs. ***1102** *Id.* at 1006. The court rejected these claims as "speculative and overly generalized," finding that the prisoner failed to make any specific factual allegations regarding the alleged harms arising from the use of an unregulated drug. *Id.* Instead, he only identified hypothetical harms that would be "applicable to every drug produced outside the United States." *Id.* The court thus held that the bare allegations that the sodium thiopental was imported and non-FDA approved did not plausibly show that the drug was "*sure or very likely* to cause serious illness and needless suffering," and the district court had properly dismissed the prisoner's Eighth Amendment claim. *Id.* at 1007.

The same prisoner mounted a second challenge to Arizona's use of sodium thiopental in its three drug lethal-injection protocol, alleging that the drug created a substantial risk of severe pain because there had been 12 adverse drug reaction reports, the drug had been manufactured for use on animals, it had caused problems in three executions in the United States, and the State obtained it unlawfully. *Cook v. Brewer,* 649 F.3d 915, 917 (9th Cir.2011). The Ninth Circuit again upheld the dismissal of the prisoner's complaint, finding that he had failed to satisfy the pleading requirements to state an Eighth Amendment claim. *Id.* at 918–19. "Because Cook's four new allegations do not support the drawing of any non-speculative conclusions, Cook has failed to state a facially plausible claim that Arizona's planned execution is *'sure or very likely* to cause ... needless suffering.' " *Id.* (quoting *Baze,* 553 U.S. at 50, 128 S.Ct. 1520).

Other circuits have also denied prisoners relief when challenging a compounded pentobarbital lethal-injection protocol. *See Whitaker v. Livingston,* 732 F.3d 465, 468 (5th Cir.), *cert. denied,* —— U.S. ——, 134 S.Ct. 417, 187 L.Ed.2d 274 (2013) (affirming denial of motion for preliminary injunction when plaintiff-prisoners failed to show state's execution protocol of compounded pentobarbital caused a substantial risk of severe pain when they had "pointed to only hypothetical possibilities" and were unable to "point to *some* hypothetical situation, based on science and fact, showing a likelihood of severe pain"); *Wellons v. Comm'r Ga. Dep't of Corr.,* 754 F.3d 1260, 1265 (11th Cir.2014) (affirming the denial of injunctive relief and declaratory judgment and denying a stay of execution when prisoner did not sufficiently allege that the use of compounded pentobarbital in the state's execution protocol amounted to an Eighth Amendment violation because "speculation that a drug that has not been approved will lead to severe pain or suffering 'cannot substitute for evidence that the use of the drug is *sure or very likely* to cause serious illness and needless suffering' " (quoting *Mann v. Palmer,* 713 F.3d 1306, 1315 (11th Cir.2013))).

4.

The prisoners have failed to include factual allegations in the second amended complaint which permit the reasonable inference that Missouri's lethal-injection protocol is "*sure or very likely* " to create a substantial risk of severe pain. Accepting the factual allegations in the complaint as true, the prisoners fail to satisfy their burden under the Eighth Amendment because they rely entirely on hypothetical and speculative harms that, if they were to occur, would only result from isolated mishaps. Like the prisoner in *Cook,* the prisoners here fail to make any specific factual allegations regarding the production of the pentobarbital that would lead to its contamination, potency problems, or improper pH, and instead rely on general risks associated with compounding pharmacies. Without such specific allegations, the prisoners' complaint contains no more than ***1103** speculative and hypothetical generalized assertions about the nature of compounding pharmacies.

Likewise, the prisoners' allegation describing concerns arising from the method of venous access selected by the State amounts to no more than speculation. In sum, the prisoners have failed to plead sufficient factual matter, consistent with *Twombly* and *Iqbal,* necessary to state a plausible claim for relief. We conclude, therefore, that their claim regarding the substantial risk of severe pain allegedly imposed by Missouri's execution protocol is inadequately pled as a matter of law.

B.

[9] Prisoners challenging a method of execution must do more than allege a substantial risk of serious harm to state a claim under the Eighth Amendment. As we explained in *Lombardi,* 741 F.3d at 895–96, to establish a constitutional violation, an inmate ultimately must prove that another execution procedure exists that is feasible and readily implemented, and that the alternative method will significantly reduce a substantial risk of severe pain. *Lombardi,* 741 F.3d at 895–96; *see Baze,* 553 U.S. at 52, 128 S.Ct. 1520 (plurality opinion); *id.* at 63, 128 S.Ct. 1520 (Alito, J., concurring); *Raby v. Livingston,* 600 F.3d 552, 560–61 (5th Cir.2010); *Cooey v. Strickland,* 589 F.3d 210, 220 (6th Cir.2009). The existence of such an alternative method of execution, therefore, is a necessary element of an Eighth Amendment claim, and this element—like any element of a claim—must be pleaded adequately.

[10] To address this point, the prisoners' second amended complaint merely "concede[s] that other methods of lethal injection the Department could choose to use would be constitutional." R. Doc. 338, at 148. In our view, this "concession" is insufficient to allege the second element of an Eighth Amendment claim that challenges a method of lethal injection. The complaint does not assert that the "other methods of lethal injection" it references are feasible and readily implemented, or that they would significantly reduce a substantial risk of severe pain allegedly caused by the present method. Even a barebones allegation to that effect, moreover, would not be adequate: a "formulaic recitation of the elements of a cause of action" is insufficient to state a claim under Rule 8(a)(2). *Iqbal,* 556 U.S. at 678, 129 S.Ct. 1937. The pleading must include "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Id.* (internal quotation marks omitted). The second amended complaint includes no factual matter that even hints at how the State—drawing on feasible and readily implemented alternatives—could modify its lethal-injection protocol to reduce significantly the alleged substantial risk of severe pain. We therefore agree with the district court that the prisoners' "naked assertion" that other methods would be constitutional, devoid of further factual enhancement, fails to state a claim under the Eighth Amendment.

The prisoners respond that the Supreme Court's decision in *Hill v. McDonough,* 547 U.S. 573, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006), illustrates the sufficiency of their complaint. The issue in *Hill* was whether a prisoner's challenge to the constitutionality of Florida's lethal-injection protocol could proceed as an action for relief under 42 U.S.C. § 1983, or whether it must be brought as an action for a writ of habeas corpus under 28 U.S.C. § 2254. *Id.* at 576, 126 S.Ct. 2096. Hill's complaint conceded that "other methods of lethal injection the Department could choose to use would be constitutional," and the State had not argued that enjoining the present method "would leave the State without any other ***1104** practicable, legal method of executing Hill by lethal injection." *Id.* at 580, 126 S.Ct. 2096. The Court held under those circumstances that the action could proceed under § 1983, because "Hill's action if successful would not necessarily prevent the State from executing him by lethal injection." *Id.* at 580, 126 S.Ct. 2096.

In reaching that conclusion, the *Hill* Court rejected a suggestion from the United States that a prisoner seeking to proceed under § 1983 rather than through habeas corpus must identify an alternative, authorized method of execution. *Id.* at 582, 126 S.Ct. 2096. The Court explained that it would not impose a "heightened pleading requirement[ ]" as a prerequisite to the prisoner proceeding under § 1983, because "[s]pecific pleading requirements are mandated by the Federal Rules of Civil Procedure, and not, as a general rule, through case-by-case determinations of the federal courts." *Id.* at 582, 126 S.Ct. 2096 (citing Fed.R.Civ.P. 8, 9; *Swierkiewicz v. Sorema N.A.,* 534 U.S. 506, 512–14, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002)).

The *Hill* opinion's references to Rule 8 and *Swierkiewicz,* and a later citation of *Hill* in *Jones v. Bock,* 549 U.S. 199, 213, 127 S.Ct. 910, 166 L.Ed.2d 798 (2007), have prompted our careful consideration. We think the better reading, however, is that *Hill* did not address the elements of a

successful claim under the Eighth Amendment or establish that Hill's complaint stated a claim that would survive a motion to dismiss. The question decided in *Hill* concerned only the *cognizability* of a complaint under § 1983, as opposed to habeas corpus. The Court said specifically that "the merits of Hill's underlying action are ... not before us." *Hill,* 547 U.S. at 585, 126 S.Ct. 2096. Whether Hill's complaint stated a claim for relief under Rule 8 and the Eighth Amendment is a question that "goes to the merits" of the underlying action. *Bond v. United States,* —— U.S. ——, 131 S.Ct. 2355, 2362, 180 L.Ed.2d 269 (2011). It was not until two years after *Hill*, in *Baze,* when the Court eventually addressed the substance of the Eighth Amendment and the elements of a claim challenging a lethal-injection protocol. *Jones,* also decided before *Baze,* simply reaffirmed a proposition with which we do not quarrel—*i.e.,* that specific pleading requirements are mandated by the federal rules and generally not through case-by-case determinations of the courts. 549 U.S. at 213, 127 S.Ct. 910. We disagree with Judge Shepherd, *post,* at 1120, and the dissenting judges, *post,* at 1116–18, that requiring a plaintiff to plead the elements of an Eighth Amendment claim as defined in *Baze* is a "heightened pleading requirement" that exceeds the requirements of Rule 8 as explained in *Iqbal* and *Twombly.* [6]

The inference that *Hill* did not address the sufficiency of Hill's complaint is strengthened by the opinions in *Baze,* where two Justices opined that "a method of execution violates the Eighth Amendment only if it is deliberately designed to inflict pain." ***1105** *Baze,* 553 U.S. at 94, 128 S.Ct. 1520 (Thomas, J., concurring). Hill alleged only that Florida's method of execution created a risk of severe pain and that other unspecified methods of execution would be constitutional; there is no indication in the opinion that he alleged a deliberate design by the State of Florida to inflict pain during an execution. That *Hill* was a unanimous opinion—joined by the concurring Justices in *Baze*—fortifies our view that the decision addressed only cognizability under § 1983, not the plausibility of the prisoner's claim under Rule 8 and the Eighth Amendment.

The prisoners contend alternatively that the rule announced in *Baze* applies only where—as in *Baze* itself—a prisoner alleges that a lethal-injection protocol is unconstitutional because the State easily could change to an alternative method of execution that is likely to reduce a significant risk of pain. We think that is an implausible reading of the *Baze* plurality opinion. On the prisoners' view, a plaintiff who alleges a significant risk of severe pain *and* an alternative that would reduce the risk must satisfy the *Baze* standard for an alternative method of execution, but a prisoner who alleges *only* a significant risk of severe pain need not propose an alternative method. The suggested rule would render the *Baze* plurality's extensive discussion of alternative methods superfluous, and we are loathe to assume that the plurality engaged in such a meaningless exercise. *See Baze,* 553 U.S. at 56–61, 128 S.Ct. 1520.

The prisoners also urge that the Supreme Court's grant of a stay of execution in *Bucklew v. Lombardi,* —— U.S. ——, 134 S.Ct. 2333, 189 L.Ed.2d 206 (2014), "repudiates the rule of *Lombardi*," and shows that a prisoner need not allege an alternative method of execution to state a claim under the Eighth Amendment. In May 2014, the Court granted a stay of Russell Bucklew's execution pending appeal in an order that stated as follows:

> Application for stay of execution of sentence of death presented to Justice ALITO and by him referred to the Court treated as an application for stay pending appeal in the United States Court of Appeals for the Eighth Circuit. Application granted pending disposition of petitioner's appeal. We leave for further consideration in the lower courts whether an evidentiary hearing is necessary.

Id.

The Court's brief order does not address the substance of Bucklew's appeal or the basis for possible success on the merits. Although Bucklew urged that the district court erred in requiring him to allege a feasible and more humane method of execution, he also asserted that "[t]o the extent that this Court, or any lower court, believes that pleading an 'alternative method' is necessary, Mr. Bucklew has indeed proposed an 'alternative.' " App. 821–22. The unexplained order in *Bucklew* thus does not resolve whether the prisoners must plead the existence of

an alternative method of execution that meets the criteria of *Baze*.

[11] The prisoners further contend that they cannot propose a reasonably available alternative method of execution without discovery of information about the State's present suppliers of lethal drugs, so the *Lombardi* rule is unworkable in practice. We doubt the rule is as "unworkable" as the prisoners suggest. Their complaint is accompanied by affidavits from experts who criticize the use of compounded pentobarbital as a lethal drug. These or similar experts presumably are in a position to know and to inform the prisoners whether some other lethal drug exists that would significantly reduce the alleged risk of pain arising from the current method. In any event, the Supreme ***1106** Court has rejected the notion that discovery must be available to a plaintiff who cannot allege sufficient factual matter to suggest plausibly an entitlement to relief. *See Twombly,* 550 U.S. at 556–57, 127 S.Ct. 1955. "Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal,* 556 U.S. at 678–79, 129 S.Ct. 1937.

Although policy reasons do not justify imposing a *heightened* pleading requirement, *see Swierkiewicz,* 534 U.S. at 513, 122 S.Ct. 992, "the practical significance of the Rule 8 entitlement requirement" should not be ignored. *Twombly,* 550 U.S. at 557–58, 127 S.Ct. 1955. In *Twombly,* the Court illustrated the practical significance of the Rule 8 requirement by adverting to the high cost of discovery in antitrust cases and the modest success of judicial supervision in checking discovery abuse. *Id.* at 558–59, 127 S.Ct. 1955. In this capital litigation, it should be remembered that one stated objective of the prisoners' lawsuit is to pressure the State's suppliers and agents to discontinue providing the drugs and other assistance necessary to carry out lawful capital sentences. The second amended complaint alleges that confidentiality of the States' drug manufacturers and suppliers "prevents the ... suppliers' associations, customers, and prescribing or referring physicians from censuring or boycotting them," and that protecting the identity of the State's health care professionals unreasonably restricts their "associations and colleagues from de-certifying or otherwise censuring them or boycotting them." R. Doc. 338, at 140–41.

In this very case, after the State's former drug supplier was identified through information in the public domain, a Missouri prisoner sued the supplier in Oklahoma. The supplier then elected to discontinue providing drugs to the State rather than endure the expense and burdens of litigation. R. Doc. 353, at 1–2, 10–13, 190–93. As for the possibility of protecting the confidentiality of sensitive identities after discovery in litigation, counsel for the prisoners expressed concern that it could be very difficult to investigate the physician, pharmacist, and laboratory without disclosing their roles in the execution process, and suggested there were "many ways in which investigating the pharmacy might place the pharmacy's identity, status, and role at issue before whoever we would be talking to." R. Doc. 224, at 12–16. The district court acknowledged that "it may be that there's just no way given the circumstances to keep it confidential because of the central nature of these people to the current dispute." *Id.* at 16.

The real potential that unwarranted discovery would serve as a back-door means to frustrate the State's ability to carry out executions by lethal injection counsels in favor of careful adherence to the requirements of Rule 8, as explicated in *Iqbal* and *Twombly*. A groundless Eighth Amendment claim should not be permitted to achieve indirectly a *de facto* injunction against a lawful method of execution.

[12] For these reasons, we adhere to our conclusion in *Lombardi* that without a plausible allegation of a feasible alternative method of execution that would significantly reduce a substantial risk of serious pain, or a purposeful design by the State to inflict unnecessary pain, the prisoners have not stated an Eighth Amendment claim based on the State's use of compounded pentobarbital in executions. We further conclude that the allegation in the second amended complaint that "other methods of lethal injection the Department ***1107** could choose would be constitutional" does not contain sufficient factual matter to state a claim to relief that is plausible on its face. The district court thus properly dismissed the prisoners' Eighth Amendment claim. [7]

III.

[13] The prisoners next argue that they have a serious medical need to be free from gratuitous pain during

their executions, and that the state officials act with deliberate indifference to their need by using compounded pentobarbital as the lethal drug in the State's execution procedure. The district court rejected this claim on two grounds: (1) that the officials are not addressing medical needs of the prisoners in carrying out executions, and (2) that the prisoners have not pleaded adequately that the State's lethal-injection protocol inflicts *unnecessary* pain in violation of the Eighth Amendment.

[14] **[15]** Assuming without deciding that an Eighth Amendment deliberate-indifference claim based on medical needs is not limited to cases involving medical procedures, *see Nelson v. Campbell,* 541 U.S. 637, 644–45, 124 S.Ct. 2117, 158 L.Ed.2d 924 (2004); *Helling,* 509 U.S. at 29–30, 113 S.Ct. 2475, we agree with the district court that the prisoners have not stated a claim. The Eighth Amendment protects against the "unnecessary and wanton infliction of pain." *Estelle v. Gamble,* 429 U.S. 97, 104, 97 S.Ct. 285, 50 L.Ed.2d 251 (1976). A prisoner must allege both that a deprivation of rights is "objectively, sufficiently serious," and that a state official is deliberately indifferent to inmate health or safety. *Farmer,* 511 U.S. at 834, 114 S.Ct. 1970 (internal quotation omitted). For reasons discussed in Part II, the prisoners have not pleaded that the use of compounded pentobarbital will result in the *unnecessary* and wanton infliction of pain.

IV.

[16] **[17]** The prisoners contend that the state officials violated the Ex Post Facto Clause of the federal Constitution when they changed the execution protocol to provide for the use of compounded pentobarbital, because the change allegedly increased the risk of a painful execution. The Ex Post Facto Clause forbids enactment of a "law that *changes the punishment,* and inflicts a *greater punishment,* than the law annexed to the crime, when committed." *Cal. Dep't of Corr. v. Morales,* 514 U.S. 499, 516, 115 S.Ct. 1597, 131 L.Ed.2d 588 (1995) (quoting *Calder v. Bull,* 3 U.S. 386, 390, 3 Dall. 386, 1 L.Ed. 648 (1798)). The prisoners' claim fails in light of *Lombardi*, where this court held that an identical *ex post facto* claim asserted in an earlier complaint failed to state a claim. 741 F.3d at 896–97. We reasoned that "[t]he manner of punishment for capital ***1108** murder in Missouri at all relevant times ... has been death by lethal injection or lethal gas." *Lombardi,* 741 F.3d at 896 (citing Mo.Rev.Stat. § 546.720.1). Where, as here, "only the mode of producing death has changed, with no allegation of superadded punishment or superior alternatives, the Ex Post Facto Clause[is] not implicated." *Id.* at 897 (internal quotation mark omitted).

[18] The prisoners also complain that they did not have fair notice that Director Lombardi could change the method of execution to include compounded pentobarbital, because that method allegedly violates the federal Food, Drug, and Cosmetics Act and the Controlled Substances Act. The prisoners note *Lombardi's* statement that when the prisoners committed their crime, they "had fair notice" that death was the prescribed punishment, and fair notice "of the Director's discretion to determine the method of execution." 741 F.3d at 897. The Ex Post Facto Clause, however, is concerned with "lack of fair notice and governmental restraint when the legislature increases punishment beyond what was prescribed when the crime was consummated." *Weaver v. Graham,* 450 U.S. 24, 30, 101 S.Ct. 960, 67 L.Ed.2d 17 (1981). Whether the prisoners had specific notice that the Director might select a particular lethal drug is not dispositive, so long as the State has not increased the punishment for the offenses of conviction. We therefore adhere to our conclusion in *Lombardi* that the prisoners fail to state a plausible *ex post facto* claim because the punishment—death—has remained the same; "only the mode of producing death has changed," and the prisoners have not alleged "superadded punishment or superior alternatives." 741 F.3d at 897 (internal quotation mark omitted).

V.

[19] **[20]** The prisoners next contend that the Missouri state officials violated their right of access to the courts under the Due Process Clause by failing to provide them with the timely and adequate notice of the proposed execution method needed to litigate the lawfulness of the execution protocol. We agree with the district court that the prisoners failed to state a claim based on alleged infringement of their right to access the courts. State prisoners have a constitutional "right of access to the courts," *Lewis v. Casey,* 518 U.S. 343, 350, 116 S.Ct. 2174, 135 L.Ed.2d 606 (1996) (emphasis omitted), but this right does not guarantee the ability "to *discover* grievances, and to *litigate effectively* once in court." *Id.* at 354, 116 S.Ct. 2174. The right of access to the courts

is satisfied if the prisoner has "the capability of bringing contemplated challenges to sentences or conditions of confinement before the courts." *Lewis,* 518 U.S. at 356, 116 S.Ct. 2174. The prisoners' claim that they are unable to discover information regarding the execution protocol is thus insufficient as a matter of law to state a due process claim. *Lewis,* 518 U.S. at 354, 116 S.Ct. 2174; *Williams v. Hobbs,* 658 F.3d 842, 851–52 (8th Cir.2011); *Giarratano v. Johnson,* 521 F.3d 298, 306 (4th Cir.2008). "The prisoners do not assert that they are physically unable to file an Eighth Amendment claim, only that they are unable to obtain the information needed to discover a potential Eighth Amendment violation." *Williams,* 658 F.3d at 852.

[21] On appeal, the prisoners present a new argument—that their "life interest entitles them to notice of material information about the lethal drug with which they will be executed." They rely on the procedural due process decision of ***1109** *Mathews v. Eldridge,* 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976), and urge that the private interests served by disclosure and the risk of an erroneous deprivation of rights without disclosure outweigh the State's interest in avoiding disclosure of details about the lethal drug and its provenance.

[22] The prisoners did not develop an argument based on *Mathews* in the district court, and it is too late to raise it for the first time on appeal. In any event, the analogy to *Mathews* is inapt. *Mathews* involved an undisputed deprivation of a property interest (denial of social security benefits), and the question was whether the claimant was entitled by the Due Process Clause to a pre-deprivation hearing as opposed to merely a post-deprivation hearing. *Id.* at 332–33, 96 S.Ct. 893. The prisoners in this case already have received due process for the deprivation of their life interests: They were convicted and sentenced to death after a trial in Missouri court, and their convictions and sentences were upheld on appeal.

[23] At this point, the prisoners seek to discover information about the State's lethal-injection protocol in order to determine whether the protocol violates the Eighth Amendment. The prisoners, however, have not pleaded a deprivation of rights under the Eighth Amendment. This is not a case like *Mathews,* therefore, where there was an undisputed deprivation of an interest protected by the Due Process Clause, and the question was what process is due before the State may accomplish the deprivation. *Id.* Rather, the prisoners here—like the plaintiffs in *Wellons,* 754 F.3d at 1267, and *Sepulvado v. Jindal,* 729 F.3d 413, 419–20 (5th Cir.2013)—claim a freestanding right to detailed disclosure about Missouri's execution protocol. We agree with the Eleventh and Fifth Circuits that the Constitution does not require such disclosure. *Wellons,* 754 F.3d at 1267; *Sepulvado,* 729 F.3d at 419–20. A prisoner's "assertion of necessity—that [the State] must disclose its protocol so he can challenge its conformity with the Eighth Amendment—does not substitute for the identification of a cognizable liberty interest." *Sepulvado,* 729 F.3d at 419.

VI.

[24] The prisoners next press a claim that the Missouri officials violate the Equal Protection Clause by executing prisoners while legal activity seeking to stay their executions is pending, because the practice contravenes the State's written Chronological Sequence of Execution policy. They cite the executions of Joseph Franklin, Alan Nicklasson, and Herbert Smulls, which were carried out while a pleading was pending in the district court, the court of appeals, or the Supreme Court. The prisoners' theory is that forestalling executions until all litigation is finished is a "core" provision of the execution protocol, and that deviating from a "core" provision violates their rights to equal protection of the laws.

The relevant portion of the execution policy provides that at 11:15 p.m. on the eve of an execution:

> Director of the Department of Corrections/designee advises (ERDCC Warden) that (Inmate Name) may be escorted to the execution room if no stay is in place and no legal activity is in progress to prevent the execution.
>
> If there is pending legal activity to halt the execution process, (Inmate Name) will remain in his holding cell and there will be no IV or line established until authority is granted to do so by the Director of the Department of Corrections/designee.

App. 335–36.

The prisoners contend that the policy permits the Director to grant the Warden ***1110** authority to escort a prisoner from his cell to the execution chamber only if there is no legal activity in progress designed to halt the execution. They reason that if the second paragraph of the policy

allowed the Director to initiate an execution procedure even while legal proceedings were pending, then the first paragraph concerning actions taken when "no legal activity is in progress" would be superfluous.

The prisoners' reading of the policy is unlikely: It would allow an inmate to thwart the State's ability to carry out a lawful sentence simply by making repeated court filings designed to prevent an execution during the 24–hour period designated by the Supreme Court of Missouri for carrying out the sentence. One can imagine counsel for a prisoner even asserting an ethical obligation to ensure that some legal activity remains in progress for a full twenty-four hours. We are skeptical of an interpretation of the State's policy that could effectively foreclose the State's ability to carry out lawful sentences.

The policy is not a model of clarity, but it should not be understood to forbid an execution whenever there is pending legal activity designed to stop the execution. The policy does not expressly require the Director to refrain from carrying out a sentence until legal activity has ceased. To the contrary, the second paragraph quoted above contemplates that the Director may grant the Warden authority to begin preparations for an execution even when legal activity is ongoing. The first quoted provision—that the Director may advise the Warden to escort the inmate to the execution room if no legal activity is in progress—applies by its terms only at 11:15 p.m. on the eve of a date of execution. The chronology does not address a circumstance in which legal activity delays an execution until later in the 24–hour period. The second quoted paragraph implies that the Director retains authority to begin preparations for an execution at a later time despite ongoing legal activity. The prisoners do not allege that the officials have escorted inmates to the execution room on the eve of the execution while legal activity is pending: In the cases of Franklin, Nicklasson, and Smulls, a district court or a panel of this court entered a stay of execution that was later vacated, and the State eventually proceeded later in the 24–hour period authorized for the execution. We therefore conclude that the prisoners have not stated a claim under the Equal Protection Clause based on alleged violations of the Department's execution policy.

[25] Assuming for the sake of analysis, however, that the state officials deviate from the execution protocol by carrying out sentences while legal activity is pending, the practice does not violate the Constitution. "The Equal Protection Clause of the Fourteenth Amendment commands that no State shall 'deny to any person within its jurisdiction the equal protection of the laws,' which is essentially a direction that all persons similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr.,* 473 U.S. 432, 439, 105 S.Ct. 3249, 87 L.Ed.2d 313 (1985). "If a legislative classification or distinction neither burdens a fundamental right nor targets a suspect class, we will uphold it so long as it bears a rational relation to some legitimate end." *Vacco v. Quill,* 521 U.S. 793, 799, 117 S.Ct. 2293, 138 L.Ed.2d 834 (1997) (internal quotation marks and brackets omitted).

The prisoners apparently invoke the "fundamental right" strand of equal protection analysis. They argue that it is unconstitutional for the State to disregard a "core provision" of its execution protocol, and that a prohibition on executions before legal activity has ceased is a "core provision." ***1111** The prisoners draw the term "core provision" from two decisions of a district court concerning Ohio's execution protocol. *See Cooey v. Kasich,* 801 F.Supp.2d 623 (S.D.Ohio 2011); *In re Ohio Execution Protocol Litig.,* 840 F.Supp.2d 1044 (S.D.Ohio), *aff'd,* 671 F.3d 601 (6th Cir.2012). The Ohio district court reasoned that because certain "core" provisions of the State's execution protocol were the "precise procedural safeguards" that had been "heralded in prior discussions of Eighth Amendment claims" in the same litigation, "core deviations" from the protocol burdened a prisoner's "fundamental right" for purposes of equal protection analysis. *Cooey,* 801 F.Supp.2d at 652–53. The court thought certain "core deviations ... subverted the key constitutional principles that control the execution process." *In re Ohio Execution Protocol Litig.,* 840 F.Supp.2d at 1049. *See also Arthur v. Thomas,* 674 F.3d 1257, 1263 (11th Cir.2012) (concluding that an inmate stated an equal protection claim by alleging that the State of Alabama substantially deviated from an execution protocol, because "[s]ignificant deviations from a protocol that protects inmates from cruel and unusual punishment can violate the Eighth Amendment").

Whatever the merits of the Ohio district court's analysis with regard to the execution protocol at issue in those decisions, the prisoners here have not stated a claim that Missouri's alleged deviations from its protocol burden a fundamental right. There is no "fundamental right" to avoid execution while no judicial stay is in effect

but legal activity is pending. *E.g., Hamilton v. Texas,* 497 U.S. 1016, 110 S.Ct. 3262, 111 L.Ed.2d 772 (1990) (denying stay of execution despite four votes to grant writ of certiorari). Fundamental rights consist of only those rights that are "explicitly or implicitly guaranteed by the Constitution." *San Antonio Indep. Sch. Dist. v. Rodriguez,* 411 U.S. 1, 32–34, 93 S.Ct. 1278, 36 L.Ed.2d 16 (1973). The State's decision to carry out a lawful sentence when there is no judicial stay in place does not burden a prisoner's rights under the Eighth Amendment or other constitutional provision. If a prisoner advances an eleventh-hour challenge to an execution, the courts have authority to enter temporary administrative stays of execution when necessary and appropriate to allow consideration of constitutional claims. The State may deem it prudent to delay an execution while litigation is pending, especially when final resolution is likely to occur before time expires for carrying out the sentence on the appointed date. But the Constitution does not require the State to implement a self-imposed stay when a state or federal court has declined to act.

VII.

[26] The prisoners also argue that they stated a claim that the First Amendment entitles them to information regarding the source of the drug to be used in their executions. A Missouri statute, Mo.Rev.Stat. § 546.720.2, provides that "[t]he identities of members of the execution team, as defined in the execution protocol of the department of corrections, shall be kept confidential." The prisoners contend that the statute violates their First Amendment rights insofar as it permits Missouri to conceal the identity of the compounding pharmacy that provides the pentobarbital and the identities of the pharmacy's suppliers of ingredients for the compounding process. The prisoners argue that concealing this information violates their right of access to records associated with governmental execution proceedings and constitutes an impermissible content-based restriction on access to information.

***1112** A divided panel of the Ninth Circuit, considering a comparable First Amendment claim, recently enjoined the execution of an Arizona inmate until the State provided him with the name and provenance of drugs to be used in his execution. The Supreme Court promptly vacated the injunction without dissent. *Wood v. Ryan,* 759 F.3d 1076, 1088 (9th Cir.), *vacated,* ——U.S. ——, 135 S.Ct. 21, 189 L.Ed.2d 873 (2014). The Eleventh Circuit has ruled that the First Amendment does not grant a prisoner a right "to know where, how, and by whom the lethal injection drugs will be manufactured." *Wellons,* 754 F.3d at 1266–67. *See also Owens v. Hill,* 295 Ga. 302, 758 S.E.2d 794, 805–06 (2014). We agree with the Eleventh Circuit and the dissenting opinion in the Ninth Circuit and conclude that the prisoners failed to state a claim under the First Amendment.

The Supreme Court held in *Press–Enterprise Co. v. Superior Court,* 478 U.S. 1, 8–13, 106 S.Ct. 2735, 92 L.Ed.2d 1 (1986), that the public enjoys a qualified right of access to certain criminal proceedings. The Court has recognized this right of access in preliminary hearings, *id.* at 10, 106 S.Ct. 2735, criminal trials, *Richmond Newspapers, Inc. v. Virginia,* 448 U.S. 555, 579–80, 100 S.Ct. 2814, 65 L.Ed.2d 973 (1980), and voir dire, *Press–Enterprise Co. v. Superior Court,* 464 U.S. 501, 505–11, 104 S.Ct. 819, 78 L.Ed.2d 629 (1984). This court has held that the First Amendment right of access applies to some records filed in criminal proceedings—specifically, documents filed in support of search warrant applications —*see In re Search Warrant for Secretarial Area Outside Office of Gunn,* 855 F.2d 569, 572–73 (8th Cir.1988), but unlike the Ninth Circuit, we have not ruled that an execution constitutes the kind of criminal proceeding to which the public enjoys a qualified right of access under the First Amendment. *Cf. Cal. First Amendment Coal. v. Woodford,* 299 F.3d 868, 877 (9th Cir.2002).

[27] **[28]** Assuming for the sake of analysis, however, that the *Press–Enterprise* analysis applies to executions, and even to information regarding the source of drugs to be used in lethal injections, the prisoners fail to state a claim for a qualified right of public access. To determine whether a First Amendment public right of access attaches to a particular proceeding, courts consider "whether the place and process have historically been open to the press and general public" and "whether public access plays a significant positive role in the functioning of the particular process in question." *Press–Enterprise,* 478 U.S. at 8, 106 S.Ct. 2735. In *Press–Enterprise,* the Court evaluated whether the preliminary hearings at issue had a "tradition of accessibility" under the first prong of the analysis, and concluded that from the early nineteenth century "until the present day, the near uniform practice of state and

federal courts has been to conduct preliminary hearings in open court." 478 U.S. at 10, 106 S.Ct. 2735.

The prisoners assert that they have a similar right to know the identities of the pharmacy that compounds the pentobarbital and of its suppliers of chemicals, yet they fail to allege a "tradition of accessibility" to that information. We have reserved judgment about whether even an execution itself must be made public, *Rice v. Kempker,* 374 F.3d 675, 678 n. 2 (8th Cir.2004), and the prisoners have not alleged facts or cited authority establishing that the particulars of execution methods have "historically been open to the press and general public." *Press–Enterprise,* 478 U.S. at 8, 106 S.Ct. 2735. The prisoners have alleged only that Missouri did not include the suppliers of drugs for lethal injections as members of the confidential execution team before October 2013. That ***1113** the identities of the drug suppliers were not made confidential by statute or regulation before October 2013 falls well short of the required "tradition of accessibility" that might give rise to a right of access. Indeed, the prisoners do not even allege that the information was accessible to the public before October 2013. Even if the prisoners can show, moreover, that Missouri "at one time voluntarily disclosed such information, it does not a tradition make." *Wood,* 759 F.3d at 1095 (Bybee, J., dissenting). In sum, the prisoners fail to state a claim of a qualified right of public access to information regarding the source of the compounded pentobarbital to be used in their executions because they do not plausibly allege a history of openness to the general public. The complaint likewise provides no basis to conclude that public access to detailed information about execution protocols plays a significant positive role in the functioning of the process in question, given that the practical effect of public disclosure would likely be frustration of the State's ability to carry out lawful sentences.

[29] The prisoners also argue that the confidentiality requirements of § 546.720.2 constitute a content-based restriction on access to information that merits strict scrutiny. They rely on *Sorrell v. IMS Health Inc.,* ——U.S. ——, 131 S.Ct. 2653, 180 L.Ed.2d 544 (2011), where the Court held that a Vermont law prohibiting the sale and use of pharmaceutical prescriber-identifying information was a restriction on "speech with a particular content," because sale of that information was permitted in certain exceptional situations "based in large part on the content of a purchaser's speech," and subsequent use of the information was limited to non-marketing purposes. *Id.* at 2662–63. The Missouri statute challenged by the prisoners is different. The statute does not limit the dissemination of identities of execution team members based on the identity of the individual seeking that information and the likely content of that individual's speech, and the law does not limit the use of any such information to certain types of speech. The prisoners thus fail to state a claim that § 546.720.2 is a content-based restriction on access to information that merits strict scrutiny.

VIII.

[30] The prisoners complain that the use of compounded pentobarbital as a lethal drug in executions violates the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.,* and the Controlled Substances Act. 21 U.S.C. §§ 801, *et seq.* They acknowledge, however, that there is no private right of action under federal law to enforce these alleged violations. 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 349 n. 4, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001); *Durr v. Strickland,* No. 2:10–cv–288, 2010 WL 1610592, at *2–3 (S.D.Ohio), *aff'd,* 602 F.3d 788, 789 (6th Cir.2010) (affirming district court's holding that no private right of action exists under the Controlled Substances Act). Instead, they assert that the Missouri Administrative Procedure Act gives them a private right of action to sue for alleged violations of the federal statutes. The district court ruled that the prisoners failed to state a claim.

Under the Missouri APA, where there is no formal hearing before a state agency in a contested case, a court may review a decision of an administrative officer or body that "determin[es] the legal rights, duties or privileges of any person." Mo.Rev.Stat. § 536.150.1; *see City of Valley Park v. Armstrong,* 273 S.W.3d 504, 506–07 (Mo.2009) (en banc); *State ex rel. Yarber v. McHenry,* 915 S.W.2d 325, 327–28 (Mo.1995) (en banc). The court may determine ***1114** whether the decision is "unconstitutional, unlawful, unreasonable, arbitrary, or capricious or involves an abuse of discretion." Mo.Rev.Stat. § 536.150.1.

[31] The prisoners fail to state a claim under the Missouri APA because they have not alleged that the decision of corrections officials to adopt the execution protocol

determines their "legal rights, duties or privileges." "Section 536.150 pertains only to review of decisions affecting private rights and interests." *St. Louis Cnty. v. State Tax Comm'n,* 608 S.W.2d 413, 414 (Mo.1980) (en banc). "[T]o make a prima facie case under Section 536.150, an individual must plead facts that, if true, would show that he has been denied some legal right or entitlement to a privilege." *McIntosh v. LaBundy,* 161 S.W.3d 413, 416 (Mo.Ct.App.2005). The plaintiff must thus identify a "rule, statute, or other authority creating a legal right or entitlement." *Id.* at 417.

The prisoners allege a right not to "be executed in a manner that violates federal laws protecting the end-users of regulated pharmaceuticals." They fail, however, to identify a statute or other authority that creates a private legal right or entitlement. The federal statutes cited in the complaint do not create private rights of action. The prisoners cannot employ the Missouri APA to allege the denial of a private legal right under the federal statutes when the federal statutes themselves do not create such a private legal right.

* * *

The judgment of the district court is affirmed.

BYE, Circuit Judge, with whom MURPHY and KELLY, Circuit Judges, join, dissenting.

The constitutionality of the death penalty itself is not before us in this case, and we proceed on the assumption the death penalty is constitutional. While it follows there must be a constitutional means of carrying out a death sentence, it has not been determined that Missouri's current execution protocol is constitutional. The district court erred in dismissing the death-row inmates' suit, and the death-row inmates should have the opportunity to conduct discovery and fully litigate their claims. I therefore respectfully dissent.

I

I disagree with the entirety of Part II of the majority's opinion, which dismisses the death-row inmates' Eighth Amendment claim. The majority provides two alternative reasons for dismissing the suit: (1) as a matter of law, the death-row inmates' claim regarding the substantial risk of severe pain imposed by Missouri's execution protocol is inadequately pled; and (2) the death-row inmates have failed to adequately plead a readily-available alternative method of execution.

A

The majority first holds the death-row inmates have failed to plead sufficient factual matter on the risk of harm to state a plausible claim of relief. Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." To withstand the State's Rule 12(b)(6) motion, the complaint must contain sufficient factual allegations to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 547, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) ***1115** (citing *Twombly,* 550 U.S. at 555, 127 S.Ct. 1955).

"[T]aking all facts alleged in the complaint as true, and making reasonable inferences in favor of the nonmoving party," the death-row inmates have sufficiently pled their Eighth Amendment claim. *Smithrud v. City of St. Paul,* 746 F.3d 391, 397 (8th Cir.) *cert. denied,* —— U.S. ——, 135 S.Ct. 361, 190 L.Ed.2d 251 (2014). The death-row inmates' complaint alleges the compounded pentobarbital used by Missouri creates a substantial risk of harm and inflicts a substantial risk of severe pain. The death-row inmates have also shown the risk of pain is objectively intolerable.

The death-row inmates' second amended complaint includes thirty-two attached exhibits, including declarations and affidavits from medical professionals. The pleadings demonstrate substantial concerns with compounded pentobarbital, including potency levels, contamination, pH levels, and shelf-life. Despite such pleadings, the majority concludes these potentialities are hypothetical and do not "rise[ ] to the level of 'sure or very likely' to cause serious harm or severe pain." The majority takes offense at the death-row inmates' "allegations of generalized harms" from compounded pentobarbital, but such allegations are exactly what must be pled to survive a Rule 12(b)(6) motion to dismiss. Rule 8 only requires "a short and plain statement" showing the death-row inmates are entitled to relief. No higher pleading

standard is applicable to this suit. *Cf.* Fed.R.Civ.P. 9(b) (establishing heightened pleading standards in certain cases, such as fraud or mistake). The death-row inmates could not possibly include allegations more specific to the compounding done for or by Missouri without the benefit of discovery. To know about Missouri's particular compounding procedure and the particular dangers of such a procedure, the death-row inmates need discovery about the various sources of the drugs, how the drugs are compounded, whether the compounded drugs are tested for potency, contamination, or pH levels, and how and for how long the compounded drugs are stored. Missouri has steadfastly refused to disclose any information related to the compounded pentobarbital. *See e.g., In re Lombardi,* 741 F.3d 888, 889 (8th Cir.), *reh'g denied,* 741 F.3d 903 (8th Cir.) and *cert. denied sub nom. Zink v. Lombardi,* —— U.S. ——, 134 S.Ct. 1790, 188 L.Ed.2d 760 (2014) (ruling in favor of Missouri in an appeal "to prohibit the district court from enforcing orders that [the State] must disclose in civil discovery, for use by opposing counsel, the identities of (1) the physician who prescribes the chemical used in Missouri executions, (2) the pharmacist who compounds the chemical, and (3) the laboratory that tests the chemical for potency, purity, and sterility"). It is not the death-row inmates' burden at the pleading stage to show their claims are "sure or very likely;" the death-row inmates must merely show they have stated a claim for relief.

The majority is unconcerned with expert opinions and a host of other evidence which shows improperly compounded pentobarbital would "sure or very likely" cause unconstitutionally painful deaths. The majority acknowledges this evidence exists but focuses on the one thing the death-row inmates cannot know at this stage: "specific factual allegations regarding the production of the pentobarbital" to be used in their executions. Because the death-row inmates have adequately pled that improperly compounded pentobarbital is sure or very likely to cause pain and suffering at an unconstitutional level, the death-row inmates have pled enough to survive a motion to dismiss under Rule 12(b)(6). Thus, the death-row inmates ***1116** should be allowed to utilize discovery in the normal course of litigation to determine the actual process used by Missouri's current compounding pharmacies.

B

In an alternative holding on the death-row inmates' Eighth Amendment claim, the majority finds the death-row inmates failed to plead a specific readily-available alternative method of execution and finds such a failure fatal to this suit. I disagree.

In *Hill v. McDonough,* 547 U.S. 573, 576, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006), the Supreme Court examined whether a death-row inmate challenging Florida's execution protocol had a cognizable suit under 42 U.S.C. § 1983, or whether such a claim needed to be brought under 28 U.S.C. § 2254. The Supreme Court clarified that a challenge to a state's execution procedure may proceed under § 1983, particularly when a "[c]omplaint does not challenge the lethal injection sentence as a general matter but seeks instead only to enjoin [the State] from executing [the plaintiff] in the manner they currently intend." *Hill,* 547 U.S. at 580, 126 S.Ct. 2096 (internal quotation marks omitted). In explaining the requirements for a § 1983 challenge to execution protocols, the Supreme Court considered and rejected the proposition that "a capital litigant's § 1983 action can proceed [only] if ... the prisoner identified an alternative, authorized method of execution." *Id.* at 582, 126 S.Ct. 2096. In rejecting that proposition, the Supreme Court explained "[i]f the relief sought would foreclose execution, recharacterizing a complaint as an action for habeas corpus might be proper." *Id.* "Imposition of heightened pleading requirements, however, is quite a different matter. Specific pleading requirements are mandated by the Federal Rules of Civil Procedure, and not, as a general rule, through case-by-case determinations of the federal courts." *Id.* (citing Fed.R.Civ.P. 8 and 9; *Swierkiewicz v. Sorema N.A.,* 534 U.S. 506, 512–14, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002)).

A year later, the Supreme Court addressed the pleading requirements of exhaustion under the Prison Litigation Reform Act in *Jones v. Bock,* 549 U.S. 199, 127 S.Ct. 910, 166 L.Ed.2d 798 (2007). The Supreme Court, relying on the Federal Rules of Civil Procedure and rejecting a heightened pleading requirement, found the usual practice under the Federal Rules should be followed in § 1983 suits. The Supreme Court thereafter reaffirmed the pleading requirements for death-row inmates: "And just last Term, in *Hill* ..., we unanimously rejected a proposal that §

1983 suits challenging a method of execution must identify an acceptable alternative." *Id.* at 212, 127 S.Ct. 910. In addressing the pleading requirements for death-row inmates challenging a method of execution, the Supreme Court has been clear: there is no heightened pleading rule requiring inmates to identify any alternative method of execution.

The majority dismisses these clear statements by the Supreme Court, and instead relies on *Baze v. Rees,* 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008), to justify the imposition of a heightened pleading standard. The *Baze* challenge to Kentucky's three-drug execution protocol came to the Supreme Court in a declaratory judgment action after "[t]he trial court held extensive hearings and entered detailed findings of fact and conclusions of law." *Id.* at 41, 128 S.Ct. 1520. The death-row inmates in *Baze,* challenging Kentucky's execution protocol, alleged a readily-available alternative. The Supreme Court held "a condemned prisoner cannot successfully challenge a State's method of execution merely by ***1117** showing a slightly or marginally safer alternative." *Id.* at 51, 128 S.Ct. 1520. Rather, the Supreme Court established that *when an alternative method of execution is proposed,* "the proffered alternatives must effectively address a substantial risk of serious harm." *Id.* at 52, 128 S.Ct. 1520 (internal quotation marks omitted). And, if a death-row inmate puts forward such a proposed alternative, it must be "feasible, readily implemented, and ... significantly reduce a substantial risk of severe pain." *Id.*

Baze does not establish the standard for all execution-protocol challenges. Instead, *Baze* establishes that when death-row inmates can show a readily-available alternative with sufficient documented advantages, "a State's refusal to change its method can be viewed as 'cruel and unusual' under the Eighth Amendment." 553 U.S. at 52, 128 S.Ct. 1520. *Baze* reaches no further than this holding. *Baze* did not purport to limit Eighth Amendment challenges of execution protocols to only those cases where death-row inmates propose an alternative method, and *Baze* did not change the pleading requirements for Eighth Amendment cases.

Despite the limited nature of *Baze,* the majority relies on *Baze* to establish that death-row inmates must plead a feasible and readily-available alternative method of execution. It is troubling the majority relies on *Baze* when *Baze* does not mention pleading requirements or the Federal Rules of Civil Procedure. *Webster v. Fall,* 266 U.S. 507, 511, 45 S.Ct. 148, 69 L.Ed. 411 (1925) ("Questions which merely lurk in the record, neither brought to the attention of the court nor ruled upon, are not to be considered as having been so decided as to constitute precedents."). But perhaps most troubling is the majority's reliance on *Baze* when *Baze* does not even mention *Hill* or *Jones. Shalala v. Ill. Council on Long Term Care, Inc.,* 529 U.S. 1, 18, 120 S.Ct. 1084, 146 L.Ed.2d 1 (2000) ("Th[e Supreme Court] does not normally overturn ... earlier authority *sub silentio*....").

The Supreme Court warns "that courts should generally not depart from the usual practice under the Federal Rules on the basis of perceived policy concerns." *Jones,* 549 U.S. at 212, 127 S.Ct. 910. Despite this rule, the majority bases its decision on policy considerations: whether discovery and litigation would pressure Missouri's suppliers and agents to discontinue providing the drugs for executions. The question of whether discovery is appropriate or necessary is not currently before this court. Neither is the question of an injunction about the potential harm the State might suffer from disclosure of drug providers. The majority appears to impose a heightened pleading standard for fear that this suit would otherwise eventually require the disclosure of information which it fears would hamper Missouri's ability to carry out executions. This is not a reason to impose a heightened pleading standard in opposition to Supreme Court precedent and the Federal Rules of Civil Procedure.

If policy concerns were relevant to the establishment of case-by-case pleading standards, policy concerns would weigh in favor of allowing this suit to proceed. It is troubling that under the majority's rule, the constitutionality of an execution method is determined *not* by the pain and suffering caused by that method, but rather by what resources a death-row inmate can garner to show an available alternative. If the manufacturers of safer drugs were willing to provide Missouri with execution drugs, Missouri's current execution protocol would likely be held unconstitutional. *See Baze,* 553 U.S. at 52, 128 S.Ct. 1520 (discussing requirements for a § 1983 ***1118** suit when an alternative method of execution is readily available). In no other area do the private acts of third-parties so influence the determination of whether a government act is unconstitutional. Making it even more difficult for death-row inmates, they now must

surpass these barriers at the pleading stage, rather than at the summary judgment stage after the completion of discovery.

Simply put, neither the Constitution nor the Federal Rules of Civil Procedure require a plaintiff challenging the constitutionality of government actions to simultaneously suggest a remedy—a remedy which cannot be to simply stop the unconstitutional activity. Such a heightened pleading standard has not been required in other constitutional cases, and should not be required here. Based on the foregoing reasons, I dissent from the imposition of any heightened pleading standards when death-row inmates challenge a state's method of execution.

C

Although I believe the pleading requirement imposed by the majority is an incorrect application of the law, I recognize my position in the minority and therefore find it prudent to comment on the resolution of this case. Even if the majority is correct in imposing this additional pleading requirement, it is improper to dismiss the death-row inmates' suit at this juncture. Rather, the matter should be remanded for the death-row inmates to amend their complaint because the death-row inmates' second amended complaint does, in fact, satisfy the pleading requirements previously suggested by the Eighth Circuit.

In my view, in denying rehearing in the case of *In re Lombardi* the Eighth Circuit clarified that death-row inmates alleging an Eighth Amendment violation based on the method of execution must, in their pleadings, (1) "concede [ ] that 'other methods of lethal injection the Department could choose to use would be constitutional,' " *In re Lombardi,* 741 F.3d 903, 905 (8th Cir.2014) (en banc) (quoting *Hill,* 547 U.S. at 580, 126 S.Ct. 2096); and (2) "allege[ ] 'that the challenged procedure presents a risk of pain the State can avoid while still being able to enforce the sentence ordering a lethal injection,' " *id.* (quoting *Hill,* 547 U.S. at 581, 126 S.Ct. 2096). In their second amended complaint, the death-row inmates "concede that other methods of lethal injection the Department could choose to use would be constitutional." *Zink v. Lombardi,* No. 12–4209, Doc. 338 at 202 (W.D.Mo. Feb. 2, 2014). Thus, the death-row inmates pleaded exactly what *In re Lombardi* required of them: a concession "that other methods of lethal injection the Department could choose to use would be constitutional." 741 F.3d at 905 (internal quotation marks omitted).

The Eighth Circuit now changes, once again, the pleading requirements for an Eighth Amendment claim. Because the death-row inmates complied with *In re Lombardi,* and because the Eighth Circuit is for the first time imposing a stricter pleading requirement, a remand is proper. The death-row inmates should have the opportunity to plead a named alternative method before the complaint is dismissed. However, in light of today's ruling dismissing the complaint, the death-row inmates, if they choose to do so, will have to settle for initiating new litigation in the district court and filing a complaint which complies with the newly-established pleading standards. For example, if the death-row inmates desire, the death-row inmates could propose as an available alternative an execution protocol using pentobarbital which was properly compounded at an FDA-approved compounding pharmacy, and has ***1119** thereafter been tested for identity, potency, purity, and contamination.

D

The majority also extends the imposition of a heightened pleading requirement beyond the death-row inmates' Eighth Amendment claims. Without an explanation of this extension, the majority resolves the death-row inmates' medical needs claim "[f]or reasons discussed in Part II." The majority also dismisses the death-row inmates' due process claim at least in part based on the death-row inmates' failure to "plead[ ] a deprivation of rights under the Eighth Amendment." I disagree with any extension of the heightened pleading requirement, and dissent from these portions of the majority's opinion.

II

The majority opinion establishes heightened pleading requirements for death-row inmates challenging a state's method of execution under the Eighth Amendment. This imposition is in opposition to governing Supreme Court precedent and the Federal Rules of Civil Procedure. In other words, the Eighth Circuit now prevents death-row inmates from truly accessing the federal courts: a death-row inmate cannot benefit from discovery and is

prohibited from challenging even a truly unconscionable method of execution if no other methods are readily available and obvious at the pleading stage.

The death-row inmates have established the risk of using alleged compounded pentobarbital to carry out an execution, and have conceded other forms of execution are constitutional. Therefore, I would reverse the district court, stay the executions of the death-row inmates pending resolution of the suit, and remand for the district court to conduct discovery in its usual and normal course of business.

SHEPHERD, Circuit Judge, dissenting in part.

In *Lombardi*, because the prisoners had not conceded that other methods of lethal injection which the state of Missouri could choose would be constitutional, "[w]e were not required to address whether alleging that the current method of execution creates a substantial risk of harm when compared to known and available alternatives, without specifying an alternative, would be sufficient to state a claim in light of *Hill* and *Baze*." *In re Lombardi,* 741 F.3d 903, 905 (8th Cir.2014). The court now holds, in Part II.B. of this opinion, that even with such a concession the prisoners must indeed identify an alternative method of execution that is feasible, can be readily implemented, and will significantly reduce a substantial risk of severe pain in order to state an Eighth Amendment claim. I cannot agree with this conclusion.

First, it is not necessary for the court to reach this issue. In Part II.A. of this opinion we explain that the second amended complaint's Eighth Amendment challenge to Missouri's method of execution by lethal injection fails to state a claim because it does not include the requisite plausible allegations that the lethal execution protocol creates a substantial risk of severe pain. So holding, we need not reach the issue of the sufficiency of the second amended complaint's allegation of an alternative method of execution. *See Raby v. Livingston,* 600 F.3d 552, 560–61 (5th Cir.2010) ("Because we find that Raby has failed to establish that the Texas lethal injection protocol creates a demonstrated risk of severe pain, we do not reach the second step of the *Baze* test, whether the risk created by the current protocol is substantial when compared to the known and available alternatives.").

Second, if in fact the issue is be addressed, I disagree substantively with the ***1120** court's holding. In *Hill v. McDonough,* the Supreme Court considered whether a prisoner's Eighth Amendment challenge to Florida's lethal-injection protocol could proceed as a § 1983 action or must proceed as a habeas action. 547 U.S. 573, 576, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006). In finding that the action could proceed under § 1983, the Court rejected the government's contention that the prisoner must plead an alternative means of execution to state a § 1983 claim. *Id.* at 582, 126 S.Ct. 2096. The *Hill* Court noted that "[s]pecific pleading requirements are mandated by the Federal Rules of Civil Procedure, and not, as a general rule, through case-by-case determinations of the federal court." *Id.* (citing *Swierkiewicz v. Sorema N.A.,* 534 U.S. 506, 512–14, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002)).

Lest there be any confusion about underpinnings of the holding, in its very next term, in *Jones v. Bock,* the Supreme Court explained, "[J]ust last Term, in *Hill v. McDonough,* we unanimously rejected a proposal that § 1983 suits challenging a method of execution must identify an acceptable alternative." 549 U.S. 199, 213, 127 S.Ct. 910, 166 L.Ed.2d 798 (2007) (internal citation omitted).

Reading *Hill* and *Jones* together, I cannot conclude that the Supreme Court has mandated a heightened pleading standard requiring identification of an alternative method of execution in this § 1983 action asserting an Eighth Amendment claim. The Supreme Court explicitly rejected such a requirement in *Jones,* and I take the Court to mean what it says. In Part II.B., this court attempts to confine *Hill* to its holding that an Eighth Amendment challenge to a lethal injection protocol may proceed under § 1983 action rather than a decision relating to the sufficiency of a complaint under the Federal Rules. In *Jones,* however, the Supreme Court addresses the adequacy of a complaint under Rule 8 and rejects court devised heightened pleading requirements.

Finally, in Part II.B., the court identifies the risk that allowing protracted discovery could have the practical effect of thwarting the State's ability to carry out any executions. Although I am cognizant of such a possibility, the Federal Rules of Civil Procedure govern the sufficiency of the second amended complaint rather than policy considerations. *See Jones,* 549 U.S. at 212, 127 S.Ct. 910 ("[C]ourts should generally not depart from

the usual practice under the Federal Rules on the basis of perceived policy concerns.").

For the reasons set forth in Part II.A. of the court's opinion, the second amended complaint's Eighth Amendment challenge to Missouri's lethal injection protocol must be dismissed because it does not include the requisite plausible allegations that the protocol creates the substantial risk of severe pain. However, I cannot agree with the court's conclusion that the prisoners must also identify an alternative method of execution in the complaint.

Accordingly, I join in all but Part II.B. of this opinion.

All Citations

783 F.3d 1089

Footnotes

1 Chief Judge Riley and Judges Wollman, Loken, Smith, and Gruender join this opinion. Judge Colloton joins all but Part II.A of this opinion. Judge Shepherd joins all but Part II.B of this opinion.

2 The Honorable Beth Phillips, United States District Judge for the Western District of Missouri.

3 The prisoners do not develop an argument on appeal concerning the dismissal of their claim alleging cruel and unusual punishment under the Missouri Constitution.

4 pH is a measure of the acidity or basicity of a solution. *See Taber's Cyclopedic Medical Dictionary* 1377 (Clayton L. Thomas ed., 16th ed. 1989). According to the affidavits attached to the prisoners' second amended complaint, maintaining a proper pH is an important aspect of a properly produced drug. If a drug is too acidic or too basic, it may be incompatible with human blood, causing various unintended reactions. *See* R. Doc. 338, at Ex. 6.

5 Central venous access involves the insertion of a catheter into a large vein in a person's neck, chest, or groin. Peripheral venous access involves the placement of a catheter in a peripheral vein, most commonly in the hand or arm. *See* 6 *The Gale Encyclopedia of Medicine* 4571–72 (Laurie J. Fundukian ed., 4th ed. 2011).

6 Judge Bye, *post,* at 1118–19, suggests incorrectly that this court's order denying rehearing in *Lombardi* established that a prisoner could state an Eighth Amendment claim without identifying a feasible alternative if he merely conceded that other methods of lethal injection the State could choose to use would be constitutional. The *Lombardi* order simply recited the concession made by the plaintiffs in *Hill*, and observed that the plaintiffs in *Lombardi* did not make such an allegation. *In re Lombardi,* 741 F.3d 903, 905 (8th Cir.2014). The order declared that "*[w]e were not required to address* whether alleging that the current method of execution creates a substantial risk of harm when compared to known and available alternatives, without specifying an alternative, would be sufficient to state a claim in light of *Hill* and *Baze.*"*Id.* (emphasis added).

7 Judge Shepherd, while voting to affirm, also files a "dissenting" opinion on the ground that Part II.B is unnecessary to the decision. It is not uncommon for courts to decide cases on alternative grounds, *e.g., United States v. Farlee,* 757 F.3d 810, 820 (8th Cir.2014), and the Supreme Court recently noted the "unremarkable proposition" that a court's decision to rely on one of two possible alternative grounds does not strip it of power to decide the second question, particularly when the court's decree is subject to review by the Supreme Court. *Already, LLC v. Nike, Inc.,* —— U.S. ——, 133 S.Ct. 721, 729, 184 L.Ed.2d 553 (2013). Given our conclusion in Part II.B, moreover, it could just as well be said that Part II.A concerning the complaint's allegations of a substantial risk of severe pain is unnecessary. Indeed, this court in *Lombardi* (joined by Judge Shepherd) concluded that a previous complaint filed by the prisoners failed to state a claim solely because the prisoners did not make a sufficient allegation about an alternative method of execution. 741 F.3d at 895–96.

656 F.3d 157
United States Court of Appeals,
Third Circuit.

Robert W. JACKSON, III
v.
Carl C. DANBERG, Commissioner, Delaware Department of Correction; Thomas L. Carroll, Warden Delaware Correctional Center; Paul Howard, Bureau Chief Delaware Bureau of Prisons; Other Unknown State Actors Responsible for and participating in the carrying out of Plaintiff's Execution.
Robert W. Jackson, III, individually and on behalf of the Certified Class, Appellant.

No. 11–9002.
|
Argued July 28, 2011.
|
Filed: Sept. 7, 2011.

Synopsis

Background: State death row inmate brought § 1983 action challenging Delaware's lethal injection protocol as cruel and unusual in violation of Eighth Amendment. Following grant of motion for class action certification, 240 F.R.D. 145, the United States District Court for the District of Delaware, Sue L. Robinson, J., 601 F.Supp.2d 589, granted the state's motion for summary judgment. Inmate appealed. The United States Court of Appeals, Fisher, Circuit Judge, 594 F.3d 210, affirmed. Shortly after affirmance, Delaware changed its protocol to include an alternative anesthetic and inmate moved to reopen and for stay of execution. The United States District Court for the District of Delaware, Sue L. Robinson, J., 2011 WL 3205453, denied motions. Inmate appealed.

Holdings: The Court of Appeals, Fisher, Circuit Judge, held that:

[1] denial of motion for stay of execution was not abuse of discretion, and

[2] substitution of anesthetic in lethal injection protocol did not violate Eighth Amendment, as required to warrant motion to reopen.

Affirmed.

West Headnotes (12)

[1] Sentencing and Punishment
Discretion of lower court

Court of Appeals reviews a district court's denial of a stay of execution for abuse of discretion, which may be found where its conclusion includes the commission of a serious error of law or a mistake in considering the facts.

2 Cases that cite this headnote

[2] Criminal Law
Discretion of Lower Court

Court of Appeals reviews a district court's denial of a motion to reopen for abuse of discretion. Fed.Rules Civ.Proc.Rule 60(b, d), 28 U.S.C.A.

19 Cases that cite this headnote

[3] Sentencing and Punishment
Stay of execution

A stay of execution is an equitable remedy that is not available as a matter of right, and equity must be sensitive to the State's strong interest in enforcing its criminal judgments without undue interference from the federal courts.

Cases that cite this headnote

[4] Sentencing and Punishment
Stay of execution

The standard for issuance of a stay of execution is like that for issuance of a preliminary injunction, and requires consideration of four factors: (1) whether the stay applicant has made a strong showing

that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

4 Cases that cite this headnote

[5] Sentencing and Punishment
Stay of execution

Inmates seeking time to challenge the manner in which the State plans to execute them must satisfy all of the requirements for a stay of execution, including a showing of a significant possibility of success on the merits.

Cases that cite this headnote

[6] Sentencing and Punishment
Methods of Punishment

Subjecting individuals to a risk of future harm-not simply actually inflicting pain-can qualify as cruel and unusual punishment; however, to constitute a violation of the Eighth Amendment, the conditions presenting the risk must be sure or very likely to cause serious illness and needless suffering, and give rise to sufficiently imminent dangers. U.S.C.A. Const.Amend. 8.

1 Cases that cite this headnote

[7] Sentencing and Punishment
Mode of execution

Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of objectively intolerable risk of harm that qualifies as cruel and unusual under the Eighth Amendment. U.S.C.A. Const.Amend. 8.

1 Cases that cite this headnote

[8] Sentencing and Punishment
Stay of execution

A stay of execution may only be granted where the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain and that the risk is substantial when compared to the known and available alternatives.

4 Cases that cite this headnote

[9] Sentencing and Punishment
Mode of execution

Sentencing and Punishment
Stay of execution

District court's denial of prisoner's motion for a stay of execution, based on prisoner's claim that Delaware's use of pentobarbital as part of its lethal injection protocol was cruel and unusual punishment in violation of Eighth Amendment, was not abuse of discretion; purpose of the anesthetic in Delaware's lethal injection protocol was to render the prisoner unconscious before administration of the second and third drugs, and there was no affirmative evidence that pentobarbital failed to do this, or that it created a demonstrated risk of severe pain. U.S.C.A. Const.Amend. 8.

4 Cases that cite this headnote

[10] Sentencing and Punishment
Mode of execution

A condemned prisoner cannot successfully challenge a state's method of execution under the Eighth Amendment merely by showing a slightly or marginally safer alternative; rather, an inmate must first show that a state's current protocol creates a demonstrated risk of severe pain. U.S.C.A. Const.Amend. 8.

3 Cases that cite this headnote

[11] Federal Civil Procedure
Catch-all provisions

Relief from judgment under civil procedure rule's "catch-all" provision is available where party seeking relief demonstrates that "extreme" and "unexpected" hardship

will result absent such relief. Fed.Rules Civ.Proc.Rule 60(b)(6), 28 U.S.C.A.

28 Cases that cite this headnote

[12] Sentencing and Punishment
Mode of execution

Delaware's substitution of pentobarbital for sodium thiopental in its three-drug lethal injection protocol did not undermine the foundation of Court of Appeals' prior decision holding that Delaware's protocol, using sodium thiopental, did not constitute cruel and unusual punishment in violation of Eighth Amendment, as required for grant of motion to reopen; pentobarbital was an effective anesthetic for purposes of the three-drug lethal injection. U.S.C.A. Const.Amend. 8; Fed.Rules Civ.Proc.Rule 60(b, d), 28 U.S.C.A.

9 Cases that cite this headnote

Attorneys and Law Firms

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Elizabeth R. McFarlan, Esq., Marc P. Niedzielski, Esq., Gregory E. Smith, Esq., Paul R. Wallace, Esq. (Argued), Morgan Zurn, Esq., State of Delaware, Department of Justice, Wilmington, DE, for Appellees.

Before: AMBRO, FISHER and HARDIMAN, Circuit Judges.

OPINION OF THE COURT

FISHER, Circuit Judge.

A class of inmates sentenced to death by the State of Delaware and named plaintiff Robert W. Jackson, III (collectively referred to in this opinion as "Plaintiffs"), appeal from the District Court's denial of their motion to reopen and their motion for a stay of Jackson's execution. After careful review, we conclude that the District Court did not abuse its discretion, and, accordingly, we affirm.

I.

A. Facts

This is our second encounter with a 42 U.S.C. § 1983 challenge related to Delaware's lethal injection protocol. Much of the background factual information in this case is the same as we recounted in *Jackson v. Danberg,* 594 F.3d 210 (3d Cir.2010) ("*Jackson I* "), and so we only will briefly outline that background material before setting forth in more detail those facts essential to the resolution of this appeal.

Delaware law provides that:

> [p]unishment of death shall, in all cases, be inflicted by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death and until such person sentenced to death is dead, and such execution procedure shall be ***160** determined and supervised by the Commissioner of the Department of Correction.

DEL.CODE ANN. tit. 11, § 4209(f) (2006 Supp.). The statute does not mandate the use of any particular drug or series of drugs.

On August 29, 2008, the Delaware Department of Correction ("DDOC") instituted a new lethal injection protocol ("2008 Protocol"). The protocol calls for the sequential intravenous ("IV") injection of three chemicals into an inmate's bloodstream. The first chemical is sodium thiopental, which renders an inmate unconscious. The second chemical is pancuronium bromide, a muscle relaxant that acts as a paralytic agent. The third and final chemical is potassium chloride, which induces cardiac arrest and causes the inmate's death. The 2008 Protocol also calls for the IV team, consisting of two people who may have at least one year of professional experience, [1] to

examine the inmate to ensure he is unconscious before the pancuronium bromide is administered. The consciousness check requires the warden to call the inmate's name out loud to observe any reaction from the inmate. At the same time, a member of the IV team assesses the inmate's consciousness by touching the inmate, shaking his shoulder, and brushing his eyelashes. If the inmate is not unconscious, the protocol requires the execution team to repeat the administration of the first chemical and subsequent consciousness checks until the inmate is deemed unconscious.

Delaware amended its protocol on May 5, 2011. The amended protocol, which is before us today, includes only one significant difference. Due to a nationwide shortage of sodium thiopental, Delaware, along with a number of other states, revised its protocol to allow for the use of an alternative barbiturate, pentobarbital, as the first chemical to be administered.

B. Procedural History

Jackson, a Delaware state inmate convicted of first degree murder and sentenced to death by the State of Delaware, commenced this action on May 8, 2006. He filed a section 1983 action [2] alleging that the State of Delaware's then-existing method of lethal injection created an unconstitutional risk of pain and suffering, cognizable under the Eighth and Fourteenth Amendments of the United States Constitution. [3] The District Court certified a class under Fed.R.Civ.P. 23(b) consisting of all Delaware death row inmates and appointed class counsel. *See Jackson v. Danberg,* 240 F.R.D. 145 (D.Del.2007).

During the course of litigation in the District Court, Defendants amended their lethal injection protocol twice. Ultimately, the 2008 Protocol was enacted in an effort to incorporate the safeguards described by ***161** the Supreme Court in *Baze v. Rees,* 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008), which upheld Kentucky's lethal injection protocol against a challenge under the Eighth Amendment. Upon adoption of the 2008 Protocol and at the direction of the District Court, Defendants moved for summary judgment. They argued that the 2008 Protocol fully complied with the mandate of *Baze* and that the lethal injection protocol, including the use of sodium thiopental, did not constitute cruel and unusual punishment. The District Court acknowledged that the DDOC had failed to follow its own procedures in certain executions but held that Plaintiffs had not shown a "substantial risk of an inadequate dose of sodium thiopental." *Jackson v. Danberg,* 601 F.Supp.2d 589, 599 (D.Del.2009). The District Court granted summary judgment to Defendants and stayed executions pending appeal. *Id.*

Plaintiffs appealed, and Defendants cross-appealed the stay of executions. We affirmed the grant of summary judgment, applying *Baze* to our analysis. *Jackson I,* 594 F.3d 210. We held that to prevail on a claim that a risk of future harm runs afoul of the Constitution, an inmate must demonstrate that "the conditions presenting the risk must be '*sure or very likely* to cause serious illness and needless suffering,' and give rise to 'sufficiently *imminent* dangers.' " *Id.* at 216 (quoting *Baze,* 553 U.S. at 50, 128 S.Ct. 1520). We noted that "the proper administration of sodium thiopental is an indispensable link in the lethal injection chain for Eighth Amendment purposes, as it ensures that an inmate will not suffer under the effects of the second two drugs." *Id.* at 225. In other words, although "[r]easonable people of good faith disagree on the morality and efficacy of capital punishment," Delaware's 2008 Protocol is not unconstitutional under existing Supreme Court precedent. *Id.* at 230 (quoting *Baze,* 553 U.S. at 61, 128 S.Ct. 1520). The Supreme Court denied certiorari on October 12, 2010. *Jackson v. Danberg,* —— U.S. ——, 131 S.Ct. 458, 178 L.Ed.2d 287 (2010).

Shortly after Delaware changed its protocol to include pentobarbital as an alternative to sodium thiopental in May 2011, Plaintiffs filed a motion to reopen under Fed.R.Civ.P. 60(b)(6) and (d) and a motion to stay Jackson's execution with the District Court. Plaintiffs argued that the substitution of pentobarbital for sodium thiopental is a factual change that undermines the foundations of the prior ruling, constituting an exceptional circumstance under Rule 60(b)(6) and a circumstance calling for an independent action to prevent a miscarriage of justice under Rule 60(d). They relied on an expert report written by David B. Waisel, M.D., in support of their motion. Defendants, in turn, relied on an expert report by Dr. Mark Dershwitz, an anesthesiologist with a Ph.D. in pharmacology. The District Court denied both of Plaintiffs' motions. It found that a stay was not warranted because Plaintiffs had "not carried their burden to prove that they are likely to succeed on the merits of their Eighth Amendment claim." *Jackson v. Danberg,*

2011 WL 3205453, at *3 (D.Del. July 27, 2011). The District Court also denied Plaintiffs' motion to reopen under both Rules 60(b)(6) and 60(d), concluding that "the record at bar is insufficient to reopen the judgment entered by [it] in 2009." *Id.* at *4. Plaintiffs timely appealed the judgment of the District Court and filed an independent motion for a stay.

We denied the motion to stay on July 28, 2011, and affirmed the judgment of the District Court with an opinion to follow.[4] Following our decision, the Supreme Court ***162** denied certiorari, and Robert Jackson was executed just after midnight on July 29, 2011, by lethal injection.[5]

II.

[1] **[2]** The District Court had jurisdiction under 28 U.S.C. § 1331. We have jurisdiction pursuant to 28 U.S.C. § 1292(a)(1) to consider the appeal by Plaintiffs from the District Court's denial of injunctive relief and under 28 U.S.C. § 1291 to consider the appeal by Plaintiffs from the District Court's denial of relief under Fed.R.Civ.P. 60(b) and (d). We review a district court's denial of a stay for abuse of discretion, which may be found where its conclusion includes the commission of a serious error of law or a mistake in considering the facts. *Bradley v. Pittsburgh Bd. of Educ.,* 910 F.2d 1172, 1175 (3d Cir.1990). We also review a district court's denial of a Rule 60(b) and (d) motion to reopen for abuse of discretion. *Morris v. Horn,* 187 F.3d 333, 341 (3d Cir.1999).

III.

A. Stay

[3] **[4]** **[5]** "[A] stay of execution is an equitable remedy" that "is not available as a matter of right, and equity must be sensitive to the State's strong interest in enforcing its criminal judgments without undue interference from the federal courts." *Hill v. McDonough,* 547 U.S. 573, 584, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006). The standard for issuance of a stay is like that for issuance of a preliminary injunction, and requires consideration of four factors:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Hilton v. Braunskill, 481 U.S. 770, 776, 107 S.Ct. 2113, 95 L.Ed.2d 724 (1987); *Republic of Phil. v. Westinghouse Elec. Corp.,* 949 F.2d 653, 658 (3d Cir.1991). In assessing these factors, we underscore that "inmates seeking time to challenge the manner in which the State plans to execute them must satisfy all of the requirements for a stay, including a showing of a significant possibility of success on the merits." *Hill,* 547 U.S. at 584, 126 S.Ct. 2096.

Plaintiffs argue that because pentobarbital is not approved by the Food and Drug Administration ("FDA") for use as an anesthetic, its performance in the three-drug protocol, namely its manner and timing of inducing unconsciousness, is unknown and unpredictable and therefore violative of the Eighth Amendment. In support of their argument that pentobarbital renders the lethal injection protocol unconstitutional, Plaintiffs proffer the following evidence: (1) the opinion of Dr. David Waisel, an anesthesiologist at Harvard Law School, who, among other things, has reviewed eyewitness accounts and has concluded that Alabama prisoner Eddie Powell and Georgia prisoner Roy Blankenship were inadequately anesthetized by pentobarbital and suffered greatly from their executions; (2) the fact that pentobarbital is not approved by the FDA for use as an anesthetic; and (3) the fact that pentobarbital is less lipid-soluble than sodium thiopental and therefore does not cross the blood-brain barrier as quickly.

[6] **[7]** **[8]** Plaintiffs' challenge to the DDOC's substitution of pentobarbital for sodium thiopental is governed by the Supreme Court's splintered decision in *Baze.* ***163** In *Baze,* the Supreme Court recognized "that subjecting individuals to a risk of future harm—not simply actually inflicting pain—can qualify as cruel and unusual punishment." 553 U.S. at 49, 128 S.Ct. 1520. However,

to constitute a violation of the Eighth Amendment, "the conditions presenting the risk must be '*sure or very likely* to cause serious illness and needless suffering,' and give rise to 'sufficiently *imminent* dangers.' " *Id.* at 50, 128 S.Ct. 1520 (quoting *Helling v. McKinney,* 509 U.S. 25, 34–35, 113 S.Ct. 2475, 125 L.Ed.2d 22 (1993)). "Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of 'objectively intolerable risk of harm' that qualifies as cruel and unusual." *Id.* Rather, a stay of execution may only be granted where "the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain ... [and] that the risk is substantial when compared to the known and available alternatives." *Id.* at 61, 128 S.Ct. 1520.

The District Court, applying the *Baze* principles, concluded that Plaintiffs failed to demonstrate that the substitution of pentobarbital resulted in a constitutionally unacceptable risk of pain and suffering. It noted that Delaware's protocol calls for the administration of five grams of pentobarbital, which on its own is a lethal dose according to Dr. Dershwitz. Moreover, the Delaware protocol calls for a consciousness check after two minutes have lapsed, followed by the administration of a second dose of pentobarbital if the inmate is still conscious after two minutes. Based upon these factual findings and procedural safeguards, the District Court concluded that Plaintiffs had not presented "affirmative evidence ... that the administration of pentobarbital as the first drug in Delaware's three-drug protocol creates a demonstrated risk of severe pain, as required by the Supreme Court." *Jackson,* 2011 WL 3205453, at *3. In other words, the District Court concluded that Plaintiffs failed to demonstrate a likelihood of success on the merits and accordingly denied the stay.

[9] After conducting our own searching review of the record, we conclude that the District Court did not abuse its discretion in denying Plaintiffs' motion for a stay. The District Court's factual findings are supported by the testimony of Defendants' expert, Dr. Dershwitz. The purpose of the anesthetic in Delaware's lethal injection protocol is to render the inmate unconscious before administration of the second and third drugs, and there is no affirmative evidence that pentobarbital fails to do this. [6]

***164** Indeed each court to consider this issue has uniformly held that the use of pentobarbital in lieu of sodium thiopental is constitutional. [7] *See, e.g., DeYoung v. Owens,* 646 F.3d 1319, 1324–25 (11th Cir.2011); *Powell v. Thomas,* 641 F.3d 1255, 1257 (11th Cir.2011) (per curiam); *Pavatt v. Jones,* 627 F.3d 1336 (10th Cir.2010). For example, the United States Court of Appeals for the Tenth Circuit approved a protocol virtually identical to Delaware's after allowing an Oklahoma death-sentenced inmate to conduct discovery, submit an expert report, and hold an evidentiary hearing. *Pavatt,* 627 F.3d at 1338–40. In *Pavatt,* the district court considered evidence that: (1) the first step of Oklahoma's lethal injection protocol mandates the intravenous administration of five grams of pentobarbital; (2) the protocol requires the attending physician to ensure that the inmate is sufficiently unconscious prior to the administration of the paralytic agent; (3) the administration of a sufficient dose of pentobarbital will render an individual unconscious; (4) the defendant's expert witness, Dr. Dershwitz, testified that the five-gram dosage will ensure that the inmate does not feel the effects of the paralytic agent; and (5) Dr. Dershwitz responded to Dr. Waisel's testimony by pointing out that the use of pentobarbital to induce a barbiturate coma takes the patient to a state of unconsciousness beyond a normal clinical level of anesthesia. *Id.* at 1339. At the conclusion of the hearing, the district court denied the motion for a stay, concluding that the prisoner failed to establish a substantial likelihood of success on the merits of his Eighth Amendment challenge.

On appeal, the Tenth Circuit held that the district court did not abuse its discretion in denying a stay. Specifically, the Tenth Circuit observed that Dr. Dershwitz had "substantially more clinical experience with the use of pentobarbital than Dr. Waisel." *Id.* at 1340. The court also noted the importance of the consciousness check to its analysis, and held that the inmate "failed to establish a substantial likelihood of success on the merits of his Eighth Amendment challenge to the ... revised protocol." *Id.; see also DeYoung,* 646 F.3d at 1327 ("DeYoung has wholly failed to show that pentobarbital, once fully administered and allowed to act, is ineffective as an anesthetic."); [8] *Powell,* 641 F.3d at 1257–58 (approving the substitution of pentobarbital for sodium thiopental). We agree with the Tenth Circuit's approach and likewise conclude that Plaintiffs cannot establish that pentobarbital is "*sure or very likely* to cause serious illness

and needless suffering." *Baze,* 553 U.S. at 50, 128 S.Ct. 1520 (quoting *Helling,* 509 U.S. at 34–35, 113 S.Ct. 2475).

Finally, Plaintiffs argue that the District Court misapplied the legal rubric of *Baze* by failing to engage in an additional inquiry with respect to their execution challenge: a comparative risk analysis. According to Plaintiffs, the District Court was required to consider the comparative risks of "known and available alternatives" to Delaware's pentobarbital three-drug protocol. Specifically, they argue the District Court should have considered the ***165** comparative risk of (1) a known anesthetic drug with a proven track record, for use as the first drug in the three-drug protocol, or (2) a single-drug execution protocol. [9]

[10] Plaintiffs' argument misstates the law. "[A] condemned prisoner cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative." *Baze,* 553 U.S. at 51, 128 S.Ct. 1520. Rather, an inmate must first show that a state's current protocol creates a "demonstrated risk of severe pain." *Id.* at 61, 128 S.Ct. 1520. Moreover, Delaware is not "compelled to change its lethal injection protocol simply because another state has elected to do so." *Jackson I,* 594 F.3d at 228. We recognize that the one-drug protocol is gaining support as an alternative to the three-drug lethal injection protocol, and we commend those states steadily striving to develop more humane alternatives to existing methods of execution. However, federal courts are not "boards of inquiry charged with determining 'best practices' for executions." *Baze,* 553 U.S. at 51, 128 S.Ct. 1520.

"Pentobarbital is a barbiturate commonly used to euthanize terminally ill patients who seek death with dignity in states such as Oregon and Washington." *Beaty v. Brewer,* 649 F.3d 1071, at 1075, 2011 WL 2040916, at *4 (9th Cir.2011) (denying rehearing en banc because inmate had no likelihood of success on Eighth Amendment claim based on pentobarbital). It has been used successfully for executions in at least four other states, and there is no evidence that it fails to render an inmate unconscious. [10] *Id.* The District Court did not abuse its discretion in finding that the use of pentobarbital did not create "a demonstrated risk of severe pain, as required by the Supreme Court." *Jackson,* 2011 WL 3205453, at *3. Thus, we affirm the District Court's denial of the stay. [11]

B. 60(b)(6) and 60(d)

[11] Rule 60(b)(6) relief from judgment is only granted in extraordinary circumstances. *See Martinez–McBean v. Govt. of Virgin Islands,* 562 F.2d 908, 911–12 (3d Cir.1977). [12] It is available where the party ***166** seeking relief demonstrates that "extreme" and "unexpected" hardship will result absent such relief. *United States v. Swift & Co.,* 286 U.S. 106, 119, 52 S.Ct. 460, 76 L.Ed. 999 (1932). Similarly, Rule 60(d) permits a court to entertain an independent action to relieve a party from a judgment in order to "prevent a grave miscarriage of justice." *United States v. Beggerly,* 524 U.S. 38, 47, 118 S.Ct. 1862, 141 L.Ed.2d 32 (1998).

[12] Plaintiffs claim that the addition of pentobarbital as an available alternative to sodium thiopental is such a circumstance. In making this argument, Plaintiffs urge that the use of sodium thiopental was central to our decision in *Jackson I,* and that the substitution of an alternative barbiturate undermines the very foundation of our decision.

In *Jackson I,* we held that Delaware's three-drug protocol did not violate the Eighth Amendment, and stated that "the proper administration of sodium thiopental is an indispensable link in the lethal injection chain for Eighth Amendment purposes, as it ensures that an inmate will not suffer under the effects of the second two drugs." 594 F.3d at 225. However, the import of both *Baze* and *Jackson I* is that use of an effective anesthetic as the first drug in a three-drug protocol is required to satisfy the Eighth Amendment. In other words, "[t]he proper administration of the first drug [must] ensure[ ] that the prisoner does not experience any pain associated with the paralysis and cardiac arrest caused by the second and third drugs." *Baze,* 553 U.S. at 44, 128 S.Ct. 1520.

We cannot say that the District Court's finding that pentobarbital is an effective anesthetic for purposes of the three-drug lethal injection is clearly erroneous, particularly based on its demonstrated uses and the testimony of Dr. Dershwitz. Accordingly, we conclude that the District Court did not abuse its discretion in denying Plaintiffs' motion to reopen, and we agree that "the substitution of pentobarbital for sodium thiopental does not constitute a factual change which undermines

the foundation of [the] prior ruling," necessitating independent action under either Rule 60(b)(6) or 60(d). *Jackson,* 2011 WL 3205453, at *4. [13]

IV.

For all of these reasons, we conclude that Plaintiffs have not demonstrated a substantial likelihood of success on the merits of their claims, and that the District Court did not abuse its discretion in denying a stay of Jackson's execution and Plaintiffs' motion to reopen. Accordingly, we will affirm.

All Citations

656 F.3d 157

Footnotes

1 Those specialists include a certified medical assistant, a phlebotomist, an emergency medical technician, a paramedic, and a military corpsman.

2 42 U.S.C. § 1983 provides, in pertinent part:

> Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured[.]

3 Jackson named the following defendants in his complaint: Stanley W. Taylor, Jr., Commissioner, Delaware Department of Correction; Thomas L. Carroll, Warden, Delaware Correctional Center; Paul Howard, Bureau Chief, Delaware Bureau of Prisons; and other unknown Delaware officials (collectively, "Defendants"). In February 2007, the District Court substituted Taylor with his successor, Carl C. Danberg.

4 The panel issued its order around 7:00 p.m. on July 28, 2011, approximately five hours before the scheduled time of execution.

5 We write on this issue as this appeal was filed on behalf of a class, and it impacts appellants other than Jackson.

6 Jackson urges us to consider Georgia's execution of Roy Blankenship and Alabama's execution of Eddie Powell as affirmative evidence that pentobarbital fails to properly anesthetize inmates. Dr. Waisel, who formulated his opinion based on witnesses' accounts of the execution and some movement by the inmates during the initial three minutes at the start of the execution process, expressed concern that Blankenship and Powell were insufficiently anesthetized. Witnesses described these executions in contradictory ways. For example:

> To some, Blankenship was just looking up and watching what was occurring, looked at his left arm (which had an IV saline drip) and then 30 to 60 seconds later looked toward his right arm where the administration of the pentobarbital was starting. To others, Blankenship appeared to grimace, or have a startled face, or jerked his arm twice, or had his mouth open and tried to mouth something.

DeYoung, 646 F.3d at 1326–27. Under Georgia's protocol, the execution could not proceed until a consciousness check was performed. The District Court was not persuaded by this equivocal evidence of consciousness in the face of strict procedural safeguards, and we see no abuse of discretion in its conclusion.

7 While these cases are not controlling, it is noteworthy that the expert reports before the District Court here were written by the same experts utilized in the other courts of appeals cases.

8 Plaintiffs' assertion that the Eleventh Circuit's denial of DeYoung's claims was based entirely on Georgia's two-year statute of limitations is only partially correct. *DeYoung,* 646 F.3d at 1324–25. The court engaged in a thorough analysis of the merits of DeYoung's claims and held in the alternative that "even if [DeYoung's claims] were timely, they fail as a matter of law ... because [he] has not established a substantial likelihood of success on the merits of his claims." *Id.*

9 With respect to the second option, Dr. Dershwitz testified that a five-gram dose of a barbiturate such as sodium thiopental or pentobarbital would cause death in all people, and that death would occur as quickly as five minutes from the injection. Ohio has used a one-drug protocol since November 2009, and Washington adopted a one-drug protocol on March 2, 2010, but permits condemned inmates to select the method. *See* Death Penalty Information Ctr., Authorized Methods, http://www.deathpenal tyinfo.org/methods-execution.

10 Plaintiffs also assert that Defendants' use of pentobarbital is violative of the Eighth Amendment because it evinces Defendants' deliberate indifference to the potential pain and suffering he will undergo. We have previously held that *Baze* did not import the "deliberate indifference" standard to lethal injection challenges. *See Jackson I,* 594 F.3d at 223 n. 16.

Instead, the *Baze* Court held that "there must be a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment.' " *Baze,* 553 U.S. at 50, 128 S.Ct. 1520 (quoting *Farmer v. Brennan,* 511 U.S. 825, 842, 846, & n. 9, 114 S.Ct. 1970, 128 L.Ed.2d 811 (1994)). Even if this language did graft the deliberate indifference standard onto lethal injection challenges, because we conclude that there was no "substantial risk of serious harm," we also conclude that there could have been no deliberate indifference to that alleged risk.

11 Because we conclude that Plaintiffs have not demonstrated a likelihood of success on the merits, we need not address the other factors required for a stay of an execution.

12 Fed.R.Civ.P. 60(b)(6) provides, in pertinent part: "On motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for ... any ... reason that justifies relief."

13 We also conclude that the District Court did not abuse its discretion in declining to grant an evidentiary hearing on the matter. Having presided over the entire case and being intimately familiar with the record to date as well as the submissions regarding pentobarbital, the District Court was well-situated to rule on the motion to reopen and the motion for the stay, and additional discovery would not further illuminate the issue at bar. *See United States v. Hines,* 628 F.3d 101, 104 (3d Cir.2010) (setting forth the standard of review).

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Distinguished by Arthur v. Thomas, 11th Cir.(Ala.), March 21, 2012

646 F.3d 1319
United States Court of Appeals,
Eleventh Circuit.

Andrew Grant DeYOUNG, Plaintiff–Appellant,
v.
Brian OWENS, Commissioner, Georgia Department of Corrections, Carl Humphrey, Warden, Georgia Diagnostic and Classification Prison, other unknown employees and agents, Georgia Department of Corrections, Defendants–Appellees.

No. 11–13235.
|
July 20, 2011.

Synopsis

Background: Georgia death-row inmate brought federal civil rights action, alleging that the State of Georgia's method of lethal execution would violate his Eighth Amendment right to be free from cruel and unusual punishment and his Fourteenth Amendment right to equal protection. Inmate moved for a temporary restraining order (TRO) and stay of execution, as well as additional declaratory and injunctive relief. The State moved to dismiss. The United States District Court for the Northern District of Georgia, No. 1:11-cv-02324-SCJ, Steve C. Jones, J., entered order denying inmate's motions for a TRO and stay of execution and granting the State's motion to dismiss, and subsequently denied inmate's motions for additional relief. Inmate appealed and moved for a stay of execution in the Court of Appeals.

Holdings: The Court of Appeals, Hull, Circuit Judge, held that:

[1] inmate's claims were barred by Georgia's two-year statute of limitations;

[2] even if the statute of limitations did not bar his action, inmate failed to demonstrate that Georgia's lethal injection protocol, which used pentobarbital as an anesthetic, violated the Eighth Amendment's prohibition of cruel and unusual punishment; and

[3] even if the statute of limitations did not bar his action, inmate failed to demonstrate that Georgia's lethal injection protocol violated his right to equal protection.

Motion for stay of execution denied; district court's order denying stay of execution affirmed.

See also 609 F.3d 1260.

West Headnotes (17)

[1] **Federal Courts**
Preliminary injunction;temporary restraining order

Court of Appeals reviews the district court's denial of appellant's motions for a temporary restraining order (TRO) and stay of execution for abuse of discretion.

2 Cases that cite this headnote

[2] **Federal Courts**
Pleading

Federal Courts
Pleadings;Dismissal

Court of Appeals reviews the district court's grant of a motion to dismiss de novo, accepting the allegations in the complaint as true and construing them in the light most favorable to the plaintiff.

3 Cases that cite this headnote

[3] **Sentencing and Punishment**
Stay of execution

Stay of execution is equitable relief which the Court of Appeals may grant only if the moving party shows that: (1) he has a substantial likelihood of success on the merits, (2) he will suffer irreparable injury unless the injunction issues, (3) the stay would not substantially harm the other litigant, and (4) if issued, the injunction would not be adverse to the public interest.

20 Cases that cite this headnote

[4] **Civil Rights**
Time to Sue
Federal Courts
Civil rights and discrimination cases

Section 1983 claims are tort actions, subject to the statute of limitations governing personal injury actions in the state where the § 1983 action has been brought. 42 U.S.C.A. § 1983.

8 Cases that cite this headnote

[5] **Limitation of Actions**
Injuries to the person

Georgia has a two-year statute of limitations for personal injury actions. West's Ga.Code Ann. § 9–3–33.

6 Cases that cite this headnote

[6] **Limitation of Actions**
Liabilities Created by Statute

Georgia's two-year limitations period for personal injury actions, which governs § 1983 claims brought by death-row inmates, begins to run on the date on which state review is complete, or the date on which the capital litigant becomes subject to a new or substantially changed execution protocol, whichever occurs later. 42 U.S.C.A. § 1983; West's Ga.Code Ann. § 9–3–33.

7 Cases that cite this headnote

[7] **Constitutional Law**
Delay in assertion of rights;laches
Limitation of Actions
Liabilities Created by Statute

Georgia death-row inmate's claims, that the State's method of lethal execution would violate his Eighth Amendment right to be free from cruel and unusual punishment and his Fourteenth Amendment right to equal protection, were barred by Georgia's two-year statute of limitations; inmate's state review became complete on May 26, 1998, the date the United States Supreme Court denied his petition for certiorari on direct appeal, inmate last became subject to a new or substantially changed execution protocol on October 5, 2001, when Georgia ended its use of execution by electrocution and adopted lethal injection as its method of execution, Georgia's substitution of pentobarbital for sodium thiopental as the anesthetic in its lethal injection protocol did not result in a "substantially changed execution protocol" that re-set the limitations period, and so two-year statute of limitations began to run on October 5, 2001, and expired nearly eight years before inmate filed his action. U.S.C.A. Const.Amends. 8, 14; 42 U.S.C.A. § 1983; West's Ga.Code Ann. § 9–3–33.

24 Cases that cite this headnote

[8] **Federal Courts**
Rehearing and reargument

Litigant's mere act of proffering additional reasons not expressly considered previously will not open the door to reconsideration of the question by a second panel of the Court of Appeals.

2 Cases that cite this headnote

[9] **Sentencing and Punishment**
Scope of Prohibition

To state an Eighth Amendment claim, plaintiff must demonstrate that (1) the State is being deliberately indifferent (2) to a condition that poses a substantial risk of serious harm to him. U.S.C.A. Const.Amend. 8.

1 Cases that cite this headnote

[10] **Sentencing and Punishment**
Mode of execution

In the lethal injection context, the standard for stating an Eighth Amendment claim requires an inmate to show an objectively intolerable risk of harm that prevents prison

officials from pleading that they were subjectively blameless for purposes of the Eighth Amendment. U.S.C.A. Const.Amend. 8.

8 Cases that cite this headnote

[11] Sentencing and Punishment

Mode of execution

To state an Eighth Amendment claim in the lethal injection context, the objectively intolerable risk of harm that an inmate must show must be sure or very likely to cause needless suffering. U.S.C.A. Const.Amend. 8.

10 Cases that cite this headnote

[12] Sentencing and Punishment

Mode of execution

Georgia death-row inmate failed to show that State's lethal injection protocol, which used pentobarbital as an anesthetic, violated the Eighth Amendment's prohibition of cruel and unusual punishment; although inmate attempted to use evidence of an earlier execution to show that administration of 5,000 mg of pentobarbital causes needless suffering in and of itself, and that the pentobarbital dose does not adequately render an inmate unconscious, thereby leading to needless suffering, evidence did not establish substantial risk of serious harm from pentobarbital, or even that inmate who was executed earlier necessarily suffered any harm, much less serious harm, from intravenous administration of pentobarbital, as none of the witnesses to that execution reported any movement by inmate after nurse's consciousness check, inmate's autopsy revealed no evidence of trauma, and there was no evidence that unconsciousness is not achieved after complete administration of a 5,000-mg dose. U.S.C.A. Const.Amend. 8; 42 U.S.C.A. § 1983.

10 Cases that cite this headnote

[13] Sentencing and Punishment

Scope of Prohibition

Eighth Amendment does not protect against all harm, only serious harm; and it does not prohibit all risks, only substantial risks. U.S.C.A. Const.Amend. 8.

Cases that cite this headnote

[14] Sentencing and Punishment

Mode of execution

Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of objectively intolerable risk of harm that qualifies as "cruel and unusual." U.S.C.A. Const.Amend. 8.

1 Cases that cite this headnote

[15] Constitutional Law

Similarly situated persons;like circumstances

To state an equal protection claim, plaintiff must show that the State will treat him disparately from other similarly situated persons. U.S.C.A. Const.Amend. 14.

18 Cases that cite this headnote

[16] Constitutional Law

Rational Basis Standard; Reasonableness

Where plaintiff does not allege that disparate treatment by the State burdens his fundamental rights or is based on his membership in a suspect class, plaintiff must show that the disparate treatment is not rationally related to a legitimate government interest. U.S.C.A. Const.Amend. 14.

9 Cases that cite this headnote

[17] Constitutional Law

Capital punishment;death penalty

Sentencing and Punishment

Mode of execution

Georgia death-row inmate failed to demonstrate that Georgia's lethal injection protocol violated his right to equal protection; there was no support for inmate's "novel proposition" that the Equal Protection Clause requires a written execution protocol sufficiently detailed to ensure that every execution is performed in a precisely identical manner, the Georgia lethal injection protocol was highly detailed as to nearly every aspect of the execution process, the "deviations" that inmate cited as leading to the disparate treatment of which he complained were all ways by which the Georgia Department of Corrections (GDOC) provided more protection for an inmate and the execution process than that provided by the written protocol, the State had a legitimate interest in ensuring that its executions occurred in a thorough manner with maximum inmate safeguards, and the alleged deviations from the written protocol were rationally related to that interest. U.S.C.A. Const.Amend. 14; 42 U.S.C.A. § 1983.

5 Cases that cite this headnote

Attorneys and Law Firms

***1321** Jeffrey Lyn Ertel, Fed. Pub. Def., Brian S. Kammer, Georgia Resource Ctr., Atlanta, GA, Mark Evan Olive, Law Offices of ***1322** Mark E. Olive, PA, Tallahassee, FL, for Plaintiff–Appellant.

Patricia Beth Attaway Burton, Joseph J. Drolet, Sabrina D. Graham, Theresa Marie Schiefer, Mary Beth Westmoreland, Atlanta, GA, for Defendants–Appellees.

Appeal from the United States District Court for the Northern District of Georgia.

Before DUBINA, Chief Judge, and EDMONDSON and HULL, Circuit Judges.

Opinion

HULL, Circuit Judge:

Georgia death-row inmate Andrew DeYoung brutally murdered his mother, his father, and his fourteen year old sister, Sarah, and was convicted and sentenced to death. *See, e.g., DeYoung v. Schofield,* 609 F.3d 1260, 1262 (11th Cir.2010), *cert. denied,* —— U.S. ——, 131 S.Ct. 1691, 179 L.Ed.2d 628 (2011). [1]

DeYoung is scheduled to be executed by lethal injection at 7:00 p.m. on Wednesday, July 20, 2011. On Friday, July 15, 2011, DeYoung filed a 42 U.S.C. § 1983 action alleging that the State of Georgia's method of lethal execution will violate his Eighth Amendment right to be free from cruel and unusual punishment and his Fourteenth Amendment right to equal protection. DeYoung moved for a temporary restraining order ("TRO") and stay of execution, as well as further declaratory and injunctive relief seeking to prevent the State from executing him using its current lethal injection protocol.

On Monday, July 18, 2011, the State moved to dismiss, arguing that DeYoung's claims are barred by the statute of limitations and fail to state a claim upon which relief can be granted. After holding an evidentiary hearing on Tuesday, July 19, 2011, the district court entered a thorough 28–page order on July 20, 2011, denying DeYoung's motions for a TRO and stay of execution and granting the State's motion to dismiss. Thereafter, the district court also denied DeYoung's motion for stay of execution pending appeal and separate motion to alter judgment pursuant to Rule 59(e) of the Federal Rules of Civil Procedure.

DeYoung appealed and filed a motion for a stay of execution in this Court. After review, we deny DeYoung's motion for a stay of execution.

I. BACKGROUND

A. Georgia's Lethal Injection Protocol

Georgia law provides that "[a]ll persons who have been convicted of a capital offense and have had imposed upon them a sentence of death shall suffer such punishment by lethal injection," which it defines as "the continuous intravenous injection of a substance or substances sufficient to cause death into the body of the person sentenced to death until such person is dead." O.C.G.A. § 17–10–38(a) (2000).

Under the lethal injection protocol promulgated by the Georgia Department of Corrections ("GDOC"), death-sentenced prisoners are administered a succession of three chemicals in the following order: (1) 5,000 milligrams of pentobarbital, an anesthetic that is administered to render the inmate unconscious; (2) 50 milligrams of pancuronium bromide, a paralytic agent; and (3) 120 milliequivalents of potassium ***1323** chloride, which induces cardiac arrest, causing the inmate's death.

The protocol calls for an IV nurse to examine the inmate to ensure he is unconscious before the pancuronium bromide is administered. If the inmate is not unconscious, the protocol requires GDOC staff to repeat the administration of pentobarbital and subsequent consciousness check until the inmate is deemed to be unconscious.

Until May 13, 2011, the anesthetic used was sodium thiopental (a/k/a sodium pentothal). Lack of sodium thiopental availability led Georgia on May 13, 2011 to switch to the use of pentobarbital as the anesthetic in its lethal injection protocol.

B. De Young's Claims

DeYoung's challenge to the State's method of execution is two-pronged. First, he contends the GDOC's lethal injection protocol violates the Eighth Amendment's prohibition of cruel and unusual punishment. Specifically, DeYoung alleges, among other things, that the use of pentobarbital as an anesthetic poses a substantial risk of serious harm to him because: (1) pentobarbital has been insufficiently tested for induction of anesthetic coma in fully conscious persons, and (2) in prior executions using pentobarbital, the drug did not painlessly anesthetize the prisoners.

Second, DeYoung contends the GDOC's lethal injection protocol, as written and as administered in practice, violates his right to equal protection under the Fourteenth Amendment because: (1) the written protocol contains gaps in the execution procedure that the GDOC fills in on an *ad hoc* basis, leading to disparate treatment for different inmates; and (2) the GDOC deviates from the written protocol, similarly leading to disparate treatment for different inmates. The State promptly filed a motion to dismiss on numerous grounds, including the statute of limitations and failure to state a claim.

C. District Court's Order

In granting the State's motion to dismiss, the district court found: (1) DeYoung's claims accrued in 2001, when Georgia adopted lethal injection as its method of execution; (2) Georgia's substitution of pentobarbital for sodium thiopental did not constitute a significant alteration to the protocol that would re-set the limitations period; (3) GDOC's alleged deviations from the written protocol began no later than May 2008; and (4) DeYoung's two-year limitations period expired eight years before he filed this action.

Alternatively, even if the statute of limitations did not bar his § 1983 action, the district court concluded that DeYoung failed to state a claim upon which relief could be granted. As to the Eighth Amendment claim, the district court found, among other things: (1) DeYoung's evidence failed to show that the administration of pentobarbital inflicts serious harm; (2) DeYoung has not proven that former inmate Roy Blankenship (who on June 23, 2011 was executed by the State of Georgia using pentobarbital as the anesthetic) suffered pain or serious harm; (3) that DeYoung's expert "failed to provide a medical explanation for why pentobarbital might have caused Blankenship pain" and "[t]o the contrary, Dr. Waisel testified that a patient will not feel pain at the moment when a drug is introduced intravenously unless it is a drug, such as potassium chloride, which causes a burning sensation"; (4) DeYoung presented no evidence indicating a 5,000–milligram dose of pentobarbital fails to cause unconsciousness; (5) a consciousness check was performed on Roy Blankenship prior to injection of the second drug pancuronium bromide as required by Georgia's legal injection procedure; ***1324** and (6) executions in Georgia do not proceed with the second drug until the inmate is unconscious and "DeYoung['s] execution cannot proceed until he is unconscious." Thus, DeYoung did not show that Georgia's use of pentobarbital creates a substantial risk of serious harm to inmates.

As to DeYoung's Fourteenth Amendment claim, the district court found: (1) there was no support for "DeYoung's novel proposition" that the Equal Protection Clause requires the State to "produce a written protocol that is detailed enough to insure that every execution is precisely identical"; (2) the "deviations" from the written protocol of which DeYoung complains (including the use of nurses to insert IVs, the presence of two nurses instead of one, performance of numerous consciousness checks,

and checks for IV infiltration or leakage) are consistent with Georgia's written protocol and "enure to the benefit" of inmates; and (3) the benign "deviations" are rationally related to the State's interest in safeguarding the execution process. Thus, DeYoung did not show an equal protection violation.

The district court denied DeYoung's request for a TRO and stay of execution because "he has absolutely no likelihood of success on the merits."

II. DISCUSSION

[1] **[2]** **[3]** On appeal, DeYoung moves this Court for a stay of execution and also appeals the district court's denial of a stay.[2] A stay of execution is equitable relief which this Court may grant "only if the moving party shows that: (1) he has a substantial likelihood of success on the merits; (2) he will suffer irreparable injury unless the injunction issues; (3) the stay would not substantially harm the other litigant; and (4) if issued, the injunction would not be adverse to the public interest." *Powell v. Thomas,* No. 11–12238, 641 F.3d 1255, 1257 (11th Cir. May 19, 2011), *cert. denied,* —— U.S. ——, 131 S.Ct. 2487, 179 L.Ed.2d 1243 (2011). We conclude that DeYoung is not entitled to a stay because he has not demonstrated, among other things, a substantial likelihood he will succeed on the merits of his claims. DeYoung's claims are barred by the statute of limitations and, even if they were timely, they fail as a matter of law. At a minimum, DeYoung has not established a substantial likelihood of success on the merits of his claims.

A. Statute of Limitations

[4] **[5]** **[6]** Section 1983 claims "are tort actions, subject to the statute of limitations governing personal injury actions in the state where the § 1983 action has been brought." *Powell v. Thomas,* No. 11–12613, 643 F.3d 1300, at 1303, 2011 WL 2437498, at *2 (11th Cir. Jun.15, 2011) (quotation marks omitted).[3] Georgia has a two-year statute of limitations for personal injury actions. O.C.G.A. § 9–3–33. The ***1325** two-year limitations period begins to run on "the date on which state review is complete, or the date on which the capital litigant becomes subject to a new or substantially changed execution protocol," whichever occurs later. *McNair v. Allen,* 515 F.3d 1168, 1174 (11th Cir.2008).

[7] DeYoung's state review became complete on May 26, 1998, the date the United States Supreme Court denied DeYoung's petition for certiorari on direct appeal. *See DeYoung v. Georgia,* 523 U.S. 1141, 118 S.Ct. 1848, 140 L.Ed.2d 1097 (1998). DeYoung last became subject to a new or substantially changed execution protocol on October 5, 2001, when the Georgia Supreme Court declared that execution by electrocution violated the state constitution and directed that "any future executions of death sentences in Georgia be carried out by lethal injection in accordance with O.C.G.A. § 17–10–38, as amended." *Dawson v. State,* 274 Ga. 327, 554 S.E.2d 137, 139 (2001). Thus, the two-year statute of limitations began to run on October 5, 2001, and expired nearly eight years before DeYoung filed this action.

DeYoung argues that Georgia's May 13, 2011 substitution of pentobarbital for sodium thiopental as the anesthetic in its lethal injection protocol resulted in a "substantially changed execution protocol." We already rejected an identical claim as to Alabama's recent switch from sodium thiopental to pentobarbital. *See Powell,* 2011 WL 2437498, at *2–4 (rejecting Eighth Amendment challenge to method of execution on statute of limitations grounds, stating, "this very argument—that the ADOC's change from sodium thiopental to pentobarbital, is a substantial or significant change in the lethal injection protocol—was rejected by a panel of this Court in *Powell (Williams),*" and "Powell's attempts to circumvent the holding of *Powell (Williams)* fall flat"); *see also Powell (Williams),* 641 F.3d at 1258 ("The replacement of sodium thiopental with pentobarbital does not constitute a significant alteration in the ADOC's lethal injection protocol ....").

[8] DeYoung acknowledges the *Powell* decision is on point, but argues that the evidence he proffered in this record undermines the premise of *Powell.* However, "the mere act of proffering additional reasons not expressly considered previously will not open the door to reconsideration of the question by a second panel." *Smith v. GTE Corp.,* 236 F.3d 1292, 1302 (11th Cir.2001) (quotation marks and ellipsis omitted). And in any event, the additional evidence DeYoung proffers does not, for the reasons set forth below, undermine *Powell*'s conclusion.

B. Merits of the Claims

1. *Eighth Amendment Claim*

[9] **[10]** **[11]** **[12]** To state an Eighth Amendment claim, DeYoung must "demonstrate that (1) the State is being deliberately indifferent (2) to a condition that poses a substantial risk of serious harm to him." *Powell (Williams),* 641 F.3d at 1257. In the lethal injection context, this standard requires an inmate to show " 'an objectively intolerable risk of harm that prevents prison officials from pleading that they were subjectively blameless for purposes of the Eighth Amendment.' " *Id.* (quoting *Baze v. Rees,* 553 U.S. 35, 50, 128 S.Ct. 1520, 1531, 170 L.Ed.2d 420 (2008) (plurality opinion)). "[T]he risk must be *sure or very likely* to cause ... needless suffering." *Baze,* 553 U.S. at 50, 128 S.Ct. at 1531 (plurality opinion) (quotation marks omitted). The evidence DeYoung provides does not satisfy this Eighth Amendment standard.

A significant part of DeYoung's Eighth Amendment claim in his § 1983 complaint is based on the State of Georgia's execution ***1326** of Roy Blankenship on June 23, 2011. DeYoung largely points to events surrounding the Blankenship execution as the basis for his Eighth Amendment claim. DeYoung attempts to use evidence of the Blankenship execution to show two things: (1) that administration of 5,000 milligrams of pentobarbital to an inmate causes needless suffering in and of itself, and (2) that the pentobarbital dose does not adequately render an inmate unconscious, thereby leading to needless suffering. [4]

After hearing testimony by DeYoung's expert and reviewing multiple affidavits, the district court found (1) that DeYoung failed to establish that pentobarbital caused Blankenship any pain during his execution given that DeYoung's expert failed to provide a medical explanation for why pentobarbital might have caused Blankenship pain, or will cause pain in executions; and (2) that, in any event, DeYoung "has absolutely no likelihood of success on the merits" of his claims.

As the district court aptly found, DeYoung's medical expert, David B. Waisel, M.D., formulated his opinion based on witnesses' accounts of the execution and some movement by Blankenship during the initial three minutes at the start of the execution process. The witnesses disagree about two things: (1) the type of movement; and (2) whether it occurred before or during the administration of the pentobarbital.

As to the movement, witnesses describe it in very different ways. To some, Blankenship was just looking up and watching what was occurring, looked at his left arm (which had an IV saline drip) and then 30 to 60 seconds later looked toward his right arm where the administration of the pentobarbital was starting. To others, Blankenship appeared to grimace, or have a startled face, or jerked his arm twice, or had his mouth open and tried to mouth something.

As to timing, some believe all the movement occurred before the pentobarbital was started in the IV and others appear to think that it was after the pentobarbital was started in the IV. In any event, the movement occurred only a few times and all briefly during a total time period of three minutes. The evidence undisputedly shows that Blankenship became still and was unconscious before the second drug was administered.

Even assuming Blankenship's movement was during the administration of the pentobarbital or right after, the evidence in this record does not establish a substantial risk of serious harm from the pentobarbital, or even that Blankenship necessarily suffered any harm, much less serious harm. First, as the district court pointed out, "Dr. Waisel entirely failed to provide a medical explanation for why pentobarbital might have caused Blankenship pain. To the contrary, Dr. Waisel testified that a patient will not feel pain at the moment when a drug is introduced intravenously unless it is a drug, such as potassium chloride, which causes a burning sensation."

[13] **[14]** Second, the district court noted that Dr. Waisel admitted that "any 'suffering' was short lived as it clearly ended within a few minutes—three minutes at the most—after the pentobarbital was injected." The Eighth Amendment ***1327** does not protect against all harm, only serious harm; and it does not prohibit all risks, only substantial risks. "Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of 'objectively intolerable risk of harm' that qualifies as cruel and unusual." *Baze,* 553 U.S. at 50, 128 S.Ct. at 1531 (plurality opinion). In any event, Dr. Waisel was not present at the Blankenship execution; rather, he opines from the witnesses' varied

descriptions of Blankenship's movements that those movements were a sign of "discomfort," which Dr. Waisel termed "suffering." Dr. Waisel acknowledged that no one reported any movement by Blankenship after the nurse's consciousness check. Further, Blankenship's autopsy revealed no evidence of trauma. The catheters were inside Blankenship's veins and the veins were not burst or broken. There was no infiltration of fluid in the soft tissue of the right arm near the catheter site.

Notably too, DeYoung presented no evidence to show that unconsciousness is not achieved after the complete administration of a 5000–mg dose of pentobarbital. [5]

All parties agree that the purpose of the anesthetic in Georgia's three-drug lethal injection protocol is to render the inmate unconscious *before administration of the second and third drugs.* As the record demonstrates, and the district court found, a consciousness check was performed on Blankenship after he was administered the pentobarbital and prior to injection of the second drug pancuronium bromide, as Georgia's lethal injection protocol requires. It is clear that Blankenship's execution did not proceed to the second drug until after he was fully unconscious. And as the district court found, DeYoung's execution, or any other under the Georgia protocol, cannot proceed until he is unconscious. To the contrary, Georgia's protocol specifically provides that GDOC officials will not administer the pancuronium bromide but will instead administer more anesthetic—and conduct more consciousness checks—until the inmate has been shown to be unconscious.

DeYoung has wholly failed to show that pentobarbital, once fully administered and allowed to act, is ineffective as an anesthetic. As the district court succinctly found, Georgia's "use of pentobarbital does not create a substantial risk of serious harm to inmates."

2. *Fourteenth Amendment Claim* [6]

[15] **[16]** To state an equal protection claim, DeYoung must show that the State will treat him disparately from other similarly situated persons. *See Amnesty Int'l, USA v. Battle,* 559 F.3d 1170, 1180 (11th Cir.2009). Because he does not allege the disparate treatment burdens his fundamental rights or is based on his membership in a suspect class, DeYoung must ***1328** show that the disparate treatment is not rationally related to a legitimate government interest. *Leib v. Hillsborough Cnty. Pub. Transp. Comm'n,* 558 F.3d 1301, 1306 (11th Cir.2009).

[17] DeYoung's equal protection claim asserts, essentially, that Georgia's written lethal injection protocol is insufficiently specific and thus the GDOC deviates from it on an *ad hoc* basis, leading to disparate treatment for different inmates. DeYoung has not shown a substantial likelihood of success on the merits of this claim.

First, as the district court correctly noted, there is no support for DeYoung's "novel proposition" that the Equal Protection Clause requires a written execution protocol sufficiently detailed to ensure that every execution is performed in a precisely identical manner. Moreover, our review of the Georgia lethal injection protocol reveals it to be highly detailed as to nearly every aspect of the execution process.

Second, the "deviations" DeYoung cites that lead to the disparate treatment of which he complains are all ways by which the GDOC provides *more* protection for an inmate and the execution process than the written protocol provides. [7] The State has a legitimate interest in ensuring that its executions occur in a thorough manner with maximum inmate safeguards, and the alleged deviations from the written protocol are rationally related to that interest. DeYoung has not shown a substantial likelihood of success on his equal protection claim.

III. CONCLUSION

For all of these reasons, the Court concludes DeYoung has not demonstrated a substantial likelihood of success on the merits of his claims. Therefore, the Court denies DeYoung's motion for a stay of execution in this Court. The Court also concludes that the district court did not abuse its discretion in denying a stay and this Court affirms.

MOTION FOR STAY OF EXECUTION DENIED; DISTRICT COURT'S ORDER DENYING STAY OF EXECUTION AFFIRMED.

All Citations

646 F.3d 1319, 23 Fla. L. Weekly Fed. C 145

Footnotes

1 DeYoung's convictions and death sentences were upheld on direct appeal and the United States Supreme Court denied certiorari review. *DeYoung v. State,* 268 Ga. 780, 493 S.E.2d 157 (1997), *cert. denied,* 523 U.S. 1141, 118 S.Ct. 1848, 140 L.Ed.2d 1097 (1998). DeYoung unsuccessfully attacked his convictions and death sentences in state and federal habeas proceedings. *See generally DeYoung v. Schofield,* 609 F.3d at 1275–82, 1291.

2 We review the district court's denial of DeYoung's motions for a TRO and stay of execution for abuse of discretion. *Powell v. Thomas,* No. 11–12238, 641 F.3d 1255, 1257 (11th Cir. May 19, 2011), *cert. denied,* —— U.S. ——, 131 S.Ct. 2487, 179 L.Ed.2d 1243 (2011); *Ingram v. Ault,* 50 F.3d 898, 900 (11th Cir.1995). "We review the district court's grant of a motion to dismiss *de novo,* accepting the allegations in the complaint as true and construing them in the light most favorable to the plaintiff." *Powell v. Thomas,* No. 11–12613, 643 F.3d 1300, at 1301–03, 2011 WL 2437498, at *1 (11th Cir. Jun.15, 2011).

3 We rely on the two *Powell* opinions throughout this opinion. Henceforth, we refer to the opinion in case No. 11–12238 as *Powell (Williams)* because that appeal concerned the claims of intervenor Jason Oric Williams. We refer to the opinion in case No. 11–12613 as *Powell* because that appeal concerned the claims of named plaintiff Eddie D. Powell.

4 DeYoung also alleges that pentobarbital has not been sufficiently tested for its ability to cause an anesthetic coma in fully conscious persons. However, DeYoung's expert candidly admits he does not know how the State's dosage of pentobarbital will affect inmates because he claims there is no way to know. This asserted *lack* of knowledge obviously cannot satisfy DeYoung's burden of affirmatively showing that a substantial risk of serious harm exists. Thus, DeYoung's evidence focuses largely on the Blankenship execution.

5 In addition to the evidence concerning the Blankenship execution, DeYoung submitted some evidence regarding the execution of Eddie Powell, who was recently executed in Alabama using a pentobarbital-pancuronium bromide-potassium chloride protocol. DeYoung's evidence about the Powell execution does not change our conclusion. Powell's attorney, who witnessed Powell's execution, testified that about a minute after the Chaplain finished praying with Powell, Powell (1) lifted his head, (2) looked confused, and (3) clenched his teeth and flexed his neck muscles as if he were extremely angry or tense or nervous. After about a minute more, Powell lay back down, closed his eyes, and did not move again. Powell's counsel did not know at what time the various chemical were administered.

6 DeYoung does not appear to raise any Fourteenth Amendment arguments in support of his motion for a stay of execution. Nevertheless, given the gravity of this appeal and out of an abundance of caution, we address this claim as well.

7 These alleged deviations include having two nurses present (whereas the protocol requires only one), performance of numerous consciousness checks (the protocol requires only one successful consciousness check before administration of pancuronium bromide), and checks for IV infiltration or leakage.

627 F.3d 1336
United States Court of Appeals,
Tenth Circuit.

James PAVATT, Plaintiff,
and
Jeffrey Matthews, Plaintiff–Intervenor–Appellant,
and
John David Duty, Plaintiff–Intervenor,
v.
Justin JONES, Director, Department of Corrections, Randall G. Workman, Warden, Oklahoma State Penitentiary; John Doe, 1–50 Unknown Executioners, Defendants–Appellees.

No. 10–6268.
|
Dec. 14, 2010.

Synopsis

Background: Oklahoma state prisoner sentenced to death by lethal injection moved for a preliminary injunction of the execution. The United State District Court for the Western District of Oklahoma denied the motion. Prisoner appealed.

Holdings: The Court of Appeals, Briscoe, Chief Judge, held that:

[1] district court did not abuse its discretion in concluding that prisoner failed to establish substantial likelihood of success on the merits of Eighth Amendment challenge, and

[2] prisoner failed to establish a substantial likelihood of prevailing on his due process challenge to State's revised protocol.

Affirmed.

West Headnotes (6)

[1] Sentencing and Punishment
Discretion of lower court

A court of appeals reviews a district court's order denying a stay of execution for an abuse of discretion.

3 Cases that cite this headnote

[2] Sentencing and Punishment
Stay of execution

A stay of execution is an equitable remedy that is not available as a matter of right, and equity must be sensitive to the State's strong interest in enforcing its criminal judgments without undue interference from the federal courts.

Cases that cite this headnote

[3] Sentencing and Punishment
Stay of execution

Like other stay applicants, inmates seeking time to challenge the manner in which the State plans to execute them must satisfy all of the requirements for a stay, including a showing of a significant possibility of success on the merits.

1 Cases that cite this headnote

[4] Sentencing and Punishment
Mode of execution

District court did not abuse its discretion by concluding, in denying stay of execution, that prisoner failed to establish a substantial likelihood of success on the merits of Eighth Amendment challenge to State's revised three-drug lethal injection protocol, in which alternative barbiturate, pentobarbital, was substituted for sodium thiopental, in light of district court's findings that State's expert persuasively rejected as unfounded prisoner's expert's concerns that there was insufficient data to allow the State to determine the proper amount of pentobarbital to use as

part of its protocol, and that the amount of pentobarbital selected for use by the State was sufficient to induce unconsciousness in an inmate, and indeed likely to be lethal in most, if not all instances, combined with portion of State's protocol that required attending physician to confirm that an inmate was unconscious prior to administration of the final two drugs. U.S.C.A. Const.Amend. 8.

21 Cases that cite this headnote

[5] Constitutional Law
Source of right or interest

A violation of state law does not by itself constitute a violation of the Federal Constitution; to the extent, however, that state law creates an interest substantial enough to rise to the level of a legitimate claim of entitlement, that interest is protected by the Due Process Clause of the Fifth Amendment. U.S.C.A. Const.Amend. 5.

2 Cases that cite this headnote

[6] Constitutional Law
Execution of sentence

Sentencing and Punishment
Execution of Sentence of Death

Prisoner failed to establish a substantial likelihood of prevailing on his due process challenge to State's newly revised execution protocol, as required to support stay of execution, absent any indication in the record that prisoner had been denied the opportunity to challenge the protocol either administratively or in state courts. U.S.C.A. Const.Amend. 5.

8 Cases that cite this headnote

Attorneys and Law Firms

***1337** Timothy R. Payne, Assistant Federal Public Defender, Western District of Oklahoma, Oklahoma City, OK, for Plaintiff–Intervenor–Appellant.

Seth S. Branham, Assistant Attorney General, W.A. Drew Edmondson, Attorney General of Oklahoma, Oklahoma City, OK, for the Defendants–Appellees.

Before BRISCOE, Chief Judge, GORSUCH, and HOLMES, Circuit Judges.

Opinion

BRISCOE, Chief Judge.

Plaintiff Jeffrey Matthews, an Oklahoma state prisoner sentenced to death by lethal injection, appeals from the district court's denial of his motion for a preliminary injunction of the execution. Exercising jurisdiction pursuant to 28 U.S.C. § 1292(a)(1), we affirm. [*]

I

Matthews was convicted in Oklahoma state court of first degree murder and sentenced to death. *See Matthews v. Workman,* 577 F.3d 1175, 1178–79 (10th Cir.2009) (outlining factual and state procedural history of Matthews' case). After Matthews exhausted the available state and federal court remedies, the Oklahoma Court of Criminal Appeals (OCCA), at the request of the Oklahoma Department of Corrections (ODC), scheduled Matthews to be executed on August 17, 2010.

On the eve of his execution, Matthews was informed by ODC officials that the anesthetic drug traditionally employed in ODC's three-drug lethal injection protocol, sodium thiopental, was unavailable and that ODC officials planned to substitute an alternative barbiturate, pentobarbital, during Matthews' execution. [1] Matthews responded ***1338** by simultaneously moving to stay his execution and to intervene in *Pavatt v. Jones,* Case No. 10–141–F (W.D.Okla.2010), an ongoing 42 U.S.C. § 1983 action filed by another Oklahoma prisoner asserting an Eighth Amendment challenge to Oklahoma's lethal injection protocol. The district court granted Matthews' motions, allowed him to file a complaint, and authorized Matthews to conduct discovery and obtain and file an expert report. On November 19, 2010, the district court held an evidentiary hearing on Matthews' motion for preliminary injunction. During that hearing, Matthews presented testimony from his expert witness, and defendants presented the videotaped deposition

testimony of their expert. At the conclusion of the hearing, the district court ruled from the bench, denying Matthews' motion for preliminary injunction. On November 22, 2010, the district court issued a memorandum and order memorializing its findings and conclusions. On that same date, the Oklahoma Attorney General's Office requested the OCCA to set January 4, 2011, as the execution date for Matthews. [2]

Matthews now appeals from the district court's denial of his motion for preliminary injunction seeking to stay his execution.

II

[1] [2] [3] "We review the district court's order for an abuse of discretion." *Hamilton v. Jones,* 472 F.3d 814, 815 (10th Cir.2007). The principles that apply to our review were outlined by the Supreme Court in *Hill v. McDonough,* 547 U.S. 573, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006). "[A] stay of execution is an equitable remedy" that "is not available as a matter of right, and equity must be sensitive to the State's strong interest in enforcing its criminal judgments without undue interference from the federal courts." 547 U.S. at 584, 126 S.Ct. 2096. Consequently, "like other stay applicants, inmates seeking time to challenge the manner in which the State plans to execute them must satisfy all of the requirements for a stay, including a showing of a significant possibility of success on the merits." *Id.*

As the district court aptly noted, Matthews' challenge to the ODC's planned lethal injection procedure, i.e., its planned substitution of pentobarbital for sodium thiopental, is governed by the Supreme Court's decision in *Baze v. Rees,* 553 U.S. 35, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008). In *Baze,* the Court acknowledged "that subjecting individuals to a risk of future harm —not simply actually inflicting pain—can qualify as cruel and unusual punishment." *Id.* at 49, 128 S.Ct. 1520. However, the Court emphasized, "[t]o establish that such exposure violates the Eighth Amendment, ... the conditions presenting the risk must be '*sure or very likely* to cause serious illness and needless suffering,' and give rise to 'sufficiently *imminent* dangers.' " *Id.* at 49–50, 128 S.Ct. 1520 (quoting *Helling v. McKinney,* 509 U.S. 25, 33, 34–35, 113 S.Ct. 2475, 125 L.Ed.2d 22 (1993) (emphasis added)). Thus, the Court held, "[s]imply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of 'objectively ***1339** intolerable risk of harm' that qualifies as cruel and unusual." *Id.* at 50, 128 S.Ct. 1520. Lastly, the Court held that "[a] stay of execution may not be granted on [such] grounds ... unless the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain ... [and] that the risk is substantial when compared to the known and available alternatives." *Id.* at 61, 128 S.Ct. 1520.

The district court, applying the *Baze* principles, concluded that Matthews failed to demonstrate such a risk in connection with his impending execution. In reaching this conclusion, the district court found:

- that the first step of the ODC's lethal injection protocol mandates the intravenous administration to the subject inmate of 5,000 milligrams of pentobarbital (2,500 milligrams in each arm);

- that the ODC's protocol requires the attending physician to "ensure that the [inmate] is sufficiently unconscious [as a result of the pentobarbital] prior to the administration of the [second drug and paralytic agent,] vecuronium bromide," Aplt. Br., Att. A at 153;

- that the administration of a sufficient dose of pentobarbital will render an individual unconscious and that the administration of a sufficient dose of pentobarbital will be lethal;

- that defendant's expert witness, Dr. Mark Dershwitz, an anesthesiologist with a Ph.D. in pharmacology, "persuasively characterized a 5,000 milligram dose of pentobarbital as 'an enormous overdose' " that "would cause a flat line of the EEG, which is the deepest measurable effect of a central nervous system depressant," and "would be lethal as a result of two physiological responses": the cessation of respiration and the drop in blood pressure "to an unsurvivable level," *id.* at 154;

- that Dershwitz "very persuasively explained" that "pentobarbital is highly likely to cause death in five minutes or within a short time thereafter," *id.;*

- that Dershwitz "credibly testified ... that the 5,000–milligram dosage will give rise ... to a virtually nil likelihood that the inmate will feel the effects of the

subsequently administered vecuronium bromide and potassium chloride," *id.* at 155; and

• that Dershwitz "persuasively responded to Dr. [David] Waisel's testimony that clinicians do not know what dosage of pentobarbital would be required to achieve anesthesia by pointing out that the use of pentobarbital to induce a barbiturate coma, which at least in Dr. Dershwitz's practice is a common use of pentobarbital, takes the patient to a state of unconsciousness beyond a normal clinical level of anesthesia," *id.* at 155–56.

Based upon these factual findings, the district court concluded that Matthews failed to establish "that the use of pentobarbital in Oklahoma's lethal injection protocol presents a constitutionally unacceptable risk of harm to the inmate." *Id.* at 156. "To the contrary," the district court concluded, "the evidence in this case clearly establishe[d] under the standards established ... in *Baze* ... that any risk associated with the use of pentobarbital in Oklahoma's lethal injection protocol falls short of the level of risk that must be shown as a prerequisite to establishing an Eighth Amendment claim." *Id.* Thus, the district court concluded that Matthews "failed to establish ... a significant possibility of success on the merits...." *Id.* Lastly, the district court concluded that the likelihood that Matthews "w[ould] suffer ... injury ... [w]as ... virtually nil." *Id.*

[4] After conducting our own review of the record, we conclude the district court ***1340** did not abuse its discretion in denying Matthews' motion. Each of the district court's factual findings are well-supported by the testimony of defendant's expert, Dr. Dershwitz. Although Matthews' expert witness, Dr. Waisel, expressed concern that there was insufficient data to allow the ODC to determine the proper amount of pentobarbital to use as part of its protocol, it was by no means clear error for the district court to find that Dr. Dershwitz, who has substantially more clinical experience with the use of pentobarbital than Dr. Waisel, persuasively rejected those concerns as unfounded. The district court likewise committed no clear error in finding that the amount of pentobarbital selected for use by the ODC as part of its protocol was sufficient to induce unconsciousness in an inmate, and indeed would likely be lethal in most, if not all, instances. Those findings, combined with the portion of the ODC's protocol that requires the attending physician to confirm that an inmate is unconscious prior to the administration of the final two drugs in the ODC's protocol, support the district court's legal conclusion that Matthews failed to establish a substantial likelihood of success on the merits of his Eighth Amendment challenge to the ODC's revised protocol.

III

Matthews also contended below, albeit in summary fashion, that the use of pentobarbital, which Dr. Dershwitz classified as an intermediate-acting barbiturate, would violate Oklahoma state law, which expressly requires the use of an "ultrashort-acting barbiturate" [3] in executions. [4] Okla. Stat. tit. 22, § 1014(A). [5] In turn, Matthews contended that the ODC's proposed execution protocol threatened to violate what he characterized as his "state-created life interest under the Fifth and Fourteenth Amendments." Aplt. Br. at 6. More specifically, Matthews contended he could not "be deprived of this Constitutional right ***1341** through the arbitrary and capricious actions of persons acting under the color of State law." *Id.*

[5] "A violation of state law does not by itself constitute a violation of the Federal Constitution." *Nordlinger v. Hahn,* 505 U.S. 1, 26, 112 S.Ct. 2326, 120 L.Ed.2d 1 (1992). To the extent, however, that state law creates an interest substantial enough to rise to the level of a "legitimate claim of entitlement," that interest is protected by the Due Process Clause of the Fifth Amendment. *Bd. of Regents of State Colls. v. Roth,* 408 U.S. 564, 577, 92 S.Ct. 2701, 33 L.Ed.2d 548 (1972). The Due Process Clause provides that "[n]o State shall ... deprive any person of life, liberty, or property, without due process of law," U.S. Const. amdt. XIV, § 1; accord amdt. V, and thus "imposes procedural limitations on a State's power to take away protected entitlements." *Dist. Attorney's Office for Third Judicial Dist. v. Osborne,* —— U.S. ——, 129 S.Ct. 2308, 2319, 174 L.Ed.2d 38 (2009).

[6] Here, as noted, Matthews asserts that he has a protected, "state-created life interest" in being executed in accordance with the precise protocol set forth in Okla. Stat. tit. 22, § 1014(A), and that defendants are threatening to violate that right. However, there is no indication in the record that defendants have denied Matthews the opportunity to challenge the protocol either administratively or in the Oklahoma state courts. [6]

Indeed, the record indicates that Matthews has, in opposition to the State's request for the OCCA to set an execution date, filed an objection specifically arguing that the ODC's newly revised execution protocol is contrary to state law. [7] Consequently, we conclude, as did the district court, that Matthews has failed to establish a substantial likelihood of prevailing on his due process challenge to the ODC's newly revised execution protocol.

AFFIRMED.

All Citations

627 F.3d 1336

Footnotes

* After examining the briefs and appellate record, this panel has determined unanimously that oral argument would not materially assist in the determination of this appeal. *See* Fed. R.App. P. 34(a)(2); 10th Cir. R. 34.1(G). The case is, therefore, submitted without oral argument.

For purposes of expediency, we previously issued a substantially similar order and judgment in this case. The clerk of the court has been now been directed to reissue the decision for publication nunc pro tunc to the original filing date.

1 According to the record, sodium thiopental is now effectively unobtainable anywhere in the United States, thus requiring Oklahoma and other death-penalty states to revise their lethal injection protocols. Two of those states, Ohio and Washington, have purportedly now replaced their three-drug protocols with a one-drug protocol based upon pentobarbital. Other states, in particular Oklahoma, have simply revised their existing three-drug protocols by substituting pentobarbital for sodium thiopental.

2 On December 14, 2010, the OCCA granted the request and established January 11, 2011 as Matthews' execution date.

3 The record on appeal establishes that Dr. Dershwitz used the terms “intermediate-acting” and “ultrashort-acting” to refer to the length of the barbiturate's effect, not on how quickly the barbiturate takes effect. Although it is not entirely clear, Oklahoma's statute appears to use the term “ultrashort-acting” in a different sense, to refer to how quickly the barbiturate takes effect. And on that score, as Dr. Dershwitz testified and the district court found, a 5,000 milligram dose of pentobarbital will quickly induce an unconscious state.

4 Matthews did not assert a separate due process claim in his intervenor complaint. Instead, he waited until filing his amended motion for preliminary injunction to assert, for the first time, that the use of pentobarbital would violate Oklahoma state law and, in turn, violate his federal due process rights. Although Matthews continued to mention the claim thereafter, including at the hearing on his motion for preliminary injunction, he presented no evidence, and few legal authorities, in support of the claim. In turn, the district court summarily rejected the claim as meritless at the preliminary injunction hearing, and did not expressly address it in its subsequent written order memorializing its oral rulings.

5 The statute provides, in its entirety:

> A. The punishment of death must be inflicted by continuous, intravenous administration of a lethal quantity of an ultrashort-acting barbiturate in combination with a chemical paralytic agent until death is pronounced by a licensed physician according to accepted standards of medical practice.
>
> B. If the execution of the sentence of death as provided in subsection A of this section is held unconstitutional by an appellate court of competent jurisdiction, then the sentence of death shall be carried out by electrocution.
>
> C. If the execution of the sentence of death as provided in subsections A and B of this section is held unconstitutional by an appellate court of competent jurisdiction, then the sentence of death shall be carried out by firing squad.

Okla. Stat. tit. 22, § 1014.

6 There was no indication in any of Matthews' district court pleadings, or in his opening appellate brief, that he was seeking to assert a substantive due process violation. More specifically, at no point in any of those pleadings did Matthews mention the concept of substantive due process, or the associated “ ‘fundamental right’ or ... ‘shocks the conscience’ standards....” *Seegmiller v. LaVerkin City,* 528 F.3d 762, 767 (10th Cir.2008).

In his appellate reply brief, Matthews mentioned the concept of substantive due process for the first time, stating in a footnote: “Mr. Matthews' asserted due process claim is as much, if not more, a substantive due process violation as it is a procedural due process violation.” Aplt. Reply Br. at 15 n. 5. We conclude, however, that any such claim has been waived. *See United States v. Smith,* 606 F.3d 1270, 1284 n. 5 (10th Cir.2010) (explaining that “issues raised by an appellant for the first time on appeal in a reply brief are generally deemed waived” (quotations omitted)).

7 In its December 14, 2010 order setting Matthews' execution date, the OCCA declined, given the narrow context of the proceeding before it, to address the merits of Matthews' argument. However, the OCCA noted that Matthews could "present any appropriate issues challenging his conviction or sentence in a second or subsequent [state] post-conviction application." *Matthews v. State,* No. D–1999–1139, slip op. at 2 n. 2 (Okla.Crim.App. Dec. 14, 2010).

920 F.3d 1317
United States Court of Appeals, Eleventh Circuit.

Christopher Lee PRICE, Plaintiff - Appellant,
v.
COMMISSIONER, Alabama DEPARTMENT OF CORRECTIONS, Warden, Holman Correctional Facility, Defendants - Appellees.

No. 19-11268
|
Non-Argument Calendar
|
April 10, 2019

Synopsis

Background: After affirmance of murder conviction and death sentence, 725 So.2d 1063, Alabama death-row inmate brought § 1983 action, alleging that Alabama Department of Corrections' (ADOC) use of midazolam in its three-drug lethal-injection protocol violated Eighth Amendment's ban on cruel and unusual punishments, and that State violated equal protection by refusing to allow him to elect nitrogen hypoxia as his method of execution, outside of 30-day opt-in period. The United States District Court for the Southern District of Alabama, No. 1:19-cv-00057-KD-MU, Kristi K. DuBose, J., 2019 WL 1509610, denied inmate's emergency motion for preliminary injunction for stay of execution and motion for summary judgment. Inmate appealed and filed motion for emergency stay of execution.

Holdings: The Court of Appeals held that:

[1] for equal protection purposes, inmate, who did not timely elect nitrogen hypoxia as alternative to State's three-drug lethal-injection protocol, was not similarly situated with inmates who made timely elections;

[2] for equal protection purposes, opt-in period was rationally related to legitimate state interests;

[3] nitrogen hypoxia was available as alternative method of execution adopted by State, though State was still developing its protocol;

[4] inmate's untimely opt-in did not affect the availability of nitrogen hypoxia as alternative method of execution;

[5] inmate was not required to provide details regarding how State could implement nitrogen hypoxia as an adopted method of execution; and

[6] inmate did not establish that nitrogen hypoxia would significantly reduce the risk of substantial pain.

Affirmed; motion for stay denied.

West Headnotes (24)

[1] Federal Courts
Summary judgment

The Court of Appeals reviews de novo an order on summary judgment. Fed. R. Civ. P. 56.

Cases that cite this headnote

[2] Federal Courts
Criminal Justice

The Court of Appeals would review for abuse of discretion the District Court's denial of state death-row inmate's motion for stay of execution, which was filed in inmate's § 1983 action challenging the constitutionality of state's lethal injection protocol for executions. 42 U.S.C.A. § 1983.

Cases that cite this headnote

[3] Federal Courts
"Clearly erroneous" standard of review in general

Under the clear error standard for reviewing a district court's factual findings, the Court of Appeals may not reverse simply because it is convinced that it would have decided the case differently.

Cases that cite this headnote

[4] **Federal Courts**
Injunction and temporary restraining order cases

The Court of Appeals could grant state death-row inmate's emergency motion for preliminary injunction for stay of execution, filed by prisoner on appeal from the District Court's denial of his summary judgment motion and motion for stay of execution in § 1983 action challenging constitutionality of state's lethal injection protocol, only if inmate established that: (1) he had a substantial likelihood of success on the merits; (2) he would suffer irreparable injury unless the injunction issued; (3) the stay would not substantially harm the State; and (4) if issued, the injunction would not be adverse to the public interest. 42 U.S.C.A. § 1983.

1 Cases that cite this headnote

[5] **Sentencing and Punishment**
Stay of execution

The first and most important question regarding a stay of execution is whether the prisoner is substantially likely to succeed on the merits of his claims.

Cases that cite this headnote

[6] **Constitutional Law**
Similarly situated persons;like circumstances

To prevail on an equal-protection claim, a plaintiff must show that the State will treat him disparately from other similarly situated persons. U.S. Const. Amend. 14.

Cases that cite this headnote

[7] **Constitutional Law**
Statutes and other written regulations and rules

Constitutional Law
Strict scrutiny and compelling interest in general

If a law treats individuals differently on the basis of a suspect classification, or if the law impinges on a fundamental right, it is subject to strict scrutiny for an equal protection violation; otherwise, plaintiff must show that the disparate treatment is not rationally related to a legitimate government interest. U.S. Const. Amend. 14.

Cases that cite this headnote

[8] **Constitutional Law**
Capital punishment;death penalty

Sentencing and Punishment
Mode of execution

Alabama death-row inmate, who did not timely elect nitrogen hypoxia as alternative to State's three-drug lethal-injection protocol using midazolam, was not similarly situated with inmates who had made timely elections, and thus, denial of inmate's untimely election did not violate equal protection. U.S. Const. Amend. 14; Ala. Code § 15-18-82.1(b)(2).

Cases that cite this headnote

[9] **Constitutional Law**
Capital punishment;death penalty

Sentencing and Punishment
Mode of execution

State's 30-day opt-in period for death-row inmates to elect nitrogen hypoxia, as an alternative to State's three-drug lethal-injection protocol using midazolam, was rationally related to State's legitimate interest in efficient and orderly use of State resources in planning and preparing for executions, and thus, different treatment of death-row inmates, based on whether they made a timely election, did not violate equal protection. U.S. Const. Amend. 14; Ala. Code § 15-18-82.1(b)(2).

Cases that cite this headnote

[10] **Constitutional Law**
Presumptions and Construction as to Constitutionality

A statute is presumed constitutional.

Cases that cite this headnote

[11] **Sentencing and Punishment**
Mode of execution

Prisoners cannot succeed on an Eighth Amendment method-of-execution claim unless they can establish that the challenged method presents a risk that is sure or very likely to cause serious illness and needless suffering, and that gives rise to sufficiently imminent dangers. U.S. Const. Amend. 8.

Cases that cite this headnote

[12] **Sentencing and Punishment**
Mode of execution

Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of objectively intolerable risk of harm that qualifies as cruel and unusual punishment prohibited by the Eighth Amendment. U.S. Const. Amend. 8.

Cases that cite this headnote

[13] **Sentencing and Punishment**
Mode of execution

To prevail on an Eighth Amendment method-of-execution claim, an inmate must show a substantial and objectively intolerable risk of serious harm that prevents prison officials from pleading that they are subjectively blameless for purposes of the Eighth Amendment. U.S. Const. Amend. 8.

Cases that cite this headnote

[14] **Sentencing and Punishment**
Mode of execution

An inmate asserting an Eighth Amendment method-of-execution claim must identify an alternative that is feasible, readily implemented, and that in fact significantly reduces a substantial risk of severe pain. U.S. Const. Amend. 8.

Cases that cite this headnote

[15] **Sentencing and Punishment**
Mode of execution

A prisoner asserting an Eighth Amendment method-of-execution claim cannot successfully challenge a State's lethal-injection protocol by showing a slightly or marginally safer alternative. U.S. Const. Amend. 8.

Cases that cite this headnote

[16] **Sentencing and Punishment**
Mode of execution

A prisoner asserting an Eighth Amendment method-of-execution claim must show a feasible and readily implemented alternative method of execution that would significantly reduce a substantial risk of severe pain, which the State has refused to adopt without a legitimate penological reason. U.S. Const. Amend. 8.

Cases that cite this headnote

[17] **Sentencing and Punishment**
Mode of execution

An inmate seeking to identify an alternative method of execution, in an Eighth Amendment challenge to a State's method of execution, is not limited to choosing among those presently authorized by the State's law, so an inmate can identify a well-established protocol in another State as a potentially viable option. U.S. Const. Amend. 8.

Cases that cite this headnote

[18] **Sentencing and Punishment**
Mode of execution

Nitrogen hypoxia was available as alternative method of execution in Alabama, as element for death-row inmate's Eighth Amendment challenge to State's use of midazolam in its three-drug lethal-injection protocol, where State had adopted nitrogen hypoxia as a

method of execution, though State was still developing a nitrogen hypoxia protocol. U.S. Const. Amend. 8.

1 Cases that cite this headnote

[19] Sentencing and Punishment
Mode of execution

To establish that a proposed alternative method of execution is available, when asserting an Eighth Amendment method-of-execution claim, an inmate must do more than show that it is theoretically feasible; he must also show that it is readily implemented, and to meet this burden, the proposed alternative must be sufficiently detailed to permit a finding that the State could carry it out relatively easily and reasonably quickly. U.S. Const. Amend. 8.

Cases that cite this headnote

[20] Sentencing and Punishment
Mode of execution

Alabama death-row inmate satisfied the availability requirement for a proposed alternative method of execution, as element for Eighth Amendment challenge to State's use of midazolam in its three-drug lethal-injection protocol, by pointing to State's adoption of nitrogen hypoxia as an additional method of execution, though the inmate himself had missed the deadline under State's 30-day opt-in period for electing nitrogen hypoxia as a method of execution. U.S. Const. Amend. 8; Ala. Code § 15-18-82.1(b)(2).

Cases that cite this headnote

[21] Sentencing and Punishment
Mode of execution

An inmate asserting an Eighth Amendment method-of-execution claim may satisfy his burden of demonstrating that an alternative method of execution is feasible and readily implemented by pointing to the executing State's official adoption of that alternative method of execution, without being required to provide details regarding how the State could implement its adopted alternative method of execution. U.S. Const. Amend. 8.

Cases that cite this headnote

[22] Sentencing and Punishment
Mode of execution

To the extent that a particular available method of execution reasonably requires a certain period for the State to prepare for execution, a prisoner asserting an Eighth Amendment method-of-execution claim may not successfully seek execution by an alternative method inside that window of time. U.S. Const. Amend. 8.

Cases that cite this headnote

[23] Sentencing and Punishment
Mode of execution

Medical expert's declaration, which merely opined that midazolam would not provide adequate analgesic effects during inmate's execution, without comparing the effectiveness of State's three-drug protocol, which used midazolam, to an alternative method of execution using only nitrogen hypoxia, did not establish that execution by nitrogen hypoxia would significantly reduce the risk of substantial pain to inmate, as would be required for inmate's Eighth Amendment method-of-execution claim. U.S. Const. Amend. 8.

Cases that cite this headnote

[24] Sentencing and Punishment
Mode of execution

University's report on nitrogen hypoxia as a method of execution did not establish that the use of nitrogen hypoxia, as alternative to State's three-drug lethal injection protocol, would significantly reduce the risk of substantial pain to inmate, as would be required for inmate's Eighth Amendment method-of-execution claim, where the report was a preliminary draft report that was

stamped with the words "Do Not Cite," and it did not compare the two methods of execution. U.S. Const. Amend. 8.

2 Cases that cite this headnote

Attorneys and Law Firms

***1320** Jonathan R. Ference-Burke, Ropes & Gray, LLP, WASHINGTON, DC, Aaron Katz, Ropes & Gray, LLP, BOSTON, MA, for Plaintiff-Appellant.

Lauren Ashley Simpson, Beth Jackson Hughes, Henry M. Johnson, Alabama Attorney General's Office, MONTGOMERY, AL, for Defendants-Appellees.

Appeal from the United States District Court for the Southern District of Alabama, D.C. Docket No. 1:19-cv-00057-KD-MU

Before TJOFLAT, WILSON, and ROSENBAUM, Circuit Judges.

Opinion

PER CURIAM:

Christopher Lee Price, an Alabama prisoner sentenced to death for killing a man during the commission of a robbery, has moved this Court for an emergency stay of his execution, which is scheduled to take place on April 11, 2019, at 6:00 p.m. Central Standard Time at the Holman Correctional Facility ("Holman"). Price also appeals the district court's order denying his motion for preliminary injunction and its order denying his renewed motion for preliminary injunction. Included within those orders is the district court's denial of Price's Cross-Motion for Summary Judgment.[1] After careful consideration, we affirm the district court's denial of Price's ***1321** Cross-Motion for Summary Judgment as well as its denial of Price's original and renewed motions for preliminary injunction. We also deny Price's motion for a stay of execution because he cannot show a substantial likelihood of success on his petition.

I. Background

Price was convicted of capital murder for killing William Lynn during the commission of a robbery, and Price was subsequently sentenced to death. *See Price v. State*, 725 So.2d 1003, 1011 (Ala. Crim. App. 1997), *aff'd sub nom. Ex parte Price*, 725 So.2d 1063 (Ala. 1998). Price filed a direct appeal of both his conviction and death sentence, but both were affirmed. *See Price*, 725 So.2d at 1062, *aff'd*, 725 So.2d 1063 (Ala. 1998). Price's conviction and sentence became final in May 1999 after the Supreme Court denied his petition for writ of certiorari. *See Price v. Alabama*, 526 U.S. 1133, 119 S.Ct. 1809, 143 L.Ed.2d 1012 (1999).

Price then filed a state post-conviction Rule 32 petition, but the petition was denied, and the Court of Criminal Appeals of Alabama affirmed. *See Price v. State*, 880 So.2d 502 (Ala. Crim. App. 2003). The Alabama Supreme Court denied certiorari review. *Ex parte Price*, 976 So.2d 1057 (Ala. 2006).

Later, Price filed a petition for writ of habeas corpus in the Northern District of Alabama. The district court issued an opinion denying the petition with prejudice and entering judgment against Price. We affirmed that judgment. *See Price v. Allen*, 679 F.3d 1315, 1319-20 (11th Cir. 2012) (per curiam). The Supreme Court also denied Price's petition for writ of certiorari. *Price v. Thomas*, 568 U.S. 1212, 133 S.Ct. 1493, 185 L.Ed.2d 548 (2013).

Price filed a successive state post-conviction Rule 32 petition in 2017, arguing that his death sentence was unconstitutional under *Hurst v. Florida*, —— U.S. ——, 136 S.Ct. 616, 193 L.Ed.2d 504 (2016). That petition was also denied, and the Court of Criminal Appeals of Alabama affirmed. *Price v. State*, No. CR-16-0785, 2017 WL 10923867 (Ala. Crim. App. Aug. 4, 2017), *reh'g denied* (Sept. 8, 2017). The Alabama Supreme Court denied certiorari.

Following his direct criminal appeals and after the State moved the Alabama Supreme Court to set an execution date, Price brought a civil lawsuit under 42 U.S.C. § 1983 alleging that the Alabama Department of Corrections's ("ADOC") use of midazolam in its three-drug lethal-injection protocol violates the Eighth Amendment's ban on cruel and unusual punishment because it is not effective in rendering an inmate insensate during execution (the "first § 1983 action"). The district court held a bench trial on Price's § 1983 claim. But the district court bifurcated the trial, addressing only whether Price could meet his burden of showing that his chosen alternative drug—pentobarbital—was available to the ADOC. The district

court found in favor of the ADOC and against Price. It concluded that Price had failed to meet his burden of showing that pentobarbital was a feasible and available drug for use by the ADOC.

Price appealed and, on September 18, 2018, we affirmed. *Price v. Comm'r, Ala. Dep't of Corr.*, 752 F. App'x 701 (11th Cir. 2018). Price recently filed a petition for writ of certiorari with the Supreme Court of the United States. That petition is currently pending.

II. Facts Relevant to this Appeal

While the appeal of Price's first § 1983 action was pending before this Court, the Alabama legislature amended the State's execution statute to add nitrogen hypoxia as an approved method of execution. The amendment became effective on June 1, 2018. *See* Ala. Code § 15-18-82.1. The statute ***1322** reads, in relevant part, "A death sentence shall be executed by lethal injection, unless the person sentenced to death affirmatively elects to be executed by electrocution or nitrogen hypoxia." Ala. Code § 15-18-82.1(a). The statute also provides that the election of death by nitrogen hypoxia is waived unless it is personally made by the inmate in writing and delivered to the warden within thirty days after the certificate of judgment pursuant to a decision by the Alabama Supreme Court affirming the sentence of death. Ala. Code § 15-18-82.1(b)(2). If a judgment was issued before June 1, 2018, as was the case with Price, the election must have been made and delivered to the warden within thirty days of June 1, 2018. *See Id.*

On January 11, 2019, the State moved the Alabama Supreme Court to set an execution date for Price. The Alabama Supreme Court granted the motion on March 1, 2019, ordering that Price be executed on April 11, 2019, by lethal injection.

In the meantime, on January 27, 2019, Price wrote a letter to the warden of Holman asking that he be executed by nitrogen hypoxia.[2] The warden responded by notifying Price that his request was past the thirty-day deadline set forth in the statute. Nevertheless, she further noted that she did not have the authority to grant, deny, or reject the request, and she indicated that any further consideration of the matter needed to go through Price's attorney to the Attorney General's Office. Price's attorney then reached out to the Attorney General's Office and reiterated Price's desire to "opt in to the nitrogen hypoxia protocol." Assistant Attorney General Henry Johnson denied the request, citing the thirty-day period to opt into the protocol.

On February 8, 2019, (approximately one month after the State sought an execution date), Price filed a civil complaint against the Commissioner of the ADOC and others. The new complaint set forth a § 1983 claim in which Price realleged many of the claims raised in his previous § 1983 action concerning the three-drug lethal-injection protocol (the "second § 1983 action"). For example, Price claims that the use of midazolam as the first drug in its three-drug lethal-injection protocol violates the Eighth Amendment's ban on cruel and unusual punishment. The complaint in the second § 1983 action also alleges that the State violated Price's Fourteenth Amendment right to equal protection by refusing to allow him to elect nitrogen hypoxia as his method of execution. With respect to that claim, Price contended that the State entered into "secret agreements" with many death row inmates allowing them to elect nitrogen hypoxia but would not allow him to do so outside of the 30-day opt-in period.[3]

***1323 III. Discussion**

[1] [2] [3] We review *de novo* an order on summary judgment. *Smith v. Owens*, 848 F.3d 975, 978 (11th Cir. 2017). As for the district court's denial of Price's motion for stay of execution, we review that for abuse of discretion. *Brooks v. Warden*, 810 F.3d 812, 818 (11th Cir. 2016). With respect to the district court's factual findings, we review those for clear error. *Glossip v. Gross*, —— U.S. ——, 135 S.Ct. 2726, 2739, 192 L.Ed.2d 761 (2015). Under this standard, we may not reverse "simply because we are convinced that we would have decided the case differently." *Id.* (cleaned up).

[4] [5] Finally, we may grant Price's motion for stay of execution filed in this Court only if Price establishes that "(1) he has a substantial likelihood of success on the merits; (2) he will suffer irreparable injury unless the injunction issues; (3) the stay would not substantially harm the other litigant; *and* (4) if issued, the injunction would not be adverse to the public interest." *Arthur v. Comm'r, Ala. Dep't of Corr.*, 840 F.3d 1268, 1321 (11th Cir. 2016) (quoting *Brooks v. Warden*, 810 F.3d 812, 818 (11th Cir. 2016) (emphases in original)), *abrogated on other grounds by Bucklew v. Precythe*, —— U.S. ——, 139 S.Ct.

1112, 1127–29, —— L.Ed.2d —— (2019). The "first and most important question" regarding a stay of execution is whether the petitioner is substantially likely to succeed on the merits of his claims. *Jones v. Comm'r. Ga. Dep't of Corr.*, 811 F.3d 1288, 1292 (11th Cir. 2016).

After careful consideration, we conclude that the district court did not err when it denied Price's Cross-Motion for Summary Judgment, although our basis for affirmance differs from the grounds set forth by the district court. We further find that the district court did not abuse its discretion when it denied Price's initial and renewed motions for preliminary injunction in which he sought a stay of execution. Finally, we deny Price's motion for stay of execution because he has not satisfied the requirements for such a stay.

We now examine each of Price's claims in turn.

A. Fourteenth Amendment Equal Protection Claim

[6] **[7]** Price contends that the State violated his Fourteenth Amendment right to equal protection by not permitting him to elect nitrogen hypoxia as a method of execution. To prevail on his equal-protection claim, Price must first show that "the State will treat him disparately from other similarly situated persons." *Arthur v. Thomas*, 674 F.3d 1257, 1262 (11th Cir. 2012) (quoting *De Young v. Owens*, 646 F.3d 1319, 1327 (11th Cir. 2011)). Second, "[i]f a law treats individuals differently on the basis of ... [a] suspect classification, or if the law impinges on a fundamental right, it is subject to strict scrutiny." *Id.* (quoting *Leib v. Hillsborough Cty. Pub. Transp. Comm'n*, 558 F.3d 1301, 1306 (11th Cir. 2009)). Otherwise, Price "must show that the disparate treatment is not rationally related to a legitimate government interest." *Id.* (quoting *De Young*, 646 F.3d at 1327–28).

The district court did not err in denying Price's equal-protection claim. Importantly, Price has not demonstrated that he was or will be treated differently than similarly situated inmates. Although Price appeared to initially contend that the State made "secret agreements" with other death-row inmates—suggesting that these inmates elected to opt in to the nitrogen hypoxia protocol outside of the thirty-day window—he seems to now concede that these other inmates made their election within the thirty-day window.

The record reveals that Price had the same opportunity as every other inmate to ***1324** elect nitrogen hypoxia as his method of execution. When the State added nitrogen hypoxia as a statutorily viable method of execution in June 2018, all inmates whose death sentences were final as of June 1, 2018, received a thirty-day period to elect nitrogen hypoxia. *See* Ala. Code § 15-18-82.1(b)(2). Significantly, Price was represented by counsel when the State added nitrogen hypoxia as a method of execution.

According to the State, all death-row inmates at Holman, including Price, were provided with a copy of an election form, and forty-eight of those inmates timely elected nitrogen hypoxia. Price did not. The record contains the affidavit of Captain Jeff Emberton, who attested to the fact that, in mid-June 2018, after the State authorized nitrogen hypoxia as a method of execution, the warden of Holman directed him to provide every death-row inmate an election form and an envelope. According to Emberton, he delivered the form to every death-row inmate at Holman as instructed. The form identified Act 2018-353 (which amended Ala. Code. § 15-18-82.1 to include nitrogen hypoxia) and allowed for the inmate to state that he was making the election of nitrogen hypoxia as the means of execution. [4] Price did not contend that he did not receive the form or that he was not given the option to make the same election.

In sharp contrast to other inmates who opted for the protocol by the July 1, 2018, deadline, Price waited until late January 2019 to seek to elect nitrogen hypoxia for his execution. Price appears to argue that the ADOC's provision of the election form was insufficient. But Price was represented by counsel, so any doubts Price had about the form could have been resolved by consulting with his attorney. Plus, several other inmates were able to make the timely election based on the provision of the form by the State. Price takes issue with the fact that most of the inmates that timely elected nitrogen hypoxia were represented by the Federal Public Defender's Office and that they were given an explanation of their rights by that office before receiving the form. But as we have noted, Price was also represented by counsel, and he could have asked for an explanation of the form. Nor does Price make any Sixth Amendment claim, in any event. Finally, the interactions between other inmates and the Federal Public Defender's Office do not support any unequal treatment by *the State* of similarly situated individuals.

Further, to the extent Price claims that he did not become aware of the change in law until January 2019, he has not asserted that the State treated Price differently than other death-row inmates with respect to this information. Moreover, the record ***1325** here shows that Price and his counsel plainly had reason to know of the change in Alabama's law before January 2019 because we specifically described that change when we issued our decision in Price's first § 1983 action appeal. *See Price*, 752 F. App'x at 703 n.3.

[8] Because Price did not timely elect the new protocol, he is not similarly situated in all material respects to the inmates who did make such an election within the thirty-day timeframe. And because Price has not shown that he is similarly situated to those inmates, he cannot demonstrate any equal-protection violation due to the State's denial of execution by nitrogen hypoxia. But even if Price were similarly situated to the other death-row inmates, he cannot establish an equal-protection violation because he was treated exactly the same as the other inmates. Every inmate was given thirty days within which to elect nitrogen hypoxia as their method of execution. Ironically, if the State *did* allow Price to make the belated election he seeks, it would be treating him differently than other death-row inmates who were not afforded the same benefit.

[9] **[10]** In the end, it appears that Price takes issue with the thirty-day election period itself, arguing that it is arbitrary. But even considering Price's claim as a challenge to the statute itself—that it treats similarly situated death-row inmates differently based on a criterion (a thirty-day election) that does not rationally further any legitimate state interest—the claim fails. As noted by the district court, a statute is presumed constitutional, and a classification not involving fundamental rights nor proceeding along suspect lines "cannot run afoul of the Equal Protection Clause if there is a rational relationship between the disparity of treatment and some legitimate governmental purpose." *Heller v. Doe by Doe*, 509 U.S. 312, 320, 113 S.Ct. 2637, 125 L.Ed.2d 257 (1993) (citations omitted). Here, a rational basis exists for the thirty-day rule—the efficient and orderly use of state resources in planning and preparing for executions. And Price has not negated this rational basis for the thirty-day election requirement.[5] *See id.* (noting "[t]he burden is on the one attacking the legislative arrangement to negate every conceivable basis which might support it").

B. Eighth Amendment Claim

The Supreme Court's decision in *Glossip v. Gross*, —— U.S. ——, 135 S.Ct. 2726, 2737, 192 L.Ed.2d 761 (2015), sets forth the relevant two-pronged standard a plaintiff must meet to succeed on an Eighth Amendment method-of-execution claim.

[11] **[12]** **[13]** Prisoners cannot succeed on a method-of-execution claim unless they can establish that the method challenged presents a risk that is " '*sure or very likely* to cause serious illness and needless suffering,' and gives rise to 'sufficiently *imminent* dangers.' " *Id.* (emphasis in original) (quoting *Baze v. Rees*, 553 U.S. 35, 50, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality opinion) (quoting ***1326** *Helling v. McKinney*, 509 U.S. 25, 33, 34-35, 113 S.Ct. 2475, 125 L.Ed.2d 22 (1993)). The Supreme Court further elaborated in *Baze*, "Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of 'objectively intolerable risk of harm' that qualifies as cruel and unusual" punishment prohibited by the Eighth Amendment. *Baze*, 553 U.S. at 50, 128 S.Ct. 1520. So to prevail on a method-of-execution claim, an inmate must show a " 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment.' " *Glossip*, 135 S.Ct. at 2737 (quoting *Baze*, 553 U.S. at 50, 128 S.Ct. 1520 (plurality opinion) (quoting *Farmer v. Brennan*, 511 U.S. 825, 846, and n. 9, 114 S.Ct. 1970, 128 L.Ed.2d 811 (1994)).

[14] **[15]** The inmate must also "identify an alternative that is 'feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain.' " *Id.* (quoting *Baze*, 553 U.S. at 52, 128 S.Ct. 1520). Where a prisoner claims a safer alternative to the State's lethal-injection protocol, he cannot make a successful challenge by showing a "slightly or marginally safer alternative." *Id.* (quoting *Baze,* 553 U.S. at 51, 128 S.Ct. 1520). Death-row inmates face a heavy burden.

[16] The Supreme Court recently reiterated an inmate's burden in an Eighth Amendment method-of-execution challenge in *Bucklew v. Precythe*, —— U.S. ——, 139 S.Ct. 1112, 1125, —— L.Ed.2d —— (2019). As summarized by

the Court, a prisoner "must show a feasible and readily implemented alternative method of execution that would significantly reduce a substantial risk of severe pain and that the State has refused to adopt without a legitimate penological reason." *Id.*

[17] In reaffirming this standard, however, the Supreme Court recognized the burden an inmate has under the *Baze*-*Glossip* test can be "overstated." *Id.* at 1128. It clarified that "[a]n inmate seeking to identify an alternative method of execution is not limited to choosing among those presently authorized by a particular State's law." *Id.* So a petitioner can identify a "well-established protocol in another State as a potentially viable option." *Id.* Justice Kavanaugh noted that all nine Justices agreed on this point. *Id.* at 1136 (Kavanaugh, J., concurring) (citing *Arthur v. Dunn*, 580 U.S. ——, 137 S.Ct. 725, 733-34, 197 L.Ed.2d 225 (2017) (Sotomayor, J. dissenting from denial of certiorari)).

For this reason, a portion of our decision in *Arthur v. Comm'r, Ala. Dep't of Corr.*, 840 F.3d 1268 (11th Cir. 2016), has been abrogated by *Bucklew*. In particular, in *Arthur*, we determined that a proposed method of execution (death by firing squad) was not an available alternative because the state in which the inmate would be executed did not authorize it. *Id.* at 1317-18. We made this determination despite the fact that another state authorized the particular method of execution proposed by the inmate. *Id.* But *Bucklew* demonstrates our conclusion in *Arthur* was incorrect. Having clarified the applicable law, we turn to the *Baze*-*Glossip* test in reverse order, tackling the availability issue first.

1. Price has shown that nitrogen hypoxia is an available alternative method of execution that is feasible and readily implemented

[18] Price claims that nitrogen hypoxia is an available method of execution for him because the Alabama legislature has authorized it. In proposing nitrogen hypoxia as an alternative to the State's midazolam lethal-injection protocol, Price emphasizes that he is merely seeking to be executed by a method of execution that the Alabama ***1327** legislature, "after considerable thought, has expressly authorized." He also argues that nitrogen hypoxia is feasible and readily implemented because pure nitrogen gas is easily purchased. No supply concerns exist for nitrogen, and counsel for Price notes that he was recently able to easily purchase a tank of 99.9% pure compressed nitrogen gas.

The State retorts that nitrogen hypoxia is not an available method of execution to Price as a matter of state law because he failed to make a timely election under the applicable statute. It also claims nitrogen hypoxia is neither feasible nor readily implemented at this date, since the ADOC has not yet finalized a nitrogen hypoxia protocol, and it is not likely that one will be in place by April 11, 2019. Finally, the State asserts Price did not meet his burden to prove a known and available alternative method of execution because he did not provide sufficient details of how the State could induce nitrogen hypoxia.

To resolve this issue, we turn to *Bucklew* for guidance. *Bucklew* sheds some light on the "availability" prong of the *Baze*-*Glossip* test, and it specifically addresses an inmate's proposal of nitrogen hypoxia as an alternative method of execution.

[19] In *Bucklew*, the Supreme Court determined that the inmate had not presented a triable question on the viability of nitrogen hypoxia as an alternative to lethal injection for two reasons. First, the Court noted, to establish that a proposed alternative method is available, an inmate must do more than show that it is theoretically "feasible"; he must also show that it is "readily implemented." *Bucklew*, 139 S.Ct. at 1129 (citing *Glossip*, 135 S.Ct. at 2737-38). To meet this burden, the inmate's proposed alternative must be "sufficiently detailed to permit a finding that the State could carry it out 'relatively easily and reasonably quickly.' " *Id.* (quoting *McGehee v. Hutchinson*, 854 F.3d 488, 493 (8th Cir. 2017); *Arthur*, 840 F.3d at 1300).

The Court in *Bucklew* found that the inmate had failed to meet this burden because he presented no evidence on details such as how nitrogen gas would be administered, in what concentration, and for how long the gas would be administered. *Id.* The inmate also did not suggest how the State could ensure the safety of the execution team. *Id.* Instead, the inmate pointed only to reports from correctional institutions in other states revealing that additional study was needed to put in place a protocol for execution by nitrogen hypoxia. *Id.*

Second, the Court in *Bucklew* determined that the State had a legitimate reason for not switching its current lethal-

injection protocol: nitrogen hypoxia was an "entirely new method—one that had 'never been used to carry out an execution' and had 'no track record of successful use.' " *Id.* (quoting *McGehee*, 854 F.3d at 493). The Court concluded by stating that the Eighth Amendment "does not compel a State to adopt 'untried and untested' (and thus unusual in the constitutional sense) methods of execution." *Id.* (quoting *Baze*, 553 U.S. at 41, 128 S.Ct. 1520). [6]

Here, the State argues that although the Code of Alabama now contemplates nitrogen hypoxia as a means of execution, it is not "available" because the ADOC is still developing a protocol, and the process will not be complete in time for Price's April 11, 2019, execution. We are not persuaded. If a State adopts a particular method of ***1328** execution—as the State of Alabama did in March 2018—it thereby concedes that the method of execution is available to its inmates. Unlike in *Bucklew*, where the inmate proposed the adoption of a new method, here, the State of Alabama chose, on its own, and after careful consideration, to offer nitrogen hypoxia as a method of execution for its death-row inmates. So unlike the inmate in *Bucklew*, Price is not attempting to "compel" the State to adopt a different and new method of execution at all. The method was already adopted well before Price's Eighth Amendment challenge—and more than a year before Price's scheduled execution date.

A State may not simultaneously offer a particular method of execution and deny it as "unavailable." Rather, because the State voluntarily included nitrogen hypoxia in its statute, we reject the State's argument that nitrogen hypoxia is not "available" to Price simply because the State has not yet developed a protocol to administer this method of execution. If we were to find otherwise, it would lead to an absurd result. States could adopt a method of execution, take no action at all to implement a protocol to effectuate it, and then defeat an inmate's Eighth Amendment challenge by simply claiming the method is not "available" due to a lack of protocol.

Roughly two years ago, the Alabama legislature introduced a bill that would make nitrogen hypoxia a statutorily authorized method of execution in Alabama. The bill was also passed and enacted into law more than a year ago, and inmates have been electing nitrogen hypoxia since June 2018. Under these circumstances, we cannot agree that nitrogen hypoxia is not available in the State of Alabama. Indeed, Alabama's official legislature-enacted policy is that nitrogen hypoxia is an available method of execution in the State.

[20] We also reject the State's suggestion that nitrogen hypoxia is not available to Price only because he missed the 30-day election period. If nitrogen hypoxia is otherwise "available" to inmates under *Bucklew*, that the State chooses to offer the chance to opt for it for a period of only 30 days does not somehow render it "unavailable" by *Bucklew*'s criteria. To the contrary, for the same reason that *Bucklew* abrogates *Arthur*'s requirement that a state offer a method of execution for it to be "available," *Bucklew* renders a state's time limit on a given execution option of no moment to whether that option is "available."

[21] The closer question is whether Price's alleged lack of detail with respect to *how* the State would implement his execution by nitrogen hypoxia defeats his Eighth Amendment claim. We agree that Price did not come forward with sufficient detail about how the State could implement nitrogen hypoxia to satisfy *Bucklew*'s requirement where the inmate proposes a new method of execution. But under the particular circumstances here —where the State by law previously adopted nitrogen hypoxia as an official method of execution—we do not believe that was Price's burden to bear. Rather, an inmate may satisfy his burden to demonstrate that the method of execution is feasible and readily implemented by pointing to the executing state's official adoption of that method of execution.

True, in *Bucklew*, the Supreme Court discussed how Bucklew had failed to set forth evidence of essential questions like how the nitrogen gas would be administered, and it used this as a basis to defeat the Eighth Amendment claim. But as we have noted, a key distinction between *Bucklew* and our case is present. Again, in *Bucklew*, the *inmate* was *proposing* a new alternative method of execution that had not yet been approved by the state. And in addressing whether the suggested alternative ***1329** method was "feasible" and "readily implemented," the Supreme Court explained that the *inmate's proposal* must be sufficiently detailed. *Bucklew*, 139 S.Ct. at 1129.

Here, Price did not "propose" a new method of execution; he pointed to one that the State already made available. The State, on its own, had already adopted nitrogen

hypoxia as an alternative to lethal injection. Under these circumstances, the State bears the responsibility to formulate a protocol detailing how to effectuate execution by nitrogen hypoxia. Indeed, it would be bizarre to put the onus on Price to come up with a proposed protocol for the State to use when the State has already adopted the particular method of execution and is required to develop a protocol for it, anyway. For these reasons, we conclude that Price's lack of detail as to how the State would implement death by nitrogen hypoxia does not prevent him from establishing that this method of execution is available to him.

[22] Finally, we acknowledge the potential for abuse in delaying execution that a state's decision to make multiple methods of execution available could present. Under *Bucklew*, 139 S.Ct. at 1133 (citation and quotation marks omitted), "[b]oth the State and the victims of crime have an important interest in the timely enforcement of a sentence." So to the extent that a particular available method of death reasonably requires a certain period for the state to prepare for execution, a prisoner may not successfully seek execution by an alternative method inside that window of time. But this is not that case.

Here, Price sought execution by nitrogen hypoxia in January 2019, and his execution is not scheduled to occur until April 11, 2019. While the State has not yet developed a protocol for execution by nitrogen hypoxia, it has submitted no evidence to suggest that once it has satisfied its burden to develop its execution-by-nitrogen-hypoxia protocol, preparing to carry out execution by nitrogen hypoxia will reasonably require more than two-and-one-half months.

2. Price has not established a substantial likelihood that he would be able to show that nitrogen hypoxia significantly reduces a substantial risk of pain when compared to the three-drug protocol

Nevertheless, Price cannot succeed on his Eighth Amendment challenge because he has not shown that nitrogen hypoxia will "significantly reduce a substantial risk of severe pain." *Bucklew*, 139 S.Ct. at 1130. As the Supreme Court in *Bucklew* recently indicated, a minor reduction in risk is not enough; "the difference must be clear and considerable." *Id.* at 1130. Here, Price has failed to meet that standard.

As an initial matter, we reject Price's contention that, by not moving for summary judgment on this issue, the State has somehow conceded that a genuine issue of material fact exists with respect to whether its lethal-injection protocol carries a substantial risk of causing severe pain. At this stage, where Price seeks a stay of execution, he bears the burden to show that a substantial likelihood of success on the merits exists. And, during the hearing before the district court, the State contended that its three-drug lethal-injection protocol using midazolam was a safe and effective constitutional method of execution.

In the district court, Price pointed to two things to support his motion: (1) the declaration of his expert Dr. David Lubarsky, which he also presented during his appeal on the first § 1983 action; and (2) a decision by a district court in the Southern District of Ohio— ***1330** *In re Ohio Execution Protocol Litigation*, No. 11-cv-1016, 2019 WL 244488, at *70 (S.D. Ohio Jan. 14, 2019). Dr. Lubarsky's declaration contains his opinion that midazolam will not provide adequate analgesic effects during Price's execution. And Price relies on the Southern District of Ohio's opinion because the court there found Ohio's lethal injection protocol—which uses midazolam—"will certainly or very likely cause [an inmate] severe pain and needless suffering."

The State submitted nothing on the record in response to contest Dr. Lubarsky's assertions. Rather, it relied on the evidence it submitted in Price's first § 1983 action. But the district court never reached this question in the first § 1983 action, and the State failed to file its evidence on this issue in the pending matter. As a result, the record contains only Dr. Lubarsky's uncontested assertions that the State's use of midazolam in the three-drug protocol presents a substantial risk of severe pain to Price. So the district court's conclusion that Price satisfied his burden to establish that lethal injection carries a substantial risk of severe pain cannot be clearly erroneous, since the only evidence of record supports that conclusion.

[23] Nevertheless, the district court did clearly err in concluding that Price had met his burden to show that execution by nitrogen hypoxia presented an alternative that would significantly reduce the risk of substantial pain to Price. The district court based its finding in this regard on Dr. Lubarsky's declaration in the first § 1983 action appeal and on a report from East Central University. But Dr. Lubarsky's declaration did not compare the

effectiveness of the current three-drug protocol to the proposed use of nitrogen hypoxia. [7]

[24] And Price's reliance on the East Central University report entitled "Nitrogen Induced Hypoxia as a Form of Capital Punishment," in which the authors studied nitrogen hypoxia, is also problematic. Importantly, the report is a preliminary draft report that is stamped with the words "Do Not Cite." So we cannot conclude that Price's reliance on this report alone could satisfy his burden to show that execution by nitrogen hypoxia would significantly reduce the risk of substantial pain to Price. And in the absence of the East Central University report, the district court was left without any evidence supporting a conclusion that nitrogen is not likely to result in any substantial physical discomfort during executions. Consequently, we find that the district court clearly erred when it found that Price satisfied his burden to establish that nitrogen would likely not result in substantial physical discomfort to Price. The district court simply had no reliable evidence upon which to make this determination.

We further note that the report itself also did not compare the two methods of execution, and to the extent Price claims he would feel like he was suffocating if executed by lethal injection, the petitioner in *Bucklew* admitted that feelings of suffocation could also occur with nitrogen gas. *Bucklew*, 139 S.Ct. at 1132. Likewise, the record in *Bucklew* supported the conclusion that the petitioner could be capable of feeling pain for 20 to 30 seconds when nitrogen is used for an execution. *Id.* The Court also recognized expert testimony that suggested the effects of nitrogen could vary depending on how it was administered. *Id.* In short, the district court clearly erred when it concluded Price had satisfied his burden to establish that nitrogen hypoxia would significantly reduce a substantial risk of severe pain. For these ***1331** reasons, Price has failed to show a substantial likelihood of success on the merits of his claim.

IV. Conclusion

For the foregoing reasons, we affirm the district court's denial of Price's Cross-Motion for Summary Judgment as well as its denial of Price's original and renewed motions for preliminary injunction. And because Price has not satisfied his burden to show a substantial likelihood of success on the merits with respect to either his Fourteenth Amendment equal-protection claim or his Eighth Amendment method-of-execution claim, we deny his emergency motion to stay his execution.

AFFIRMED and MOTION FOR STAY DENIED.

All Citations

920 F.3d 1317

Footnotes

1 Price's Notice of Appeal makes clear that he appeals from "any and all adverse rulings incorporated in, antecedent to, or ancillary to" those orders.

2 Price suggests that he was unaware of the ability to elect nitrogen hypoxia as a means of execution until his pro bono counsel, Aaron Katz, called Federal Public Defender John Palombi on January 12, 2019. According to Price, during that phone conversation, Palombi "informed Attorney Katz about the Alabama legislature's March 2018 amendments to the State's execution protocol." However, as we note later in this opinion, our opinion in Price's first § 1983 action, which we issued in September 2018, specifically referenced the fact that Alabama had adopted nitrogen hypoxia as a means of execution. We further noted that Price apparently had not elected this option.

3 The complaint in the second § 1983 action further alleges that the State failed to take steps to prevent material deviations from its lethal-injection procedures in future executions, but Price abandoned that claim, as he did not argue it to the district court below, and it is not part of the present appeal. *Access Now, Inc. v. Sw. Airlines Co.*, 385 F.3d 1324, 1330 (11th Cir. 2004) (claims or arguments not briefed before an appellate court are deemed abandoned and will not be addressed).

4 The form stated as follows:

ELECTION TO BE EXECUTED BY NITROGEN HYPOXIA

Pursuant to Act No. 2018-353, if I am to be executed, I elect that it be by nitrogen hypoxia rather than by lethal injection. This election is not intended to affect the status of any challenge(s) (current or future) to my conviction(s) or sentence(s), nor waive my right to challenge the constitutionality of any protocol adopted for carrying out execution by nitrogen hypoxia. Dated this _____ day of June, 2018.

Name/Inmate Number Signature

ECF No. 19-2. The State admits though that it did not create the election form. Rather, it claims the Federal Public Defender's Office created the form and gave a copy of it to the warden of Holman. But inmates not represented by the Federal Public Defender's Office were among those who timely completed the form.

5 On appeal, Price claims that the district court committed error in refusing to apply strict scrutiny to the State's alleged differential treatment of him. He argues that once the district court concluded he was substantially likely to prevail on his allegation that the State's lethal-injection protocol will cause him severe pain and needless suffering, it should have applied strict scrutiny to his equal-protection claim, since the right to be free from cruel and unusual punishment is a fundamental right. We do not evaluate this argument of Price's, as we conclude that binding precedent requires us to find on this record that Price is not substantially likely to prevail on his allegation that the State's lethal-injection protocol will cause him severe pain.

6 The Supreme Court did note, however, while the case was pending, a "few" states had authorized nitrogen hypoxia as a method of execution. *Bucklew*, 139 S.Ct. at 1130 n. 1. But, it emphasized, "[t]o date, no one in this case has pointed us to an execution in this country using nitrogen gas." *Id.*

7 The district court likewise recognized that Dr. Lubarsky offered no opinion regarding the comparison between the pain incurred with the lethal-injection protocol and that incurred with the administration of nitrogen hypoxia.

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840 F.3d 1268
United States Court of Appeals,
Eleventh Circuit.

Thomas D. ARTHUR, Plaintiff–Appellant,
v.
COMMISSIONER, ALABAMA DEPARTMENT OF CORRECTIONS, Warden, Defendants–Appellees.

No. 16-15549
|
Non–Argument Calendar
|
Date Filed: 11/02/2016

Synopsis

Background: Death row inmate brought § 1983 action against Commissioner of Alabama Department of Corrections, challenging State's method of **execution** under Eighth and Fourteenth Amendments. Following a bench trial, the United States District Court for the Middle District of Alabama, No. 2:11–cv–00438–WKW–TFM, W. Keith Watkins, Chief Judge, 2016 WL 1551475, entered judgment for Commissioner, and subsequently entered an order denying inmate's motion for a new trial, 2016 WL 3912038. Inmate appealed.

Holdings: The Court of Appeals, Hull, Circuit Judge, held that:

[1] inmate failed to demonstrate that compounded pentobarbital was a feasible alternative to midazolam in State's three-drug lethal injection **protocol**;

[2] inmate failed to demonstrate that midazolam created a substantial risk of severe pain;

[3] inmate's allegations could not support an equal protection claim; and

[4] inmate failed to demonstrate that a firing squad was a feasible alternative.

Affirmed.

Wilson, Circuit Judge, filed a dissenting opinion.

West Headnotes (23)

[1] **Sentencing and Punishment**
Mode of **execution**

To prevail on a method-of-**execution** claim under the Eighth Amendment's prohibition of cruel and unusual punishment, there must be a substantial risk of serious harm. U.S. Const. Amend. 8.

1 Cases that cite this headnote

[2] **Sentencing and Punishment**
Mode of **execution**

A method-of-**execution** claim under the Eighth Amendment's prohibition of cruel and unusual punishment requires more than merely showing a slightly or marginally safer alternative; rather, a prisoner is required to identify an alternative that is feasible and readily implemented, and that in fact significantly reduces a substantial risk of severe pain. U.S. Const. Amend. 8.

4 Cases that cite this headnote

[3] **Sentencing and Punishment**
Mode of **execution**

To prevail on a method-of-**execution** claim under the Eighth Amendment's prohibition of cruel and unusual punishment, a prisoner must demonstrate that the risk of severe pain is substantial when compared to the known and available alternatives. U.S. Const. Amend. 8.

2 Cases that cite this headnote

[4] **Sentencing and Punishment**
Mode of **execution**

The "known and available alternative" test on a method-of-**execution** claim under the Eighth Amendment's prohibition of cruel

and unusual punishment requires a prisoner prove that: (1) the State actually has access to an alternative; (2) the State is able to carry out the alternative method of **execution** relatively easily and reasonably quickly; and (3) the requested alternative would in fact significantly reduce a substantial risk of severe pain relative to the State's intended method of **execution**. U.S. Const. Amend. 8.

11 Cases that cite this headnote

[5] Sentencing and Punishment
Mode of **execution**

Death row inmate failed to demonstrate that compounded pentobarbital was a feasible and readily implemented alternative to midazolam for use in Alabama's three-drug lethal injection **protocol**, and, thus, he could not prevail on his method-of-**execution** claim under Eighth Amendment's prohibition of cruel and unusual punishment, even though pharmacies throughout state were theoretically capable of compounding drug, and four other states had been able to procure and use compound to carry out recent **executions**, where State's supply of commercially manufactured pentobarbital had expired, and despite contacting 29 potential sources, State was unable to procure any compounded pentobarbital for use in **executions**. U.S. Const. Amend. 8.

7 Cases that cite this headnote

[6] Sentencing and Punishment
Mode of **execution**

An alternative drug that its manufacturer and compounding pharmacies refuse to supply for lethal injection is no drug at all for purposes of showing a known and available alternative on a method-of-**execution** claim under the Eighth Amendment's prohibition of cruel and unusual punishment. U.S. Const. Amend. 8.

9 Cases that cite this headnote

[7] Sentencing and Punishment
Mode of **execution**

The burden is on a prisoner to plead and prove a known and available alternative method of **execution** on a claim under the Eighth Amendment's prohibition of cruel and unusual punishment, and the State need not make a good faith effort to obtain such an alternative. U.S. Const. Amend. 8.

4 Cases that cite this headnote

[8] Sentencing and Punishment
Mode of **execution**

Death row inmate failed to demonstrate that Alabama's use of midazolam in its three-drug lethal injection **protocol** created a substantial risk of severe pain when compared to available alternatives, and, thus, he could not prevail on his method-of-**execution** claim under Eighth Amendment's prohibition of cruel and unusual punishment, where midazolam had been repeatedly and successfully used without problems to induce a coma-like state and render inmates insensate to pain. U.S. Const. Amend. 8.

4 Cases that cite this headnote

[9] Federal Courts
Depositions and discovery

The Court of Appeals reviews a district court's discovery decisions for abuse of discretion.

1 Cases that cite this headnote

[10] Federal Civil Procedure
Identity and location of witnesses and others

In death row inmate's § 1983 action challenging Alabama's method of **execution** under Eighth Amendment's prohibition of cruel and unusual punishment, district court did not abuse its discretion in denying inmate's request for discovery of names of drug suppliers who talked with State during its efforts to procure compounded pentobarbital for use in its three-drug lethal injection **protocol**, where inmate was allowed to obtain

information he needed to prove his claim, and he offered only speculation as to how names of drug suppliers were relevant. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

2 Cases that cite this headnote

[11] Federal Courts
Summary judgment

The Court of Appeals reviews a district court's ruling on summary judgment de novo.

Cases that cite this headnote

[12] Federal Civil Procedure
Presumptions

On summary judgment, the evidence must be viewed in the light most favorable to the nonmoving party.

1 Cases that cite this headnote

[13] Sentencing and Punishment
Mode of **execution**

Death row inmate, who possibly suffered from coronary artery disease, failed to demonstrate that his proposed modification to midazolam **protocol** as part of Alabama's three-drug lethal injection procedure would significantly reduce risk that he would suffer a heart attack before full sedation, and, thus, his proposed modification was not an available alternative and did not support his as-applied method-of-**execution** claim under Eighth Amendment's prohibition of cruel and unusual punishment, where inmate admitted that his proposed modification would reduce to some extent likelihood that he would suffer a heart attack, but that it would not ameliorate risk entirely. U.S. Const. Amend. 8.

Cases that cite this headnote

[14] Sentencing and Punishment
Mode of **execution**

There was no evidence Alabama's use of midazolam in its three-drug lethal injection **protocol** created a substantial risk that death row inmate, who possibly suffered from coronary artery disease, would suffer a heart attack before full sedation, and, thus, inmate could not prevail on his as-applied method-of-**execution** claim under Eighth Amendment's prohibition of cruel and unusual punishment. U.S. Const. Amend. 8.

4 Cases that cite this headnote

[15] Federal Courts
Expert evidence and witnesses

The Court of Appeals reviews a district court's decision to exclude expert testimony under *Daubert* for an abuse of discretion. Fed. R. Evid. 702.

Cases that cite this headnote

[16] Federal Courts
Expert evidence and witnesses

Under the abuse-of-discretion standard for reviewing a district court's decision to exclude expert testimony under *Daubert*, the Court of Appeals defers to the district court's ruling unless it is manifestly erroneous. Fed. R. Evid. 702.

Cases that cite this headnote

[17] Federal Courts
Expert evidence and witnesses

The deferential abuse-of-discretion standard for reviewing a district court's decision to exclude expert testimony under *Daubert* is not relaxed even though a such ruling may be outcome determinative. Fed. R. Evid. 702.

Cases that cite this headnote

[18] Evidence
Preliminary evidence as to competency

The party offering an expert has the burden of proving the admissibility of her testimony by a preponderance of the evidence. Fed. R. Evid. 702.

Cases that cite this headnote

[19] Evidence
Medical testimony

Expert's testimony that Alabama's procedure for administering midazolam as part of its three-drug lethal injection **protocol** would cause death row inmate, who possibly suffered from coronary artery disease, to suffer a heart attack before full sedation was inadmissible in inmate's § 1983 action challenging State's method of **execution** under Eighth Amendment's prohibition of cruel and unusual punishment, where expert presented only speculative evidence that there was a gap between hemodynamic effects and sedative effects of a 500 milligram dose of drug and that such a dose was highly likely to cause a rapid drop in blood pressure and result in a heart attack. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983; Fed. R. Evid. 702.

Cases that cite this headnote

[20] Constitutional Law
Capital punishment;death penalty

Sentencing and Punishment
Mode of **execution**

Death row inmate's allegation that Alabama had materially deviated from its written lethal injection **protocol** by failing to perform a medical-grade pinch to assess consciousness, thereby impermissibly burdening inmate's right to be free from cruel and unusual punishment, could not support a claim for violation of inmate's equal protection rights, since safeguards implemented during an **execution** were not required to match a medical standard of care. U.S. Const. Amend. 14.

Cases that cite this headnote

[21] Federal Courts
Pleading

The Court of Appeals generally reviews the denial of a motion for leave to amend a complaint for abuse of discretion.

Cases that cite this headnote

[22] Federal Courts
Pleading

A district court's decision to deny leave to amend based on futility is a legal conclusion, and the Court of Appeals reviews such decisions de novo.

Cases that cite this headnote

[23] Sentencing and Punishment
Mode of **execution**

Death row inmate failed to demonstrate that a firing squad was a feasible and readily implemented alternative to Alabama's three-drug lethal injection **protocol**, and, thus, he could not prevail on his method-of-**execution** claim under Eighth Amendment's prohibition of cruel and unusual punishment; a firing squad was not a valid or lawful method of **execution** in Alabama, neither lethal injection nor electrocution, which were only methods of **execution** authorized by Alabama statute, had been held unconstitutional, and State had never carried out an **execution** by firing squad or statutorily recognized it as a method for carrying out an **execution**. U.S. Const. Amend. 8; Ala. Code § 15-18-82.1.

11 Cases that cite this headnote

***1271** Appeal from the United States District Court for the Middle District of Alabama, D.C. Docket No. 2:11–cv–00438–WKW–TFM

Attorneys and Law Firms

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Daniel T. Fenske, Jenner and Block, LLP, Chicago, IL, for Amici Curiae.

Before HULL, MARCUS and WILSON, Circuit Judges.

Opinion

HULL, Circuit Judge:

It has been 34 years since Thomas Arthur brutally murdered Troy Wicker. During 1982 to 1992, Thomas Arthur was thrice tried, convicted, and sentenced to death for Wicker's murder. After his third death sentence in 1992, Arthur for the next 24 years has pursued, unsuccessfully, dozens of direct and post-conviction appeals in both state and federal courts.

In addition, starting nine years ago in 2007 and on three separate occasions, Arthur has filed civil lawsuits under 42 U.S.C. § 1983 challenging the drug **protocol** to be used in his **execution**. This is Arthur's third such § 1983 case, and this current § 1983 case was filed in 2011. For the last five years Arthur has pursued this § 1983 case with the benefit of lengthy discovery. The district court held a two-day trial and entered two comprehensive orders denying Arthur § 1983 relief. Those orders are the focus of the instant appeal.

After thorough review, we conclude substantial evidence supported the district court's fact findings and, thus, Arthur has shown no clear error in them. Further, Arthur has shown no error in the district court's conclusions of law, inter alia, that: (1) Arthur failed to carry his burden to show compounded pentobarbital is a feasible, readily implemented, and available drug to the Alabama Department of Corrections ("ADOC") for use in **executions**; (2) Alabama's consciousness assessment **protocol** does not violate the Eighth Amendment or the Equal Protection Clause; and (3) Arthur's belated firing-squad claim lacks merit.

I. CONVICTION AND APPEALS

The Alabama Supreme Court summarized the facts underlying Arthur's criminal conviction as follows:

> More than 20 years ago, Arthur's relationship with his common-law wife ultimately led to his brutally murdering a relative of the woman. Arthur shot the victim in the right eye with a pistol, causing nearly instant death. He was convicted in a 1977 trial and was sentenced to life imprisonment.
>
> While on work release during the life sentence, Arthur had an affair with a woman that ultimately led to his brutally murdering that woman's husband, Troy Wicker, in 1982. Arthur shot Wicker in the right eye with a pistol, causing nearly instant death.

Ex parte Arthur, 711 So.2d 1097, 1098 (Ala. 1997).

In 1982, Arthur was convicted and sentenced to death for Wicker's murder, but the Alabama Supreme Court reversed that conviction in 1985. Arthur v. King, 500 F.3d 1335, 1337 (11th Cir. 2007). In 1987, Arthur was again convicted and sentenced to death, but that conviction was overturned by Alabama's Court of Criminal Appeals in 1990. Id. After his third trial in 1991, Arthur was again convicted of Wicker's murder and sentenced to death in 1992. Id. This time, his conviction and sentence were affirmed. Id. He did not file a petition for writ of certiorari with the United States Supreme Court. Id. at 1337–38.

***1273** At his third sentencing proceeding, Arthur asked for a death sentence, stating that a capital sentence would provide him better prison accommodations, more access to the law library, more time to devote to his appeal, and a more extensive appeals process. Arthur v. Thomas, 739 F.3d 611, 614 (11th Cir. 2014). Arthur told the jury that he did not believe he would be **executed**. Id. Arthur's murder of Wicker was a capital offense under Alabama law because Arthur had been convicted of another murder in the 20 years preceding his second murder. See Ala. Code § 13A–5–40(a)(13) (1975); Arthur v. State, 71 So.3d 733, 735 (Ala. Crim. App. 2010).

In 2001, after exhausting his state court remedies, Arthur filed a federal habeas corpus petition pursuant to 28 U.S.C. § 2254. Arthur v. Allen, 452 F.3d 1234, 1238, 1240–43 (11th Cir.), modified on reh'g, 459 F.3d 1310 (11th Cir. 2006). The district court dismissed the § 2254 petition as untimely, but granted a certificate of appealability as to Arthur's claims of actual innocence, statutory

tolling, and equitable tolling. Id. at 1243. In 2006, this Court affirmed the dismissal of Arthur's § 2254 petition, concluding that Arthur had not shown actual innocence or entitlement to statutory or equitable tolling. Id. at 1253–54. [1] The Supreme Court denied Arthur's petition for writ of certiorari. Arthur v. Allen, 549 U.S. 1338, 127 S.Ct. 2033, 167 L.Ed.2d 763 (Mem.) (2007).

With this background, we turn to Arthur's current § 1983 case, challenging Alabama's use of midazolam in its lethal injection **protocol**. To place Arthur's current § 1983 claim in context, we review the history of lethal injection in Alabama and how Alabama has had to change the drugs used due to unavailability. For years, Arthur challenged the use of sodium thiopental and then pentobarbital. But now that the ADOC has not been able to procure sodium thiopental or pentobarbital and has had to switch to midazolam, Arthur is currently challenging midazolam and now asks to go back to sodium thiopental or pentobarbital as his preferred alternatives. We thus review in great detail how this case got here today.

II. HISTORY OF LETHAL INJECTION IN ALABAMA

When Arthur was sentenced to death, Alabama **executed** inmates by electrocution. See McNair v. Allen, 515 F.3d 1168, 1171 (11th Cir. 2008). On July 1, 2002, the Alabama legislature adopted lethal injection as the state's preferred form of **execution**. Id. The legislature allowed inmates already under a sentence of death a 30–day window to choose electrocution as their method of **execution**, after which time they would be deemed to have waived the right to request a method other than lethal injection. Ala. Code § 15–18–82.1(b).

Alabama's method-of-**execution** statute further provides that:

> If electrocution or lethal injection is held to be unconstitutional by the Alabama Supreme Court under the Constitution of Alabama of 1901, or held to be unconstitutional by the United States Supreme Court under the United States Constitution, or if the United States Supreme ***1274** Court declines to review any judgment holding a method of **execution** to be unconstitutional under the United States Constitution made by the Alabama Supreme Court or the United States Court of Appeals that has jurisdiction over Alabama, all persons sentenced to death for a capital crime shall be **executed** by any constitutional method of **execution**.

Id. § 15–18–82.1(c). The Alabama statute does not prescribe any particular method of lethal injection; the legislature left it to the ADOC to devise the policies and procedures governing lethal injection **executions**, and exempted the ADOC from the Alabama Administrative Procedure Act in exercising that authority. Id. § 15–18–82.1(g).

The ADOC has used a three-drug lethal injection **protocol** since it began performing **executions** by lethal injection in 2002. See Brooks v. Warden, 810 F.3d 812, 823 (11th Cir.), cert. denied sub nom. Brooks v. Dunn, —U.S. ——, 136 S.Ct. 979, 193 L.Ed.2d 813 (2016). Each drug in a three-drug **protocol** is intended to serve a specific purpose. The first drug should render the inmate unconscious to "ensure[ ] that the prisoner does not experience any pain associated with the paralysis and cardiac arrest caused by the second and third drugs"; the second drug is a paralytic agent that "inhibits all muscular-skeletal movements and, by paralyzing the diaphragm, stops respiration"; and the third drug "interferes with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest." Baze v. Rees, 553 U.S. 35, 44, 128 S.Ct. 1520, 1527, 170 L.Ed.2d 420 (2008) (plurality opinion).

The third drug in the ADOC **protocol** has always been potassium chloride, and the second drug has always been a paralytic agent—either pancuronium bromide or rocuronium bromide. Brooks, 810 F.3d at 823. However, the ADOC has changed the first drug in its **protocol** twice. Id. From 2002 until April 2011, it used sodium thiopental as the first drug in the three-drug sequence. Id. But a national shortage of sodium thiopental forced states, including Alabama, to seek a replacement for sodium thiopental as the first drug in the series. See Glossip v. Gross, 576 U.S. ——, ——, 135 S.Ct. 2726, 2733, 192 L.Ed.2d 761 (2015) (explaining that the sole domestic

manufacturer of sodium thiopental ceased production of the drug in 2009 and exited the market entirely in 2011).

From April 2011 until September 10, 2014, Alabama used pentobarbital as the first drug. Brooks, 810 F.3d at 823. As the Supreme Court has noted, "[b]efore long, however, pentobarbital also became unavailable." Glossip, 135 S.Ct. at 2733. Arthur has acknowledged that Alabama's supply of commercially manufactured pentobarbital expired on or around November 2013. From September 11, 2014, until the present, Alabama has used midazolam as the first drug in the series. Brooks, 810 F.3d at 823.

Currently, Alabama's lethal injection **protocol** calls for the administration of: (1) a 500–mg dose of midazolam, (2) followed by a 600–mg dose of rocuronium bromide, and (3) finally, 240 milliequivalents of potassium chloride. This lethal injection **protocol** involves the same drugs, administered in the same sequence, as the **protocol** at issue in Glossip. 135 S.Ct. at 2734–35.

III. 2011: COMPLAINT ABOUT PENTOBARBITAL

Arthur's **execution** date is currently set for November 3, 2016. This is the sixth ***1275** time that Alabama has scheduled his **execution**, [2] and this case is Arthur's third § 1983 challenge to lethal injection as the method of his **execution**. [3]

In May 2007, shortly after the State filed a motion to set an **execution** date, Arthur filed a § 1983 action challenging Alabama's lethal injection **protocol** which in 2007 included sodium thiopental as the first drug. (CM/ECF for the U.S. Dist. Ct. for the S.D. Ala., case no. 1:07–cv–342, doc. 1 at 1-2, 6; doc. 15 at 11). The district court dismissed that complaint based on laches, and this Court affirmed. (Id., docs. 19, 20, 27, 28). In October 2007, Arthur filed a second challenge to Alabama's lethal injection **protocol**, which the district court again dismissed for unreasonable delay, and this Court affirmed. (CM/ECF for the S.D. Ala., case no. 1:07–cv–722, docs. 1, 22, 23, 28, 29).

In April 2011, Alabama switched from using sodium thiopental to pentobarbital as the first drug in its lethal injection **protocol**. Brooks, 810 F.3d at 823. On June 8, 2011, Arthur filed another § 1983 complaint in federal district court, challenging Alabama's new lethal injection **protocol**, especially its use of pentobarbital as the first drug.

As amended, Arthur's complaint raised three § 1983 claims: (1) the ADOC's use of pentobarbital as the first drug in its three-drug lethal injection **protocol** violated the Eighth Amendment's prohibition on cruel and unusual punishment; (2) the ADOC's secrecy in adopting and revising its lethal injection **protocol** violated the Fourteenth Amendment's Due Process Clause; and (3) the ADOC had materially deviated from its lethal injection **protocol** by failing to conduct a "consciousness assessment" during an earlier **execution**, thereby violating the Fourteenth Amendment's Equal Protection Clause. Arthur also alleged that Alabama's lethal injection statute violated the state constitution.

The district court dismissed Arthur's Eighth Amendment and Due Process claims on statute-of-limitations grounds and his Equal Protection claim for failing to state a claim upon which relief could be granted. Arthur v. Thomas, 674 F.3d 1257, 1259 (11th Cir. 2012). Because Alabama began its lethal injection **protocol** in 2002, the district court determined that Arthur's 2011 complaint challenging it was banned by the two-year statute of limitations applicable to § 1983 claims. Id. Arthur appealed. Id.

This Court reversed the district court's dismissal as to only Arthur's Eighth Amendment and Equal Protection claims. Id. at 1262, 1263. As to the Eighth Amendment claim, this Court concluded that Arthur's allegations and his filed affidavits created factual issues as to whether Alabama's new lethal injection drugs and procedures constituted such a significant change in the lethal injection **protocol** as to warrant a new limitations period and some ***1276** factual development, including discovery. Id. at 1260–62.

As to the Equal Protection claim, this Court held that Arthur had "alleged enough facts to constitute a plausible Equal Protection claim because he alleges that Alabama has substantially deviated from its **execution protocol**" by failing to perform the pinch test as part of the required consciousness assessment. Id. at 1263. Accepting Arthur's particular allegations as true at the early Rule 12(b)(6) stage, this Court remanded for further factual development. Id.

In the years after this Court's 2012 remand, the parties conducted extensive discovery. Before the final hearing

on Arthur's § 1983 challenge to pentobarbital, the State was no longer able to procure pentobarbital. In September 2014, the State changed its lethal injection **protocol** to substitute midazolam hydrochloride for pentobarbital as the first drug, and rocuronium bromide for pancuronium bromide as the second drug in its three-drug cocktail.

IV. 2015: SECOND AMENDED COMPLAINT ABOUT MIDAZOLAM

On January 7, 2015, after receiving leave from the district court to amend his 2011 complaint, Arthur filed a complaint (the "Second Amended Complaint"), raising two claims. Arthur raised an Eighth Amendment claim, alleging that the ADOC's use of midazolam as the first drug "creates a substantial risk of serious harm because ... there is a high likelihood that midazolam will fail to render [him] insensate from the excruciatingly painful and agonizing effects of the second and third drugs."

Despite challenging pentobarbital for more than three years, Arthur now suggested that he would prefer for the State to use a one-drug **protocol** of compounded pentobarbital in his **execution** instead of midazolam. Arthur's Second Amended Complaint recycled his earlier argument about pentobarbital, which was that it would cause him to suffer a drop in blood pressure and then a heart attack. Arthur now made the same claim about midazolam, alleging that he had "clinically significant obstructive coronary disease" and that the State's use of midazolam created a substantial risk that he would suffer a painful heart attack before losing consciousness.

Arthur's Second Amended Complaint also raised an Equal Protection claim, alleging that the ADOC had "materially deviated from their written **execution protocol**, impermissibly burdening Mr. Arthur's right to be free from cruel and unusual punishment." Arthur claimed that Alabama employs a lethal injection **protocol** that requires a "consciousness assessment" after the first drug is injected. This consciousness assessment has three parts: (1) calling the inmate's name, (2) gently stroking his eyelash, and (3) pinching his arm.

Arthur's Second Amended Complaint alleged that during "numerous **executions**," including the 2011 **execution** of Eddie Powell, witnesses did not observe the pinch test being performed. Arthur also alleged that the ADOC failed to adequately train its personnel in how to perform properly the consciousness assessment. He claimed that there existed a "significant risk that Defendants will deviate from their **protocol** in [his] **execution**," thus burdening his rights under the Fourteenth Amendment.

In March 2015, the district court elected to stay Arthur's § 1983 case challenging midazolam until after the U.S. Supreme Court issued its decision in ***1277** Glossip v. Gross. [4]

V. JUNE 2015: GLOSSIP IS DECIDED

On June 29, 2015, the Supreme Court decided Glossip, holding that, in order to challenge successfully a method of **execution**, a plaintiff must plead and prove: (1) that the proposed **execution** method presents a risk that is " '*sure or very likely* to cause serious illness and needless suffering,' and give rise to 'sufficiently *imminent* dangers,' " and (2) that there is "an alternative [method of **execution**] that is 'feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain.' " 135 S.Ct. at 2737 (quoting Baze, 553 U.S. at 50, 52, 128 S.Ct. at 1530–31, 1532) (alteration in original).

After Glossip, the district court subsequently lifted its stay of proceedings in this case, and the parties conducted some additional discovery.

On August 25, 2015, Arthur sought leave to file a third amended complaint, seeking (1) to switch back to compounded pentobarbital as an alternative method of **execution**, (2) to suggest sodium thiopental and a firing squad as additional alternative methods, and (3) to include additional allegations that midazolam was constitutionally inadequate. The district court granted Arthur leave to amend his complaint except as to the firing squad as an alternative method of **execution**. The district court concluded, inter alia, that "**execution** by firing squad is not permitted by [Alabama] statute and, therefore, is not a method of **execution** that could be considered either feasible or readily implemented by Alabama at this time." The district court set trial to begin on January 12, 2016.

VI. OCT. 2015: THIRD AMENDED COMPLAINT

On October 13, 2015, Arthur filed his Third Amended Complaint, alleging substantially identical claims to those raised in his Second Amended Complaint and requesting single-drug **protocols** of compounded pentobarbital or sodium thiopental as alleged feasible alternative methods of **execution**. The ADOC filed (1) a "Motion to Dismiss and, In the Alternative, Motion for Summary Judgment," arguing that Arthur's Eighth Amendment claim was untimely, that both claims should be dismissed for failure to state a claim, and that there was no genuine issue of material fact regarding whether compounded pentobarbital or sodium thiopental are known and available alternatives; and (2) a "Motion for Summary Judgment of Arthur's Eighth Amendment Claim," arguing again that compounded pentobarbital and sodium thiopental are not known and available alternatives and, further, that Arthur failed to present any evidence showing how compounded pentobarbital could be administered to prevent a painful heart attack. [5] The ADOC's motions included arguments ***1278** regarding its present inability to obtain either pentobarbital or sodium thiopental.

On January 7, 2016, the district court issued an order limiting the issues at trial to: (1) Arthur's Equal Protection claim, and (2) the availability of alternative methods of **execution**. The district court wrote that, if Arthur met his burden to prove an alternative method of **execution** that is feasible and readily available, the court would schedule a second phase of trial to address other issues, such as whether the use of midazolam "presents a risk that is sure or very likely to cause serious illness and needless suffering, and give rise to sufficiently imminent dangers."

The district court held a two-day bench trial on January 12 and 13, 2016.

VII. TRIAL EVIDENCE ABOUT ALTERNATIVE DRUGS

A. Arthur's Evidence

As noted above, although for four years Arthur had challenged pentobarbital as the first drug, one of his requested alternatives is now a single drug of compounded pentobarbital. Arthur called Dr. Gaylen M. Zentner to testify about compounded pentobarbital. [6]

Dr. Zentner obtained a Ph.D. in pharmaceutics and was a licensed pharmacist in Utah for 40 years. After obtaining his Ph.D., Dr. Zentner taught pharmacy at the University of Connecticut, including teaching in the compounding lab. He worked for 13 years for a large pharmaceutical company in their "advanced drug delivery dosage form design unit." He was later in charge of "all formulation and dosage form design" at another large pharmaceutical company. He had held two adjunct professorships in pharmacy. Since 2012, Dr. Zentner had worked as an "independent consultant" to the pharmaceutical industry. He testified that he had hands-on experience with manufacturing drugs and he had personally compounded drugs, although he had no experience preparing compounded pentobarbital sodium. The district court accepted Dr. Zentner as an expert witness in the fields of pharmaceutical chemistry, manufacturing, and compounding.

Dr. Zentner testified that, in his opinion, "the talent, expertise, and facilities to perform sterile compounding" existed within Alabama and that "all ingredients required to formulate a compounded preparation of pentobarbital sodium" were "readily available."

Dr. Zentner explained that, in its pure form, pentobarbital sodium was a white powder, which could be compounded with other ingredients to form an injectable solution. He described pentobarbital as a "long-known and well-established drug product" that was "available to the medical sciences for decades." He stated that Nembutal, the trade name for an industrially manufactured version of injectable pentobarbital sodium, was available for sale in the United States. He said that pentobarbital sodium for injection was listed in the FDA's Orange Book, which listed all "approved drugs" in the United States. The Orange Book stated that there were no active patents on this drug, meaning that anyone was permitted to make it.

Dr. Zentner described the process of compounding a solution of pentobarbital ***1279** sodium, calling it "a very simple matter" and a "straightforward process." During his testimony, Dr. Zentner relied on a 2015 article from the Journal of Pharmacological and Toxicological Methods that described the preparation of an injectable pentobarbital sodium solution by laboratory scientists that was essentially identical to the commercial product and was stable for one year.

Dr. Zentner contended that there were "numerous sources" for both the active and inactive ingredients needed to compound pentobarbital, including professional drug sourcing services. He said that these ingredients were available for sale in the United States and could be found through an Internet search. For example, Dr. Zentner found pentobarbital sodium listed on a drug manufacturer's product listing, which listing indicated that the drug was produced in the United States. He stated that other manufacturers might offer it for sale or the drug could be synthesized in a lab. He said that he knew of one lab that would be willing to synthesize the drug and he suspected "all of them would be willing."

Dr. Zentner stated that he conducted an Internet search of sterile compounding pharmacies in Alabama from the listing available on the Accreditation Commission for Health Care's Web site, and found 19 such pharmacies, although two were essentially the same company. Dr. Zentner gave his list to the ADOC. Dr. Zentner contacted two of these pharmacies, and they said that they did perform sterile compounding. Dr. Zentner admitted that he did not ask them whether they would be willing to compound pentobarbital for use in an **execution** by the ADOC. In his deposition, Dr. Zentner clarified that he did not ask these two pharmacies any questions whatsoever regarding compounded pentobarbital.

Accordingly, Dr. Zentner could only give his opinion that (1) pentobarbital sodium is available for purchase in the United States, and (2) there are compounding pharmacies that "have the skills and licenses to perform sterile compounding of pentobarbital sodium."

On cross-examination, Dr. Zentner admitted that he had not contacted any drug companies at all about their willingness to sell pentobarbital to the ADOC for **executions**. He also admitted that he was unaware that the company that currently owned Nembutal had restrictions in place to keep that drug from being purchased for use in lethal injections. Dr. Zentner admitted that he had no knowledge of whether the pharmacies that he found would be able to procure pentobarbital, nor did he ever personally attempt to purchase the drug from a manufacturer. He stated that one drug synthesis company that he has a "long-term relationship" with was "willing to discuss" producing compounded pentobarbital. Dr. Zentner admitted that sodium thiopental is not listed in the FDA Orange Book, meaning it is not an approved product in the United States, although he stated that it is "available offshore and conceivably could be imported."

B. ADOC's Evidence

Anne Adams Hill,[7] ADOC's general counsel, testified on behalf of the agency. Hill explained that, as part of her job, she was "routinely" in contact with other states' departments of corrections and that the subject of pentobarbital and lethal injection ***1280** came up in her conversations. Her job required her to constantly look for ways to procure new drugs and new sources for drugs.

Hill was aware that, in 2015, Georgia, Missouri, Texas, and Virginia **executed** inmates using a single-drug **protocol** of compounded pentobarbital. Hill testified that she contacted representatives from the departments of corrections in these four states in the fall of 2015 in an effort to obtain compounded pentobarbital. With respect to these four states she recalled asking "specifically if they had compounded pentobarbital and, if they did, if they would be willing to provide it to the [ADOC] and, if not, if they would provide us their source." All four refused.

Hill stated that she was not aware of whether these four states had exclusive contracts with their drug sources, but that all four had refused to name those sources.

Hill reiterated her deposition testimony that, in between September 2014 and November 2015, she had contacted 11 potential sources of pentobarbital, including those 4 states and 7 pharmacies within Alabama. She asked these pharmacies whether they would be willing to compound pentobarbital and provide it to the ADOC, and they all said no.

Hill also testified that, in December 2015, she reached out to all of the 18 pharmacies on Dr. Zentner's list[8] regarding their willingness and/or capability to compound pentobarbital for the ADOC's use. None of the pharmacies agreed to provide the drug to ADOC, with two saying they were incapable of obtaining the ingredients, another claiming that it no longer did compounding, yet another saying it only produced one drug, and the remainder stating that "they're not able to compound pentobarbital." In total, Hill testified that she reached out to "at least 29" potential sources in an attempt to procure compounded pentobarbital for the ADOC.

Hill admitted that she did not contact drug manufacturers, buying groups, or drug synthesis labs in an effort to find pentobarbital, nor did she conduct any Internet searches to obtain the drug.

Hill also testified that she had made no effort since September 2014 to obtain sodium thiopental and made no efforts to determine whether it could be imported. Hill said that she did not think sodium thiopental was available in the United States, and she was not aware of any other state that had access to sodium thiopental.

VIII. TRIAL EVIDENCE ABOUT CONSCIOUSNESS ASSESSMENT

Since October 2007, the ADOC's written **execution protocol** has included a three-step consciousness assessment, to be performed after the administration of the first drug, but before administration of the second and third drugs. The purpose of this assessment is to ensure that the inmate has been rendered unconscious by the first drug. The assessment has three parts: (1) calling the inmate's name; (2) fluttering the inmate's eyelash; and (3) pinching the inmate's arm.

A. Arthur's Evidence on the Consciousness Assessment

Arthur presented four witnesses who attended prior **executions** at Holman Correctional ***1281** Facility, where Arthur is housed. These witnesses included three attorneys who worked for the Federal Defenders Office for the Middle District of Alabama and the videotaped deposition of Don Blocker, a volunteer lay minister at Holman. To varying degrees, they all testified that they did not see prison staff perform the pinch test at these **executions**.[9] All four witnessed the **executions** from the viewing room reserved for the inmate's family, and they had a clear view of the inmate's left side.

Two of the attorneys, however, admitted that their view of the inmate was obstructed when a correctional officer stepped up to the gurney to perform the consciousness assessment. All three attorneys admitted that, at the time of the **executions** they saw, they were unaware that there was even a consciousness assessment that was supposed to be performed. Similarly, Blocker acknowledged three times on cross-examination that it was "possible" that he did not see parts of the consciousness assessment that were performed.

At trial, Arthur also presented Dr. Alan David Kaye, who holds a medical degree and a Ph.D. in pharmacology.[10] He completed a residency in anesthesia and was currently employed as the chairman of the anesthesia department at Louisiana State University ("LSU"). He is the director of anesthesia services at LSU's "flagship" hospital, has authored articles and books, and maintains an active anesthesiology practice. The court accepted Dr. Kaye as an expert witness in the field of anesthesiology.

Dr. Kaye explained that "sedation" is understood by people in his field as a continuum. This can range from "mild sedation in which a person can easily respond to verbal cues," to moderate sedation, deep sedation, and, finally, anesthesia, "the deepest level of the continuum." In his opinion, Alabama's consciousness assessment "is inadequate to measure deep sedation or anesthesia." While Dr. Kaye has not witnessed any **executions** in Alabama, he opined that the ADOC had not "adequately administered" the assessment that was in place. Dr. Kaye gave four reasons for his opinion.

First, from reviewing the testimony of certain ADOC personnel, Dr. Kaye opined that "it appears that the consciousness assessment may not have been performed at all in a number of prior **executions**." Second, statements given by certain ADOC personnel gave the impression to Dr. Kaye that their training was inadequate because they did not know how to properly perform the pinch test and/or communicate the results of the assessment. Third, again based on the prior testimony of certain ADOC officials, it was Dr. Kaye's opinion that members of Alabama's **execution** team do not pinch inmates with sufficient force. Fourth, it appeared to Dr. Kaye that members of the **execution** team did not adequately communicate the results of the consciousness assessment.

Dr. Kaye testified that, in anesthesiology medical practice, you have to perform "the hardest pinch that you can pinch," hard enough to bruise. Dr. Kaye explained, ***1282** "As firm and as hard as you can. Not in a mild way; not in a moderate way. In a very significant way." Dr. Kaye testified that the ADOC personnel's testimony—that (1) "We don't inflict pain on people"; (2) "I pinch hard enough that [a conscious person] would jerk their arm away from me"; and (3) "[I pinch] hard enough to wake

[the inmate] if he's asleep"—are all inadequate to meet the proper threshold and speaks to the lack of training and inadequacy of the safeguard.

B. ADOC's Evidence on the Consciousness Assessment

The ADOC presented the testimony, either live or through deposition designations, of six current or former ADOC personnel, all of whom testified that all parts of the consciousness assessment were performed at every **execution** that they witnessed and/or participated in.

At trial, Hill, the ADOC's general counsel, testified that she had attended nine or ten **executions** since the implementation of the consciousness assessment and observed all parts of the assessment being performed in all of those **executions**. Hill stated that, in her role as the ADOC general counsel, she had never received any information that the assessment was not performed.

Hill testified that she viewed the **executions** from the commissioner's viewing room, which is positioned directly in front of each inmate's feet as he lies on the gurney, and that her view was not obstructed. Hill was present at Powell's **execution**, and she testified that all parts of the assessment were performed at Powell's **execution**. She said that the correct and complete performance of the consciousness assessment is something she looks for in the **executions** that she attends.

Hill stated that correctional officers are aware that the consciousness assessment is a mandatory part of the **execution protocol**, and they are trained on how to perform it. They are instructed to perform the pinch test on the back of the inmate's left arm and to "pinch hard." Hill stated that correctional officers practice performing the consciousness assessment before an **execution**. They are also trained to look for "any reaction" from the inmate and to report any reaction.

The ADOC also presented the deposition testimony of: (1) G.C., Holman's warden from 2002 until 2009; (2) A.P., the Holman warden who succeeded G.C.; (3) D.C., the former captain of Holman's **execution** team; (4) W.H., the **execution**-team captain who succeeded D.C.; and (5) C.S., the chaplain at Holman. The wardens and captains testified that they were trained on the consciousness **protocol**, knew it was mandatory, and understood its purpose and importance.

The wardens both testified that they were present at **executions** and all parts of the assessment, including the pinch test, were performed at every **execution** that they witnessed. Similarly, the captains of the **execution** team testified that they personally performed every aspect of the assessment, including the pinch test, at every **execution**. The Holman chaplain testified that he has witnessed approximately 40 **executions** at the prison since 1997. He witnessed the **execution** of Eddie Powell, and remembered seeing the consciousness assessment performed.

G.C. testified that he was the warden when the consciousness assessment was implemented and that ADOC representatives explained the assessment to him and told him when it should be performed. He testified that a team consisting of himself, ***1283** D.C., Hill, and former ADOC Commissioner Kim Thomas all agreed that inmates should be pinched on the back of the arm because it was "inconspicuous" but "fairly sensitive." G.C. testified that he sat in the control room with another officer during **executions** and, on the warden's command, that officer would "radio[ ] to the correctional personnel that's in the **execution** chamber that it's time to perform the consciousness test." If there was any reaction from the inmate, the procedure was for the officer in the **execution** chamber to radio back to the officer in the control room, but if the officer performing the consciousness assessment stepped away from the inmate, "that was [his] cue to proceed" with administration of the second and third drugs. G.C. testified that, during his tenure as warden, no inmate ever reacted to administration of the first drug.

A.P. succeeded G.C. as warden and also testified that, once the officer performing the consciousness assessment stepped away from the inmate, he knew he could proceed with the **execution**.

D.C. was the captain of the **execution** team at Holman until his retirement in 2009 and was the captain when the consciousness assessment was introduced. It was his practice to do all three steps of the assessment simultaneously. He testified that, if the inmate showed any reaction to the consciousness assessment, he would turn and face the warden. In performing the pinch test, D.C. would pinch hard enough that, "if it was a conscious person, they would jerk their arm away from me." He never received any reaction in the nine or ten **executions** in which he participated.

W.H. succeeded D.C. as the execution-team captain at Holman in 2009. As captain, W.H. would pinch the inmate's arm "hard enough to wake him if he's asleep." W.H. testified that he received oral, written, and physical training regarding the consciousness assessment from A.P., D.C., and another officer. W.H. testified that A.P. instructed him to stay at his place by the gurney if the inmate reacted. W.H. stated that no inmate ever reacted after he performed the consciousness assessment.

IX. DISTRICT COURT'S APRIL 15, 2016 ORDER

After setting out the factual background and procedural history of the case, the district court proceeded, first, to consideration of Arthur's Eighth Amendment claim. The district court summarized the trial testimonies of Dr. Zentner and ADOC attorney Hill on the issue of alternatives to midazolam—namely, pentobarbital and sodium thiopental. The district court then made these findings of fact, among others:

(1) The ADOC's supply of commercially manufactured pentobarbital, Nembutal, expired around November 2013, and the commercial supplier of Nembutal is prohibited from providing it for use in executions. Thus, Nembutal is no longer available to the ADOC.

(2) When a drug is no longer commercially available, but remains listed in the FDA Orange Book, a licensed pharmacist may legally create the drug through compounding or some other process.

(3) Pentobarbital sodium is the active ingredient in compounded pentobarbital, and there is a formulation for compounding an injectable solution of pentobarbital sodium.

(4) Georgia, Missouri, Texas, and Virginia have all performed executions using compounded pentobarbital after Nembutal became unavailable.

(5) The ADOC has attempted to obtain compounded pentobarbital for use in executions ***1284** from the departments of correction in all four of these states, but those efforts were unsuccessful.

(6) The ADOC has contacted all of the accredited compounding pharmacies in Alabama to ascertain whether any of these pharmacies would be willing and able to provide compounded pentobarbital to the ADOC, but those efforts have been unsuccessful.

(7) Thus, pentobarbital is not feasible and readily implemented as an execution drug in Alabama, nor is it readily available to the ADOC, either compounded or commercially.

(8) Per the FDA Orange Book, sodium thiopental is no longer legally available in the United States, and there is no evidence that the FDA has approved the import of sodium thiopental from other countries.

(9) Thus, sodium thiopental is unavailable to the ADOC for use in lethal injections.

The district court then made these conclusions of law:

(1) Arthur has the burden to plead and prove a known and available alternative method of execution under Glossip. It is Arthur's burden to identify an alternative method that is both feasible and readily implemented.

(2) To meet his burden, Arthur proposed execution with a one-drug protocol of either compounded pentobarbital or sodium thiopental.

(3) Dr. Zentner's testimony that the active ingredient for pentobarbital is "available for purchase" and that there are compounding pharmacies that could "hypothetically" perform compounding did not meet Arthur's burden "to prove that compounded pentobarbital is readily available to the ADOC for use in lethal injections. That it should, could, or may be falls far short of Arthur's burden."

(4) Further, Arthur's proof that (i) other states have procured compounded pentobarbital for use in their executions, (ii) "with effort it can be compounded," and (iii) "indications on the internet" are that pentobarbital is available for sale all fail to meet Arthur's burden to show that the drug was readily available to the ADOC. "At best, it proves a 'maybe.' "

(5) The fact that compounded pentobarbital was available to other states "at some point over the past two years does not, without more, establish that it is available to Alabama."

(6) Although the ADOC did not have the burden of proof on this issue, Hill's testimony lent "further

support for the finding that compounded pentobarbital is not presently available to the ADOC."

(7) Arthur also failed to carry his burden of showing that sodium thiopental was an available alternative because sodium thiopental is not legally available in the United States and evidence of its possible availability overseas does not satisfy Glossip.

(8) Therefore, "Arthur sufficiently pleaded an Eighth Amendment claim, but he failed to meet his burden of proof. Defendants are entitled to judgment in their favor on Arthur's Eighth Amendment claim." [11]

***1285** The district court then proceeded to evaluate Arthur's Equal Protection claim, which is based on the consciousness assessment. After summarizing the evidence on this claim, the district court made these findings of fact, among others:

(1) In October 2007, the ADOC adopted a consciousness assessment in order to provide an "additional safeguard to lethal injection **executions** to ensure that an inmate is unconscious" before the second and third drugs are administered.

(2) While there was conflicting testimony as to whether the ADOC performed the pinch test at all **executions** after October 2007, the district court credited the testimony of ADOC's witnesses over that of Arthur's witnesses. The district court gave two reasons for these findings. First, Hill and the other ADOC witnesses are all present or former ADOC employees who were knowledgeable about the consciousness assessment and were trained "to understand how, why, and when it is performed." Second, it found Arthur's witnesses, while "truthful from their perspective," to be "less direct and less probative" because (i) testimony that they "didn't see" something is less probative than testimony that it "didn't happen"; and (ii) Arthur's witnesses had obstructed views of the **execution** and/or did not know to look for the various steps of the consciousness assessment.

(3) Based on the evidence and these findings, the district court found that "the evidence establishes that the pinch test was performed in all **executions** that the ADOC has conducted after the ADOC adopted the consciousness assessment and incorporated it as a mandatory part of the written **execution protocol**." The district court found that any contradictory evidence did not "overcome" the direct testimony from current and former ADOC wardens and other personnel who said "without equivocation that they performed the assessment."

(4) Further, because the consciousness assessment had been performed in every instance, the district court found that there was no deficiency in training, practice, or procedure.

The district court then made these conclusions of law, among others:

(1) The evidence that Arthur presented was "insufficient to prove that that [sic] the ADOC had inconsistently applied the **protocol's** mandatory consciousness assessment by failing to perform the pinch test during some **executions**, or has otherwise deviated substantially from its **execution protocol**."

(2) Further, Arthur's Equal Protection challenge "to the general adequacy of the ADOC's consciousness assessment, claiming that it should meet certain training and medical standards but does not, also fails." In support, the district court relied on language from Baze and Glossip to hold that "[t]he Eighth Amendment does not require that such medical training and standards or procedures be employed," noting that the Supreme Court held in Baze that a consciousness assessment "much simpler than the one implemented by the ADOC" was not required under the ***1286** Eighth Amendment. Indeed, the district court wrote, there is no constitutional requirement that a state perform a consciousness assessment at all.

(3) Accordingly, "Arthur's attempt to apply a medical standard of care to **execution** procedures and training for them, in this case, procedures that are not required by the Eighth Amendment, does not state a plausible equal protection claim. This principle is applicable to Arthur's Equal Protection claim challenging the 'adequacy' of the consciousness assessment and the training therefor, including the force used in the pinch test."

(4) For these reasons, the district court held that the ADOC was entitled to judgment on the Equal Protection claim.

After entering judgment in the ADOC's favor, the only issue remaining concerned the interplay of the current protocol with Arthur's alleged idiosyncratic health issues and medical condition, which the district court would address later. [12]

X. AS–APPLIED CLAIM

On May 6, 2016, as to Arthur's as-applied claim based on his alleged health issues, the ADOC filed a motion for judgment on the pleadings or, in the alternative, for summary judgment. ADOC's motion argued that, to the extent that Arthur even adequately alleged an Eighth Amendment as-applied challenge based on his health concerns, the Defendants were entitled to summary judgment because (1) Arthur had failed to produce evidence of a genuine disputed fact that the use of midazolam is "sure or very likely to cause serious illness or needless suffering" by causing him to experience a painful heart attack; (2) Arthur had still failed to produce evidence of a genuine disputed fact that there are known and available alternatives that are feasible, readily implemented, and significantly reduce a substantial risk of severe pain; and (3) the district court should reject the "sham affidavits" offered by Arthur in support.

The ADOC attached to its motion a November 16, 2015, declaration by Dr. J. Russell Strader, Jr., Arthur's witness, and a transcript of Dr. Strader's December 8, 2015, deposition. Notably, Dr. Strader's November 2015 declaration about midazolam is his third declaration filed in this case. We first review Dr. Strader's two prior declarations about pentobarbital before addressing his declaration about midazolam.

A. Dr. Strader's 2013 and 2015 Declarations About Pentobarbital

In his first declaration back in March 2013, Dr. Strader criticized the use of pentobarbital for Arthur's execution. Although Arthur wants pentobarbital used now that Alabama cannot obtain it and must use midazolam, it is relevant to consider Arthur's previous position about pentobarbital. Back in 2013, Dr. Strader opined that (1) Arthur's "likelihood of having clinically significant obstructive coronary disease ["CAD"] is at least 70%"; (2) for people with CAD, the use of a 2,500–mg dose of pentobarbital was likely to induce a rapid and dangerous reduction in blood pressure, thereby triggering a heart attack; (3) ***1287** the heart attack would occur more quickly than the appropriate sedation; and (4) "[g]iven the slower onset of the sedative effects of pentobarbital, it is likely that [Arthur] would experience the pain of said heart attack until such time as the sedative effects have onset to a sufficient degree to diminish the pain of the heart attack." (Emphasis added). In short, Dr. Strader's opinion about pentobarbital was that it would take a longer duration of time to induce appropriate sedation than that required for the onset of myocardial ischemia/infarction.

In his March 2013 declaration about pentobarbital, Dr. Strader stated that he was a board-certified cardiologist and the current Chief of Cardiovascular Services at a Texas hospital. As part of his routine clinical practice, he assessed the cardiovascular risk of patients scheduled to undergo surgery and anesthesia and, in particular, he assessed the likelihood that a patient would suffer a heart attack during or immediately after a cardiac procedure.

Dr. Strader's declaration included explanations of the "Hemodynamic and Anesthetic Actions of Pentobarbital and Thiopental," along with an overview of the relevant aspects of cardiovascular anatomy and physiology, coronary atherosclerosis, and myocardial ischemia/infarction. His declaration included an explanation that a coronary artery needs to be 70% obstructed before it is hemodynamically significant. It also stated that, "[i]n clinical practice, myocardial ischemia and infarction can occur due solely and exclusively to a drop in blood pressure" and that this drop in blood pressure may be due to anesthesia.

Dr. Strader's March 2013 declaration admitted that he had not examined Arthur but had reviewed his medical records only up until 2009. Although Dr. Strader's declaration did not indicate precisely what records he reviewed, approximately 68 pages worth of Arthur's medical history was included with the ADOC's summary judgment motion. These medical records indicate that Arthur has repeatedly refused to be seen by a doctor since at least 2009. Arthur was seen in the prison infirmary on January 17, 2009, where he complained of chest pain and atrial fibrillation. Arthur, however, refused medical care on this occasion, including a refusal to submit to an electrocardiogram ("EKG") on January 20, 2009.

The medical records include dozens of similar waivers, signed by Arthur, refusing various medical treatments. These waivers extend from 2009 until 2015. There is no indication that Dr. Strader, as of his first declaration in 2013, had access to or reviewed any probative post–2009 medical records for Arthur. There is also no reference, much less a diagnosis, to Arthur's ever having had a heart attack in his medical records.

According to Dr. Strader's review of Arthur's medical records as of 2009, Arthur was then 71 years old, with a history of hypertension (high blood pressure) and atrial fibrillation (irregular heart rhythm). In June 1999, Arthur visited the prison clinic and he complained of being short of breath, sweaty, and dizzy. According to the prison report, an EKG was performed at that time, and it was "abnormal." Dr. Strader opined that these symptoms are "identical to those experienced by persons with ongoing myocardial infarction."

In October 2004, Arthur was hospitalized for abdominal surgery, and he suffered from atrial fibrillation during that hospitalization. However, an echocardiogram performed around that time came back "essentially normal."

***1288** According to Dr. Strader, an EKG dated January 15, 2009 showed "atrial fibrillation with a rapid ventricular response, along with Q waves in the inferior leads (leads II and aVF)." Dr. Strader opined that, "[t]he abnormalities on this [EKG]" indicated that Arthur had suffered a prior heart attack. A request for a cardiology consult, dated January 26, 2009, indicated that Arthur was experiencing chest pain and rapid heart rate.

After reviewing these medical documents through January 2009, Dr. Strader opined that:

> Arthur's abnormal [EKG] showing evidence of a prior myocardial infarction,[13] history of recurrent atrial fibrillation, age, presence of hypertension, and symptoms of recurrent chest pain, all of which are independent risk factors for coronary heart disease, confer a risk of having clinically significant obstructive coronary artery disease of at least 70% at a minimum, and possibly greater.

Dr. Strader opined that the use of pentobarbital would cause a drop in blood pressure and a heart attack in Arthur before the onset of the drug's sedative effect. Dr. Strader admits the sedative effect from pentobarbital will occur but opines that Arthur will experience pain from a heart attack "until such time" as the sedative effect reduces the pain.

After Alabama changed the first drug from pentobarbital to midazolam, Dr. Strader switched positions and wrote a second declaration. This time, in that second declaration, Dr. Strader now suggested pentobarbital should actually be used in Arthur's **execution** but only as a one-drug **protocol**. Dr. Strader opined that if pentobarbital were used as a one-drug **protocol** and "administered gradually and with due consideration for Mr. Arthur's medical condition," he did not believe that Arthur would suffer a heart attack before being properly anesthetized. Dr. Strader's second declaration was conclusory and gave no specifics on what "administered gradually" would mean or what steps would be necessary as "due consideration for Mr. Arthur's medical condition."

B. Dr. Strader's Nov. 16, 2015 Declaration

In his third declaration, Dr. Strader now criticizes the use of midazolam for use in **executions**, using precisely the same reasoning (and often the exact same wording) used in his earlier declaration condemning pentobarbital. Specifically, Dr. Strader now opines that (1) Arthur's likelihood of having obstructive CAD is at least 70%; (2) for patients with obstructive CAD, a large bolus dose of midazolam is "highly likely" to rapidly reduce blood pressure in patients with this disease, thereby triggering a heart attack; (3) the heart attack would occur before the appropriate sedation from midazolam; and (4) given the length of time between the onset of heart attack and the onset of sedation, "it is likely that Mr. Arthur would experience the pain of the heart attack until the sedative effects take effect to a sufficient degree to diminish the pain of the heart attack, which could occur several minutes after the onset of the heart attack." While the drug at issue was different, Dr. Strader's opinion and reasoning remained the same—that Arthur was "likely" to experience the pain of a heart attack before being fully sedated.

Dr. Strader's November 2015 declaration is essentially a recycled version of his ***1289** original March 2013

declaration, but with the following added information about midazolam:

• As part of his routine clinical practice, Dr. Strader administers "midazolam to patients for the purpose of achieving sedation for invasive cardiac procedures." Dr. Strader has performed approximately 3,500 invasive cardiac procedures in cardiac patients using midazolam as a sedative.

• As to Arthur's likelihood of having CAD, Dr. Strader updated Arthur's age to 73 years old, deleted his earlier declaration's reference to Arthur's normal echocardiogram report in October 2004, and added a paragraph regarding Arthur's family history of "heart trouble."

• In Dr. Strader's clinical experience, "where midazolam in small doses (2–5 mg) is used to sedate patients undergoing invasive cardiac procedures, midazolam's sedative effects generally take 5 minutes or more to take effect" and the hemodynamic effects of the drug can occur more quickly, within 1–2 minutes. (Emphasis added). He stated that, when used in clinical doses, midazolam typically produces a 10–20% drop in blood pressure. Dr. Strader opined that, when midazolam is given in the large 500 mg bolus dose contemplated by the ADOC **protocol**, it is "highly likely that such drop in blood pressure would occur more quickly than it would occur in the administration of a clinical dose."

• Dr. Strader explained that the hemodynamic effects of midazolam occur more quickly than the sedative effects because the effect on vasculature is immediate, while the drug must travel to and affect the brain before sedation takes place. Dr. Strader, however, acknowledged that there is no "institutional experience" regarding a 500–mg dose of midazolam.

C. Dr. Strader's Dec. 8, 2015 Deposition

In his 2015 deposition, Dr. Strader elaborated on this opinion:

1. Likelihood of Arthur having CAD

Dr. Strader reviewed Arthur's medical records but admitted that he had never personally examined Arthur, had never spoken to Arthur, and had never spoken to any doctors who had treated Arthur.

Based on the medical records provided to him, Dr. Strader noted that Arthur had high blood pressure, atrial fibrillation, and abnormalities on his EKGs that were "highly suggestive of coronary disease." Dr. Strader testified regarding the incident in June 1999 (where Arthur visited the prison clinic with complaints of being short of breath, sweaty, and dizzy and then had an EKG come back with "abnormal" results), and he stated that Arthur's symptoms and his abnormal EKG made it "possible" that Arthur had a heart attack back in 1999.

Dr. Strader reiterated his opinion from his declaration that the abnormal EKG, taken on January 15, 2009, was "diagnostic" of Arthur having suffered a previous heart attack, although Dr. Strader could not say when this prior heart attack occurred. When asked if he could diagnose a previous heart attack based just on an EKG, Dr. Strader replied, "Yes. Absolutely." Dr. Strader also referenced the January 2009 request for a cardiology consult contained in Arthur's medical records, but admitted that he did not know whether Arthur was ever actually evaluated by a cardiologist.

2. Midazolam Leads to a Drop in Blood Pressure

In Dr. Strader's opinion, if you administered even a 100–mg dose of midazolam to ***1290** a patient, such large doses "are expected to have ... rapid, significant hemodynamic effects." He explained that "hemodynamic effect" means a drop in blood pressure. To correct this issue, he suggested that doctors would give "pressors," very large amounts of IV fluids and medication, to stabilize the blood pressure.

Dr. Strader testified that, in his clinical practice, drops in blood pressure from 2–5 mg doses of midazolam can occur "within just a minute or two, sometimes sooner." He went on to say that, "extrapolating off of that experience to this very large dose, you would expect to see an extremely rapid and very large drop in blood pressure."

He explained that, for people with obstructed arteries, this rapid blood-pressure drop could result in a heart attack, because "you have to maintain a certain amount of pressure in order to keep fluid going through a tube that's got a fair amount of blockage in it. This is ... applied physics." He further explained that older people, starting at around age 70, tended to have bigger drops in blood pressure in response to the administration of midazolam.

In his deposition, Dr. Strader reviewed the medical articles and other material that he cited in his November 2015 declaration, which he stated lent support to the idea that midazolam leads to a drop in blood pressure. Dr. Strader admitted that (1) none of the articles or materials dealt with such high doses, and (2) none of the articles or materials explicitly stated that midazolam should not be used on people with CAD.

3. The Heart Attack Would Occur Before Sedation

Dr. Strader stated that, based on his clinical experience, the sedation effects of a clinical dose of 2–5 mg of midazolam typically take about five minutes to take effect. He testified that he would typically use this dosage of midazolam on patients before "invasive cardiac procedure[s]." (Emphasis added). When a patient is administered a clinical dose of midazolam (2 to 5 mg), the patient goes into a deep sleep. They can be aroused and spoken to, but they are "very comfortable." (Emphasis added). He explained that in his clinic, he would titrate the midazolam, giving it in small doses until appropriate sedation was achieved. Dr. Strader admitted that he normally gave some sort of pain medication, such as **fentanyl**, along with the midazolam, but that this was not required. He could proceed with the procedure using midazolam alone, although it would require a higher dose. He stated that the largest dose of midazolam he ever administered to a patient was a 20–mg dose, used because the patient had no sedative response to the medication.

While he opined that a 100–mg dose of midazolam would cause sedation within "three to five minutes," he could not give an exact time because such a dose is "far outside of the realm of anybody's clinical experience" and, indeed, the time to sedation "could be a very wide range." When asked about a 250–mg or 500–mg dose of midazolam, Dr. Strader stated that, "I'm not sure anybody really knows to what degree [sedation] would onset." Dr. Strader then indicated he would need to defer to an anesthesiologist about the onset time of sedation from a 500–mg dose of midazolam:

> Q. Now, in an **execution**, is it your opinion that it would take five minutes before a person becomes unconscious if they're administered 500 milligrams of midazolam?
>
> ***1291** [Objection]
>
> A. No, I don't think I gave any opinion as to—as to the timing for ... consciousness to abate.... In a clinical setting, I would defer that to an anesthesiology colleague who is, you know, more familiar with the concept of consciousness. That's outside my realm of practice. Again, I think you'd see a very rapid decrease, almost instantaneous decrease in blood pressure, and hemodynamic effects would be virtually instantaneous.
>
> Q. But regarding the sedative effects, you just don't know how long?
>
> A. I think it would take longer; how much longer, I don't know.
>
> ...
>
> Q. But you can't give us a specific amount of time?
>
> A. No, sir.
>
> Q. Okay.
>
> A. I don't think anybody can give you a specific amount of time.

(Emphasis added).

Dr. Strader later stated he was aware that anesthesiologists use midazolam to induce anesthesia but he had never done that as it was outside the scope of his area of practice:

> Q. Have you ever known an anesthesiologist to use midazolam to cause unconsciousness?
>
> [Objection]
>
> A. I would assume that anesthesiologists use midazolam in part of their routine practice for the—you know, in anesthesia. I don't know the details of what they do, or when they choose, or why they choose what they choose, so ...
>
> Q. But are you aware of it being used to induce anesthesia?
>
> [Objection]

A. I'm aware that it's approved for that use, and I think some anesthesiologists use it for that purpose. I don't have any direct knowledge of what they do.

Q. Okay. So you're never involved in a procedure where an anesthesiologist might use midazolam to induce anesthesia?

[Objection]

A. No, I don't—that's outside the scope of my clinical practice. You know, I just let them choose what they need to choose[.]

(Emphasis added). Similarly, when asked if he knew whether midazolam "is ever used to maintain anesthesia," he replied that the drug "carries an indication for that[, but] I wouldn't have direct knowledge any particular anesthesiologist's use of it for that reason."

Dr. Strader explained that anesthesiologists were not present when he performed his invasive cardiac procedures, and there was no policy or procedure on how much midazolam to give patients. Dr. Strader reiterated that he uses midazolam "in patients with coronary disease all the time in routine clinical practice."

4. Gradual Administration of Pentobarbital

Despite stating in his first declaration that a 2,500–mg bolus dose of pentobarbital was also likely to induce a heart attack, Dr. Strader reiterated his conclusion from ***1292** his second declaration that, if pentobarbital were administered gradually as part of a one-drug **protocol**, he did not believe that Arthur would suffer a heart attack before being properly anesthetized. Dr. Strader admitted he would not know how to administer 2,500 mg of pentobarbital gradually and he would defer on that matter to an anesthesiologist:

A. I wouldn't know how gradual to do it. I know that the analogy holds to what we do with cardiac patients in the cath lab with midazolam. You know, again, we use small doses gradually over longer periods of time in order to prevent acute onset of myocardial ischemia and acute drops in blood pressure.

Q. So when you're talking about 2,500 milligrams, how long would that take—[Objection]—if you administered the drug gradually?

[Objection]

A. I would have no idea.

Q. I mean, are we talking minutes or hours—[Objection]—or do you know?

A. I would—I would defer that to an anesthesiologist who has more experience with the drug.

Q. Well, I mean, you're the one making the sworn declaration, and you said, "administered gradually," and I'm asking you, you know, how gradually would you have to administer it?

[Objection]

A. Yeah. Again, I think it's the general concept that gradual administration in small doses, you know, is the general paradigm to prevent adverse effects. Exactly what "gradual" would be defined as in this instance I wouldn't—I wouldn't know specifics or have specifics to recommend.

Dr. Strader also would not know how to administer a large dose of midazolam gradually but would defer to an anesthesiologist:

Q. Okay. Do you have the same opinion on if midazolam is used in a one-drug **protocol**—[Objection]—if it was administered gradually?

A. I think the general paradigm holds in order to avoid adverse effects with these medications, you administer them in low doses slowly. To what extent midazolam would produce full unconsciousness or anesthesia, again, I would defer that to an anesthesiologist. It's outside of my scope of practice.

(Emphasis added).

D. Dr. Buffington's Nov. 23, 2015 Declaration

As to midazolam, the ADOC offered a declaration from Dr. Daniel Buffington, an expert witness in the field of pharmacy. Dr. Buffington is a clinical pharmacologist who holds a Doctor of Pharmacy and Master of Business Administration degrees. He is on the faculty of the University of South Florida Colleges of Pharmacy and Medicine, and he is also the president of the American Institute of Pharmaceutical Sciences.

Dr. Buffington agreed with Dr. Strader that a common clinical dosage of midazolam is 2 to 5 mg, and that the 500–mg dosage contemplated in the ADOC's **protocol** "is well beyond the dosage of any existing therapeutic application." Dr. Buffington explained that, when clinical doses of midazolam (2–5 mg) are used as an "anesthetic ***1293** induction agent, sedation occurs ... within 2–2.5 minutes without narcotic pre-medications or other pre-medications with sedative effects."

Dr. Buffington stated that the medical literature "contradicts Strader's theoretical concerns" and "[t]here is no scientific or medical evidence to support the theory or concerns that midazolam (IV), at low or high dosages, would result in a significant hypotensive event ... prior to the onset of sedation, or is capable of inducing or worsening ischemic cardiac damage, acute cardiac events, excruciating pain and/or suffering." [14] According to Dr. Buffington, a rapid infusion of midazolam could result in induction of anesthesia in as little as 30 seconds.

E. Midazolam Package Insert

The ADOC also submitted the midazolam manufacturer's package insert with its summary judgment motion. The insert states that sedation is achieved in 3 to 5 minutes after IV injection, and that, when midazolam is given as an anesthetic induction agent, "induction of anesthesia occurs ... in 2 to 2.5 minutes without narcotic premedication or other sedative premedication." (Emphasis added).

F. Dr. Strader's March 29, 2016 Declaration

In February 2016, the district court ordered the parties to meet and confer about a possible modified **execution protocol**. On March 8, 2016, as part of these negotiations, Arthur's counsel sent a letter to the ADOC about gradual administration of midazolam, requesting a trained professional to use several pieces of medical monitoring equipment and to administer other medication:

> [Arthur's] position is that a **protocol** designed to administer midazolam gradually and with due consideration for Mr. Arthur's medical condition—including with medical monitoring of Mr. Arthur's health by a trained professional during the **protocol** with the use of an electroencephalogram, an electrocardiogram, a bispectral index monitor and/or other appropriate methods [which] may reduce to some extent the likelihood of Mr. Arthur suffering the pain of a heart attack during administration of the **protocol**, although it would not ameliorate those risks entirely or address the other previously identified reasons why the use of midazolam in a three-drug **execution protocol** is violative of Mr. Arthur's constitutional rights. Such a modified **protocol** may also require the administration of other medication to prevent cardiac complications.

(Emphasis added).

Arthur also submitted Dr. Strader's fourth declaration, dated March 29, 2016. Dr. Strader stated that he was ethically prohibited from suggesting modifications to a lethal injection **protocol**. Accordingly, he merely explained what precautions are taken and procedures followed when administering midazolam in a clinical setting. Those precautions are:

- administration of midazolam "at a gradual rate closer to that used in clinical practice—i.e., 0.5 mg to 2 mg at a time, repeated every 2 to 4 minutes," along with;

***1294** • a trained professional (although this person need not have a medical degree);

- who assesses the patient's response to the prior dose before continuing with another;
- continuous EKG monitoring;
- continuous pulse oximetry monitoring;
- frequent blood pressure monitoring;
- the ability to give fluids and medication via IV to raise blood pressure; and
- use of the opioid **fentanyl**.

Ultimately, the negotiations reached an impasse with the parties unable to agree on a modified **execution protocol**.

XI. MOTION FOR NEW TRIAL

On May 13, 2016, Arthur moved for a new trial on his Eighth Amendment claim. He claimed that, three months after the trial, he discovered new evidence that compounded pentobarbital is available to the ADOC. He alleged that, after trial, the ADOC proffered Dr. Buffington as an expert for deposition in another case, [15] on March 17, 2016. Arthur alleged that Dr. Buffington said that he "personally knew compounding pharmacists who would be willing to compound pentobarbital for ADOC.... To obtain pentobarbital ... defendants would 'just have to ask'—which they did not do." Arthur attached only excerpts from Dr. Buffington's deposition testimony.

The ADOC opposed Arthur's motion for a new trial, arguing that Arthur had misrepresented Dr. Buffington's testimony. The ADOC submitted a more fulsome excerpt from Dr. Buffington's March 17, 2016, deposition testimony, which reflects that Dr. Buffington actually testified that (1) he knows pharmacists who are capable of compounding pentobarbital and would do it for the ADOC, but that (2) he would have to check with them first before he could give their names to the ADOC:

> Q. And would you be willing to compound pentobarbital for the State of Alabama?
>
> A. I can identify numerous other individuals who would be probably more readily capable based on equipment and site and instrumentation to do that, but I know that there are multiple facilities that can do that.
>
> Q. Would they do it for the Alabama Department of Corrections?
>
> A. We'd just have to ask.
>
> Q. Okay. Is it something—There's a lot of controversy around—The whole reason that we're here is because ***1295** there's been a crackdown on certain drugs by the manufacturers.
>
> A. Well, I wouldn't call it a crackdown. I would say limited market availability.
>
> Q. Right. They won't sell it to Departments of Corrections for **executions**.
>
> A. That's correct.
>
> Q. Are all pharmacists sort of locked in in that regard and wouldn't sell it for purposes of an **execution**?
>
> A. No. I'm sure just like physicians where somebody may exercise a conscious clause that do find that within pharmacy as well. As a matter of fact, it's been an open area of discussion across the country.
>
> ...
>
> Q. So you know a lot of pharmacists from going to conventions and being on the Board [of Trustees of the American Pharmacists Association] and teaching future pharmacists?
>
> A. That's correct.
>
> Q. And you don't think that it would be difficult for you to direct the Alabama Department of Corrections to a compounding pharmacist who would be willing to compound pentobarbital for them? ...
>
> A. I think that's a resolvable question. ... Level of difficulty, how many calls it would take, where that particular practice may reside. I know that they're there.
>
> ...
>
> Q. Have you at any of the conferences that you go to or any of these—You said that it's being discussed, the use of pharmaceuticals for lethal injection.
>
> A. Absolutely.
>
> Q. Okay. Have you ever had a discussion with colleagues at one of these meetings about pentobarbital for lethal injection?
>
> A. Yes.
>
> Q. All right. And when you talked to people, did any of them say I would do it?
>
> A. Yes.

Q. And you know these people personally.

A. Yes.

Q. And would you be willing to provide their names to the Alabama Attorney General?

A. I would check with them first, but what you're asking is would—and I haven't been asked to do this at this juncture—would it be possible to identify appropriately-trained and well-staffed facilities to perform that function, and the answer would be yes.

Q. And assuming that they gave you permission, you would share their information with Mr. Govan or someone from the Alabama Attorney General's office?

A. Or whoever was asking me to do that, yes.

Q. If Ms. Hill, the general counsel for ADOC, asked you, you would assist her if you could?

A. Yes.

Subsequently, Dr. Buffington contacted these pharmacists but none were willing to compound pentobarbital for the ADOC or even allow Dr. Buffington to reveal their names. To show this, the ADOC submitted an affidavit from Dr. Buffington, dated ***1296** April 22, 2016. Dr. Buffington averred that, "[n]one of the 15 pharmacists that I contacted were able and willing to supply compounded pentobarbital for use in lethal injections to the ADOC. In addition, none of the pharmacists provided me permission to share their names and contact information with the ADOC or counsel for the Defendants." (Emphasis added).

In his affidavit, Dr. Buffington further stated that he had testified at his earlier deposition that "the use of pharmaceuticals in lethal injections is an area of open discussion in the pharmacy community and that some colleagues I have encountered at professional events such as national conventions and conferences have commented that they would be willing to compound pentobarbital for use in lethal injections." Dr. Buffington explained that, after that deposition, counsel for the defendants asked him to contact pharmacists and pharmacies "to inquire if any were willing to be contacted directly by the ADOC concerning the performance of this type of technical service." To this end, he contacted 15 pharmacists, both within and outside of Alabama, and asked them "about their capability to compound sterile pentobarbital for intravenous [IV] use."

Dr. Buffington concluded that he maintained his belief that "there are pharmacists in the United States that are able to compound pentobarbital for use in lethal injections because other states have been reported to have obtained [it]," but he was not able to locate any that were willing and able to do so.

XII. DISTRICT COURT'S JULY 19, 2016 ORDER

The district court wrote that, "[d]istilled to its essence, Arthur's as-applied claim is that his cardiovascular issues, combined with age and emotional makeup, [16] create a constitutionally unacceptable risk of pain that will result in a violation of the Eighth Amendment if he is **executed** under the ADOC's current **protocol**." The district court applied, as it must, the same Baze/Glossip standard to Arthur's as-applied challenge as it applied to his facial challenge.

As to Arthur's health issues, the district court concluded Arthur's Third Amended Complaint had failed to plead adequately or properly an "as-applied" claim and, alternatively, the district court questioned whether Arthur had presented sufficient evidence of any truly "unique health concerns" as to his **execution**. But in "an abundance of caution" the district court considered the merits of Arthur's as-applied claim.

Because that "as-applied" claim was based on Dr. Strader's declarations, the district court examined the methodology and foundation, or lack thereof, underlying Dr. Strader's opinions. The district court ultimately concluded that Dr. Strader's opinion was speculative and unreliable under Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). We thus review the district court's analysis of Dr. Strader's opinion and then its reasons for excluding it.

The district court pointed out that these facts are undisputed: (1) Dr. Strader has never examined Arthur; (2) Arthur has repeatedly refused to submit to medical examination; and (3) Arthur has not been seen or examined by a cardiologist since 2009.

***1297** Turning first to the alternative-method prong in Arthur's as-applied claim, the district court determined that "Arthur failed entirely" to establish the existence of a known and available alternative. To the extent Arthur relied on a one-drug **protocol** of pentobarbital or sodium thiopental, the district court found these options were "foreclosed" for the reasons given in its earlier order. [17]

The district court found that Dr. Strader's opinion—that Arthur's blood pressure would drop before sedation took effect—is "speculative and unreliable when extrapolated from a clinical dose of 2 to 5 mg, to a non-clinical, bolus dose of 500 mg." The district court noted that there was no record evidence regarding whether a time "gap"—between midazolam's hemodynamic effects and its sedative effects at a 500–mg dose—would occur at all or, if such a gap does occur, in what sequence it would occur. The district court then "ventur[ed] into [the] technical thicket" of available medical and scientific evidence, parsing it into four parts: (1) the hemodynamic and anesthetic effects of midazolam; (2) a clinical dose for sedation; (3) a clinical dose for anesthesia; and (4) a 500–mg bolus dose.

First, the district court noted that there was evidence that clinical doses of midazolam were known to produce a drop in blood pressure. Moreover, Dr. Strader characterized the drug as both a sedative and an anesthetic.

The district court noted Dr. Strader's testimony that, with a clinical dose (2–5 mg) of midazolam, there was typically a gap of three to four minutes between the hemodynamic effects and the sedation effects of midazolam in clinical practice. But Dr. Strader acknowledged that none of the medical literature he relied on cautioned against using midazolam for patients with CAD and, indeed, Dr. Strader himself used midazolam routinely to sedate his cardiac patients during invasive cardiac procedures. Taking Dr. Strader's claim that he, as a cardiologist, had performed approximately 3,500 cardiac procedures with midazolam as a sedative and only 24 of those patients experienced a heart attack after being sedated, the district court calculated that less than 1% of those 3,500 patients suffered a heart attack following the administration of a clinical dose of midazolam.

The district court also analyzed the evidence regarding use of midazolam for "anesthesia." Dr. Strader had administered midazolam only for sedation purposes—which is a lighter level of sedation than full anesthesia. Dr. Strader "had no opinion as to what would be a clinical dose of midazolam sufficient to induce anesthesia." However, the midazolam package insert explains that, even at small clinical dosage levels, midazolam can induce both sedation and anesthesia in as little as 2 minutes without narcotic premedication. In other words, if a 2–5 mg dose of midazolam produced sedation or anesthesia in two minutes, Arthur had failed to show how long it took a 500–mg dose to achieve ***1298** anesthesia or that both the blood pressure drop and a heart attack would occur before a 500–mg dose achieved anesthesia.

The district court also pointed out that: (1) Dr. Strader had experience with small doses; (2) Dr. Strader declined to offer any opinion about the length of time it would take a 500–mg dose of midazolam to render a patient unconscious, reiterating many times that anesthesia was outside his field of expertise; and (3) nevertheless, Dr. Strader "remained of the opinion that the sedative effects of a 500–mg bolus dose would take longer than the hemodynamic effects."

The district court rejected Dr. Strader's opinion of the time gap as unreliable under Daubert. The district court stressed three reasons. First, Dr. Strader was incapable of saying how much time it would take a 500–mg dose to render a patient unconscious and, therefore, "it is impossible for him to extrapolate a sequence of hemodynamic effect and sedation." Second, any theoretical "gap" between hemodynamic and sedative effects is speculative because this gap is connected with much lower dosages. Third, Dr. Strader himself has never administered more than 20 mg of midazolam during his career. In short, Arthur had provided no "admissible medical expert opinion testimony to establish either the clinical dosage of midazolam necessary to induce anesthesia or the time-frame within which that would occur." (Emphasis added).

Even as to whether Arthur has CAD in the first place, the district court determined that, because Arthur had not submitted to a medical examination since 2009, Dr. Strader's opinion that Arthur suffered from CAD also "borders on being speculative and unreliable." As the district court explained, "[b]oth must exist—the heart condition and the gap [in time between the hemodynamic effects and the sedation effects of midazolam] Dr. Strader expects—for there to be a realistic likelihood of the heart

attack" before sedation takes effect. Based on the evidence as presented, the court determined that "it cannot be said that a heart attack is sure or very likely at all; one cannot make that connection from the medical evidence." Therefore, Arthur had failed to raise a genuine dispute of material fact of a "sure or very likely risk of severe pain in the application of Alabama's **execution protocol** as applied to him," and this failure "dooms his as-applied Eighth Amendment claim."

As to Arthur's motion for a new trial, the district court concluded that "Arthur's 'new evidence' is nothing but generic testimony from Dr. Buffington describing passing conversations he has had with other pharmacists during national conventions concerning the use of pharmaceuticals, including pentobarbital, for lethal injection." However, in his subsequent affidavit, Dr. Buffington actually admitted that he contacted 15 pharmacists and none were willing or able to provide compounded pentobarbital for use in lethal injections for the ADOC. Thus, Dr. Buffington's earlier deposition testimony was not "likely to produce a new result" at trial, and the motion for a new trial was denied.

On July 19, 2016, the district court entered its final judgment in favor of the defendants. Arthur timely appealed the final judgment to our Court. We read the Final Judgment to encompass both the April 15, 2016 and July 19, 2016 orders. This Court ordered expedited briefing, which is now complete as of October 19, 2016. The Alabama Supreme Court has set an **execution** date of November 3, 2016.

XIII. RELEVANT LAW

With this lengthy procedural history in mind, we turn to Arthur's arguments on ***1299** appeal. Before we do so, however, it is helpful to set forth the legal framework within which we must resolve Arthur's claims.

A. Glossip and Baze

The Eighth Amendment prohibits "cruel and unusual punishments." U.S. Const. amend. VIII. The Supreme Court has repeatedly held the death penalty to be constitutional. See Glossip, 135 S.Ct. at 2739. "[I]t necessarily follows that there must be a constitutional means of carrying it out." Id. at 2732–33 (alterations adopted) (quoting Baze, 553 U.S. at 47, 128 S.Ct. at 1529) (internal quotation marks omitted). Further, the Supreme Court has held that "some risk of pain is inherent in any method of **execution**," and that the Constitution does not require "the avoidance of all risk of pain." Id. at 2733 (quoting Baze, 553 U.S. at 47, 128 S.Ct. at 1529).

[1] The Supreme Court has required prisoners seeking to challenge a state's method of **execution** to meet a "heavy burden." Baze, 553 U.S. at 53, 128 S.Ct. at 1533 (internal quotation marks omitted). Thus, in order to succeed on an Eighth Amendment method-of-**execution** claim, the Supreme Court has instructed that prisoners must demonstrate that the challenged method of **execution** presents a risk that is "*sure or very likely* to cause serious illness and needless suffering, and give rise to sufficiently *imminent* dangers." Glossip, 135 S.Ct. at 2737 (quoting Baze, 553 U.S. at 50, 128 S.Ct. at 1531) (internal quotation marks omitted). "To prevail on such a claim, there must be a substantial risk of serious harm, an objectively intolerable risk of harm." Id. (internal quotation marks omitted).

[2] **[3]** This requires more than merely showing "a slightly or marginally safer alternative." Id. (quoting Baze, 553 U.S. at 51, 128 S.Ct. at 1531) (internal quotation marks omitted). Instead, prisoners are required to "identify an alternative that is feasible, readily implemented, and in fact significantly reduces a substantial risk of severe pain." Id. (citing Baze, 553 U.S. at 52, 128 S.Ct. at 1532) (internal quotation marks and alteration omitted). In other words, the prisoner must demonstrate that the risk of severe pain is substantial "when compared to the known and available alternatives." Id. (emphasis added) (citing Baze, 553 U.S. at 61, 128 S.Ct. at 1537). Thus, we must view the two "prongs" of the Baze/Glossip test in concert —it is not enough to ask merely if the risk of severe pain is substantial. Instead, the risk of severe pain must be substantial and objectively intolerable in comparison to an alternative method that is feasible and readily implemented. Id. And that alternative method must "significantly reduce" a substantial risk of severe pain. Id. "As the Supreme Court made abundantly clear in Glossip itself, the burden rests with the claimant to 'plead and prove' both prongs of the test." Brooks, 810 F.3d at 819.

Critical to this case, Glossip involved the same three-drug **protocol** that the ADOC will use in Arthur's **execution**.

135 S.Ct. at 2734–35. In Glossip, the Supreme Court concluded, inter alia, that the petitioner had not "proved that any risk posed by midazolam is substantial when compared to known and available alternative methods of **execution**." Id. at 2737–38. The Supreme Court later repeated that the petitioners had not satisfied their burden of establishing that any risk of harm was substantial when compared to a known and available alternative method of **execution**. Id. at 2738–39.

B. Feasible, Readily Implemented, and Significantly Safer

While the Supreme Court in Glossip did not explicitly define "feasible," "readily implemented," ***1300** or "known and available," it upheld a factual finding that both sodium thiopental and pentobarbital were unavailable to Oklahoma by 2014 for use in **executions** where the state was unable to procure those drugs due to supplier problems. Glossip, 135 S.Ct. at 2733–34, 2738.

And earlier in 2016, in another Alabama-**execution** case, this Court rejected an inmate's claim that the exact same alternatives that Arthur proposes here—namely, single-drug **protocols** of either pentobarbital [18] or sodium thiopental—were alternatives "available to the ADOC that significantly reduce the risk of an unconstitutional level of pain." Brooks, 810 F.3d at 819. [19] This Court concluded that (1) "the fact that the drug [pentobarbital] was available in those states at some point over the past two years does not, without more, make it likely that it is available to Alabama now"; and (2) Brooks had not shown that "there is now a source for pentobarbital that would sell it to the ADOC for use in **executions**." Id. at 819–20.

In that same Alabama-**execution** case, this Court determined that petitioner Brooks had not shown that sodium thiopental was available. Id. at 820–21. Brooks had relied on certain news articles that other states had been able to obtain the drug, but these sources actually undermined his claim that the ADOC "could readily import sodium thiopental." Id. As to Brooks's request for a single-drug midazolam **protocol**, this Court noted that Brooks had conceded that a midazolam-only **protocol** had never been used in an **execution**, and his concession "deeply undercut his claim that it is a known, readily implementable, and materially safer lethal injection alternative." Id. at 821–22. And given the dearth of evidence presented on the safety of this untested alternative, Brooks was unlikely to establish that it was "materially safer than a **protocol** that is identical to one approved by the Supreme Court." Id. at 822 (citing Glossip, 135 S.Ct. at 2734–35).

[4] Viewing these precedents together, we conclude that Glossip's "known and available" alternative test requires that a petitioner must prove that (1) the State actually has access to the alternative; (2) the State is able to carry out the alternative method of **execution** relatively easily and reasonably quickly; and (3) the requested alternative would "in fact significantly reduce [ ] a substantial risk of severe pain" relative to the State's intended method of **execution**. Glossip, 135 S.Ct. at 2737; Brooks, 810 F.3d at 819–23.

With this legal framework in mind, we now address each of Arthur's arguments on appeal in turn.

XIV. PENTOBARBITAL IS NOT AVAILABLE TO ADOC

Arthur claims that the district court erred in finding that he had not carried his burden to show that pentobarbital is a feasible and readily implemented alternative ***1301** method of **execution** available to the ADOC. [20]

The standard of review and burden of persuasion are critical to the resolution of this case. The Supreme Court has made unequivocally clear that, in method-of-**execution** challenges, (1) the district court's factual findings are reviewed under a deferential clear error standard, and (2) the petitioner-inmate bears the burden of persuasion. Glossip, 135 S.Ct. at 2739. This includes the requirement that a plaintiff inmate must "plead and prove a known and available alternative." Id. at 2738, 2739.

In Glossip, the Supreme Court considered a challenge to the identical lethal injection **protocol** at issue in this case—midazolam, followed by a bromide-based paralytic, followed by potassium chloride. Id. at 2734–35. The dosage of midazolam is the same here as in Glossip: 500 milligrams. Id. at 2740. The Glossip plaintiffs brought a § 1983 action alleging that this **protocol**, particularly midazolam, created an unacceptable risk of severe pain and sought a preliminary injunction. Id. at 2731.

The Supreme Court in Glossip affirmed the district court's denial of relief for two reasons. First, it held that the plaintiffs had not identified a "known and available alternative method of **execution** that entails a lesser risk of pain, a requirement of all Eighth Amendment method-of-**execution** claims." Id. (emphasis added). Second, it determined that the district court did not clearly err in finding that the prisoners failed to establish that Oklahoma's use of a large dose of midazolam in its **execution protocol** entailed "a substantial risk of severe pain." Id. We follow the Supreme Court's lead and address the requirements of the Baze/Glossip test in that order: (1) proof of known and available alternatives; (2) proof that 500 mg of midazolam will cause a substantial risk of severe pain and that known and available alternatives will "significantly reduce" that substantial risk of severe pain.

[5] Here, the district court's factual finding that pentobarbital was not available to the ADOC for use in **executions** was not clearly erroneous. On the contrary, substantial record evidence supports that finding, including (1) Arthur's own concession that the ADOC's supply of commercially manufactured pentobarbital expired in November 2013; (2) Dr. Zentner's inability to point to any source willing to compound pentobarbital for the ADOC; and (3) ADOC lawyer Hill's testimony that, despite contacting 29 potential sources for compounded pentobarbital (including the departments of corrections of four states and all of the compounding pharmacies on Dr. Zentner's list), she was unable to procure any compounded pentobarbital for the ADOC's use in **executions**.

Arthur would have us hold that if a drug is capable of being made and/or in use by other entities, then it is "available" to the ADOC. Arthur stresses that: (1) pharmacies throughout Alabama are theoretically capable of compounding the drug; (2) the active ingredient for compounded pentobarbital (pentobarbital sodium) is generally available for sale in the United States; and (3) four other states were able to procure and use compounded pentobarbital ***1302** to carry out **executions** in 2015. [21]

We expressly hold that the fact that other states in the past have procured a compounded drug and pharmacies in Alabama have the skills to compound the drug does not make it available to the ADOC for use in lethal injections in **executions**. The evidentiary burden on Arthur is to show that "there is now a source for pentobarbital that would sell it to the ADOC for use in **executions**." Brooks, 810 F.3d at 820 (emphases added).

To adopt Arthur's definition of "feasible" and "readily implemented" would cut the Supreme Court's directives in Baze and Glossip off at the knees. As this Court explained in Brooks, a petitioner must show that "there is now a source for pentobarbital that would sell it to the ADOC for use in **executions**." 810 F.3d at 820 (emphases added). This Arthur patently did not do. Arthur's own expert witness, Dr. Zentner, could not even identify any pharmacies that had actually compounded an injectable solution of compounded pentobarbital for **executions** or were willing to do so for the ADOC. And when ADOC attorney Hill actually asked the pharmacies identified by Dr. Zentner if they would be willing to compound pentobarbital for the ADOC, they all refused. What's more, Hill contacted no less than 29 potential sources for compounded pentobarbital—including numerous pharmacies and four states' departments of corrections. All of these efforts were unsuccessful.

[6] And while four states had recently used compounded pentobarbital in their own **execution** procedures, the evidence demonstrated that none were willing to give the drug to the ADOC or name their source. As we have explained, "the fact that the drug was available in those states at some point ... does not, without more, make it likely that it is available to Alabama now." Brooks, 810 F.3d at 819. On this evidence, the district court did not clearly err in determining that Arthur failed to carry his burden to show compounded pentobarbital is a known and available alternative to the ADOC. An alternative drug that its manufacturer or compounding pharmacies refuse to supply for lethal injection "is no drug at all for Baze purposes." Chavez v. Florida SP Warden, 742 F.3d 1267, 1275 (11th Cir. 2014) (Carnes, C.J., concurring).

[7] Arthur also argues that the ADOC did not make a "good faith effort" to obtain pentobarbital. Glossip did not impose ***1303** such a requirement on the ADOC. In Glossip, the Supreme Court upheld the district court's factual finding that the proposed alternative drugs were not "available." See Glossip, 135 S.Ct. at 2738. It continued, "[o]n the contrary, the record shows that Oklahoma has been unable to procure those drugs despite a good-faith effort to do so." Id. Nothing in Glossip changed the fact that it is not the state's burden to plead

and prove "that it cannot acquire the drug." Brooks, 810 F.3d at 820.[22] The State need not make any showing because it is Arthur's burden, not the State's, to plead and prove both a known and available alternative method of execution and that such alternative method significantly reduces a substantial risk of severe pain. Glossip, 135 S.Ct. at 2737, 2739.

As an alternative, independent reason for affirmance, we also conclude that even if Glossip somehow imposes a good-faith effort on the State, the ADOC made such an effort here by contacting 29 potential sources for the drug, including four other departments of correction and multiple compounding pharmacies.

Under these record facts, we cannot fault at all the district court's finding that the procurement of compounded pentobarbital was not "feasible and readily implemented as an execution drug in Alabama, nor [was] it readily available to the ADOC."

We also reject Arthur's argument that the district court's ruling was a "nullification" of his Eighth Amendment rights. The district court even waited for Glossip to be decided and then followed Glossip's requirement that the inmate must show that the risk of severe pain from the chosen method is substantial "when compared to the known and available alternatives." Glossip, 135 S.Ct. at 2737 (emphasis added). As we discussed above, Arthur did not show that his alternative was "known and available," much less (as discussed more later) that his suggested alternative "significantly reduce[d]" a substantial risk of severe pain. See id.

[8] As for the alleged risk of severe pain in Alabama's current protocol, "it is difficult to regard a practice as 'objectively intolerable' when it is in fact widely tolerated." Baze, 553 U.S. at 53, 128 S.Ct. at 1532. Both this Court and the Supreme Court have upheld the midazolam-based execution protocol that Arthur challenges here. Glossip, 135 S.Ct. at 2739–40 (noting that "numerous courts have concluded that the use of midazolam as the first drug in a three-drug protocol is likely to render an inmate insensate to pain that might result from administration of the paralytic agent and potassium chloride."); Brooks, 810 F.3d at 818, 819 (concluding that petitioner Brooks had not established a substantial likelihood that Alabama's lethal injection protocol creates a "demonstrated risk of severe pain," and noting that this was "an especially difficult burden" given the Supreme Court's approval of the exact same protocol in Glossip); Chavez, 742 F.3d at 1269 ***1304** (affirming the dismissal of Eighth Amendment challenge to Florida's nearly identical lethal injection protocol that uses 500 mg of midazolam as the first drug).

Indeed, in Glossip, the Supreme Court emphasized that midazolam has been repeatedly and successfully used without problems as the first drug in the three-drug lethal injection protocol. 135 S.Ct. at 2734, 2740–46. The Supreme Court observed that, in October 2013, Florida became the first state to substitute midazolam for pentobarbital as part of a three-drug protocol. Id. at 2734. The Supreme Court stressed that, at the time that it decided Glossip in June 2015, Florida had conducted 11 executions using this lethal injection protocol (with midazolam as the first drug). Id. (citing Brief for State of Florida as *Amicus Curiae* 2–3 and Chavez, 742 F.3d at 1269). The Glossip Court noted that 12 executions total (including the 11 from Florida and one from Oklahoma) had been conducted using this three-drug protocol "without any significant problems." Id. at 2734, 2746. Since then, Florida has executed two additional inmates under that protocol. See Execution List: 1976—present, FLA. DEP'T OF CORR., http://www.dc.state.fl.us/oth/deathrow/execlist.html (providing the list of executed Florida inmates); Execution by Lethal Injection Procedures, FLA. DEP'T OF CORR. (Jan. 9, 2015), http://www.dc.state.fl.us/oth/deathrow/lethal-injection-procedures-as-of_01-09-15.pdf (describing Florida's current lethal injection protocol).

Arthur has failed to show not only that compounded pentobarbital is an available alternative to the ADOC but also that ADOC's protocol creates a substantial risk of severe pain when compared to available alternatives. See Glossip, 135 S.Ct. at 2737.

For all of these reasons, we affirm the district court's determination that the ADOC was entitled to judgment on Arthur's facial Eighth Amendment challenge.

XV. DISCOVERY CLAIM

[9] Before leaving pentobarbital, we address one more claim Arthur raises about that drug. Arthur argues that the district court abused its discretion in limiting his

discovery regarding primarily the ADOC's knowledge of and efforts to obtain compounded pentobarbital as an alternative method of **execution**. We review the district court's discovery decisions for abuse of discretion. Burger King Corp. v. Weaver, 169 F.3d 1310, 1315 (11th Cir. 1999); Sanderlin v. Seminole Tribe of Fla., 243 F.3d 1282, 1285 (11th Cir. 2001) (explaining that this Court reviews a district court's denial of a motion to compel discovery for abuse of discretion). As we have explained:

> A district court has wide discretion in discovery matters and our review is "accordingly deferential." A court abuses its discretion if it makes a "clear error of judgment" or applies an incorrect legal standard. Moreover, a district court's denial of additional discovery must result in substantial harm to a party's case in order to establish an abuse of discretion.

Bradley v. King, 556 F.3d 1225, 1229 (11th Cir. 2009) (citations omitted).

[10] Here, the district court did not disallow all discovery about pentobarbital but did restrict the scope of some additional discovery. For example, the district court allowed additional discovery as to the "availability or unavailability of pentobarbital or compounded pentobarbital" to the ADOC, including a general description of the State's "efforts to obtain pentobarbital, including whether the pentobarbital was ***1305** obtained and, if not, the reasons why it could not be obtained." This information was precisely what Arthur needed to prove his Eighth Amendment claim.

Accordingly, during ADOC lawyer Hill's November 2015 deposition and again at the January 2016 trial, Arthur questioned Hill about the ADOC's attempts to obtain compounded pentobarbital. According to Hill, although she repeatedly attempted to obtain compounded pentobarbital from various sources, including the 18 pharmacies identified by Arthur's expert witness, all of her attempts were unsuccessful.

Arthur complains that the district court did not require the ADOC to disclose the names of the drug suppliers who talked to the ADOC about pentobarbital during the ADOC's efforts to procure the drug for **executions**. Given the controversial nature of the death penalty, it is not surprising that parties who might supply these drugs are reluctant to have their names disclosed.

Considering the district court's broad discretion, we cannot say its decision about discovery resulted in "substantial harm" to Arthur's case. See Bradley, 556 F.3d at 1229.

On appeal, Arthur argues that "if discovery revealed" that ADOC did not pursue certain sources, or "if discovery revealed" that negotiations broke down over prices, it would impact his claim. He worries that, without access to this discovery, the ADOC "could have presented self-serving representations." All of this is pure speculation. Arthur never deposed or questioned even the prospective suppliers that his own expert identified about whether they would provide compounded pentobarbital to the ADOC. Arthur has given us no reason to think that the ADOC lied or presented false evidence either during discovery or at trial and, indeed, the district court noted that the ADOC had claimed to produce everything of relevance. Under these circumstances, we cannot say that the district court abused its discretion in denying the discovery sought by Arthur.

XVI. AS–APPLIED EIGHTH AMENDMENT CLAIM

[11] **[12]** Because Arthur's facial Eighth Amendment claim so readily fails, Arthur turns his focus in this appeal to his "as-applied" Eighth Amendment claim. We explain why the district court did not err in granting summary judgment on Arthur's "as-applied" claim. [23]

The first hurdle for Arthur is that the pleading burden and standard of proof set forth in Baze and Glossip apply to both facial and as-applied Eighth Amendment method-of-**execution** claims. See Gissendaner v. Comm'r, Ga. Dep't of Corr., 803 F.3d 565, 569 (11th Cir.), cert. denied sub nom. Gissendaner v. Bryson, —— U.S. ——, 136 S.Ct. 26, 192 L.Ed.2d 996 (2015) ("[T]here is no logical reason why there should be a readily available alternative requirement in facial challenges to lethal injection **protocols** but not to as-applied challenges to them."); see id. at 568–69 (holding that a Georgia death-row inmate ***1306** had failed to adequately allege that there was a substantial risk to her personally because the

state had improperly stored the particular drug to be used at her execution).

Thus, Arthur had the burden to present evidence sufficient to create a genuine issue of disputed material fact as to whether midazolam creates a substantial risk of severe pain as applied to him uniquely "when compared to the known and available alternatives" for his execution as applied to him. Glossip, 135 S.Ct. at 2737; Gissendaner, 803 F.3d at 568–69. This he did not do. We address Arthur's proposed alternatives and then Arthur's allegation that midazolam will affect him differently and uniquely from other inmates by causing him to experience the pain of a heart attack a few minutes before being rendered unconscious.

A. As–Applied Alternatives

[13] As to the alternative-method requirement for his as-applied claim, Arthur has not established, as explained above, that a one-drug protocol consisting of compounded pentobarbital (or, for that matter, a one-drug protocol consisting of sodium thiopental) is a "known and available" alternative to the ADOC at this time for any inmate, much less as to Arthur on November 3, 2016. That leaves only his proposed alternative of material and extensive modifications to Alabama's current protocol, which Arthur suggests will reduce "to some extent" but not eliminate the risk of his having a heart attack. [24]

Arthur's proposed modified protocol has many components, starting with the administration of midazolam gradually. In his fourth declaration, Dr. Strader opined that administration of midazolam at a rate "closer to that used in clinical practice—*i.e.*, 0.5 mg to 2 mg at a time, repeated every two to four minutes" would reduce the risk of a precipitous drop in blood pressure. Dr. Strader's fourth declaration does not state how long these small dosages should be administered to the inmate, what the intended effect would be, how to gauge when that intended effect would be reached, at what point unconsciousness would be reached in gradual administration, or at what point the second and third drugs should be administered. Arthur concedes, as he must, that a gradual administration of midazolam has not previously ever been used in a lethal-injection execution, which alone suggests Arthur's difficulty in proving that a gradual administration is a significantly safer alternative. See Brooks, 810 F.3d at 821–22 (concluding that the petitioner had not met his burden of showing that a midazolam-only protocol was a "feasible, readily implementable, and significantly safer" method of execution where such a protocol had never been used).

Arthur's proposed modified protocol also includes extensive monitoring with multiple pieces of sophisticated medical equipment, the use of additional "medication" and IV fluids, and the attendance of a "trained professional." Arthur's March 8, 2016, letter to the ADOC's attorneys requested that a "trained professional" use an electroencephalogram, an electrocardiogram ("EKG"), and a bispectral index monitor "and/or other appropriate methods" ***1307** to monitor Arthur throughout the execution. Arthur also requested the availability of "other medication to prevent cardiac complications."

Dr. Strader echoed that, "[i]n the clinical setting, continuous EKG monitoring, continuous pulse oximetry monitoring ... and frequent blood pressure monitoring (every one to two minutes) are common." As to the additional medication and fluids, Dr. Strader stated that, "[i]n clinical practice," if a patient is in danger of a heart attack, "pressors" or "agents to increase blood pressure are typically given, such as intravenous phenylephrine (Neosynephrine) or intravenous dopamine." In addition, "in clinical practice, the opioid fentanyl is often administered with midazolam, and the drug romazicon may be used to reverse midazolam's effects."

Again, Arthur's proposed modified protocol is light on specifics. Other than Dr. Strader's assertion that the "trained professional" need not hold a medical degree, Arthur does not posit what training, or how much training, this professional must have, who this person might be or where the ADOC might find them to participate in an execution within a prison setting. Arthur does not explain how the addition of five separate monitoring machines and/or procedures would be incorporated into the ADOC's current protocol. Arthur does not state what sort of anomaly in that monitoring would require action by the trained professional, nor what those actions would include.

While Dr. Strader stated that "changes in EKG monitoring" indicating the onset of a heart attack could lead to the administration of pressors, he does not state

what sort of "changes" would require this, the amount of pressors to be given, or in what order in relation to the rest of the lethal injection **protocol** they should be administered. Arthur does not suggest at what dosage the trained professional would administer the opioid **fentanyl** or the drug romazicon to the inmate or under what factual circumstances those drugs should be administered and for how long. Arthur also has presented no evidence that suppliers would provide these medicines, such as **fentanyl**, to the ADOC for use in **executions**.

More importantly, though, is that Arthur admitted in a letter to the ADOC's counsel that his proposed modified **protocol** "may reduce to some extent the likelihood of Mr. Arthur suffering the pain of a heart attack during administration of the **protocol**, although it would not ameliorate those risks entirely." (emphases added). Glossip cautions us that prisoners cannot successfully challenge a method of **execution** " 'merely by showing a slightly or marginally safer alternative.' " 135 S.Ct. at 2737 (quoting Baze, 553 U.S. at 51, 128 S.Ct. at 1531). But a "marginally safer" alternative is, at best, all that Arthur has suggested. It is not enough to meet his burden under Glossip and Baze. See Baze, 553 U.S. at 56–57, 128 S.Ct. at 1534–35 (rejecting the petitioners' proposed alternative method of **execution** where there was no evidence demonstrating that it was an "equally effective manner" of death than the three-drug **protocol** used in Kentucky); Brooks, 810 F.3d at 821–22 (holding that, given the lack of available evidence regarding a midazolam-only lethal injection **protocol**, Brooks was unlikely to establish "that a heretofore untested lethal injection **protocol** ... is materially safer than a **protocol** that is identical to one approved by the Supreme Court [in Glossip.]").

Alternatively, we agree with the district court that Arthur has not introduced any ***1308** evidence of sufficient specifics to make his proposed modified **protocol** a viable and feasible alternative method of **execution** that the ADOC could "readily implement" for his **execution** on November 3, 2016. Arthur argues that he could not provide more specifics because doctors are prohibited from participating in lethal injections.[25] This seems contradicted by Dr. Strader's testimony, which outlines the broad components of Arthur's proposal, albeit without many of the specifics necessary to implement it.

In any event, we need not rely on the lack of specifics because Arthur has not shown that his proposed modified **protocol** will "significantly reduce" any "substantial risk of severe pain" or is constitutionally required.[26] See Glossip, 135 S.Ct. at 2737. If anything, the vastly reduced levels of midazolam seem more complicated and designed to prolong the **execution** proceeding itself, which may create more, not less, risk of error.

Thus, the district court did not err in concluding that there was no genuine dispute of material fact as to whether Arthur could meet his burden of proof to show that his proposed material and extensive changes to the midazolam **protocol** would be a known and available alternative that would "significantly reduce a substantial risk of severe pain." Without a proper showing on this alternative-method prong, Arthur's as-applied Eighth Amendment claim is without merit and this alone warranted the district court's grant of summary judgment. However, because the district court went on to address the substantial-risk-of-severe-pain prong of the Baze/Glossip test, and Arthur's arguments on appeal focus on this portion of the district court's order, we too will consider that issue.

B. As–Applied Substantial Risk of Severe Pain

[14] To be clear, because, in his as-applied claim, Arthur has not carried his burden to show a known and available alternative, we need not reach his claim that the ADOC's use of 500 mg of midazolam ***1309** will cause him uniquely to suffer a heart attack a few minutes before full sedation. But we do so because it is so apparent that Arthur's as-applied claim fails on that separate prong too. Indeed, Arthur failed to present any admissible evidence that 500 mg of midazolam, as applied to him, will cause a heart attack before full sedation. Dr. Strader is Arthur's only expert witness on this as-applied issue. And the district court excluded this time-gap part of his opinion testimony under Daubert.

[15] **[16]** **[17]** **[18]** We review a district court's decision to exclude expert testimony under Daubert for an abuse of discretion. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 142–43, 118 S.Ct. 512, 517, 139 L.Ed.2d 508 (1997). Under this standard, this Court defers to the district court's ruling unless it is manifestly erroneous. Quiet Tech. DC–8, Inc. v. Hurel–Dubois UK Ltd., 326 F.3d 1333, 1340 (11th Cir. 2003). This deferential standard is not relaxed even

though a Daubert ruling may be outcome determinative. Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1334–35 (11th Cir. 2010). In addition, the party offering the expert has the burden of proving the admissibility of the testimony by a preponderance of the evidence. Id.

Federal Rule of Evidence 702 governs the admission of expert testimony in federal court and provides that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Applying these principles, this Court has held that, to be admissible, three requirements must be met:

> First, the expert must be qualified to testify competently regarding the matter he or she intends to address. Second, the methodology used must be reliable as determined by a Daubert inquiry. Third, the testimony must assist the trier of fact through the application of expertise to understand the evidence or determine a fact in issue.

Kilpatrick, 613 F.3d at 1335.

[19] Dr. Strader is a qualified cardiologist and competent to testify as such. But Dr. Strader's opinion testimony hinged on the existence of a measurable time gap between the hemodynamic and sedative effects of a 500–mg dose of midazolam on patients with CAD. The district court's Daubert exclusion was based on Dr. Strader's methodology being speculative and unreliable.

Dr. Strader's opinion was based on at least five underlying ingredients in his methodology mix: (1) Arthur actually has, or is "highly likely" to have, a clinically significant case of CAD; (2) a 500–mg dose of midazolam will result in a precipitous and dangerous blood pressure drop in Arthur; (3) that blood pressure drop will in turn trigger a heart attack in Arthur; (4) the sedative effects of a 500–mg dose of midazolam will take longer than both this hemodynamic effect and the heart attack to occur; and (5) due to this time gap, ***1310** Arthur is "likely" to feel the pain of the heart attack for a few minutes before he is rendered fully unconscious. The district court, in effect, concluded that each of these steps in Dr. Strader's methodology were speculative and not reliable. Without even one of these steps, Dr. Strader's opinion folds like a house of cards. We explain why the district court did not abuse its discretion in concluding that Dr. Strader's methodology was unreliable and in excluding his time-gap opinion.

First, we address Dr. Strader's medical opinion that Arthur "likely" has CAD. It is undisputed that (1) no doctor has ever actually diagnosed Arthur with CAD; and (2) Dr. Strader himself has never examined Arthur, talked to Arthur's treating physicians, or done anything more than review the medical records given to him. Further, Arthur's medical records nowhere state that Arthur has ever had a heart attack, has ever been diagnosed with a heart attack, or has ever had a procedure performed to assess whether Arthur has any blockage in his arteries or at what level.

The most the medical records say is that Arthur had "abnormal" EKGs in 1999 and 2009, twice had atrial fibrillation (during his 2004 abdominal surgery and his 2009 EKG), and had a normal echocardiogram in 2004. There is no description of what was "abnormal" in the EKGs. Arthur did visit the prison clinic on two occasions complaining of being short of breath, dizzy, sweaty, and/or having chest pains. But these two visits (in 1999 and 2009) were ten years apart, and Arthur has never requested any medical treatment from a cardiologist.

In fact, Dr. Strader relies primarily on Arthur's age, hypertension, atrial fibrillation, and "symptoms of recurrent chest pain" as merely "risk factors" for coronary heart disease, as opposed to the missing diagnosis of coronary heart disease. The State argues that it was not an abuse of discretion for the district court to find Dr.

Strader's opinion—that it was "highly likely" that Arthur suffers from CAD—"borders on being speculative and unreliable." The State asserts that a "likelihood" is not evidence that Arthur actually suffers from an obstructive coronary heart condition.

We need not resolve the CAD debate because the district court did not abuse its discretion in concluding Dr. Strader's time-gap theory was speculative and not reliable. We will assume that Arthur likely has CAD and examine the next steps in Dr. Strader's methodology. Dr. Strader offered the opinion that "[w]hen midazolam is administered in doses larger than those administered in clinical practice, including the 500 mg dose directed by the ADOC **protocol**, it is highly likely that" the drug will cause a rapid drop in blood pressure and that this drop will in turn "immediate[ly]" cause a heart attack in Arthur. Dr. Strader's basis for his opinion about what will happen upon administration of a 500–mg bolus dose of midazolam is based solely on his clinical experience with dosages of 2–5 mg of midazolam that he has used to sedate his own cardiac patients into a deep, but arousable, sleep for invasive cardiac procedures. Dr. Strader admitted that he had no experience with a 500–mg dose of midazolam, or any dose larger than 20 mg. See Glossip, 135 S.Ct. at 2742 (stating that "[t]he effect of a small dose of midazolam has minimal probative value about the effect of a 500–milligram dose.").

In his deposition, Dr. Strader conceded that the medical literature that he relied upon did not address such large doses of midazolam nor did it expressly state that ***1311** midazolam should not be used on patients with CAD. Indeed, Dr. Strader admitted that he uses midazolam "in patients with coronary disease all the time in routine clinical practice." Dr. Strader testified that he has only observed about 24 patients (some his cardiac patients and some not) who were sedated with midazolam suffer a heart attack. If compared to the approximately 3,500 invasive cardiac procedures that Dr. Strader has performed, that works out to less than 1% of all his cardiac patients.

Nonetheless, we will assume that Arthur likely has CAD and 500 mg of midazolam will cause Arthur "likely" to have a drop in blood pressure and then suffer a heart attack. The most critical, but most speculative, part of Dr. Strader's opinion is his time-gap theory. According to Dr. Strader's best guess, a 500–mg dose of midazolam could cause sedation in three to five minutes, but the heart attack will occur "immediately" after the drop in blood pressure, which he testified happens in one to two minutes with small clinical doses of midazolam. Dr. Strader's time gap is imprecise and even, under one reading of his own testimony, it may take two minutes for the blood pressure to drop but the sedation may occur in three minutes, leaving one minute for the heart attack to start before sedation. The district court did not abuse its discretion in concluding this time-gap part of Dr. Strader's testimony was speculative and unreliable.

Here, Dr. Strader admitted he had used midazolam only for sedation, an entirely different goal than what the ADOC uses it for: anesthesia. And sedation, as Dr. Kaye testified, is different from anesthesia—it is a lighter form of unconsciousness. Dr. Strader is not an anesthesiologist. While Dr. Strader testified that he was aware that midazolam was approved for use in "anesthesia," and he "thinks some anesthesiologists use it for that purpose," Dr. Strader did not have "any direct knowledge of what they do." The midazolam package insert corroborates this difference between sedation and anesthesia, noting that while "sedation" may take 3–5 minutes, use of midazolam as an anesthetic induction agent can take as little as 2 minutes without narcotic premedication.[27] Even Dr. Strader acknowledges it can take up to two minutes for the blood pressure drop to occur, with the heart attack beginning thereafter.

Moreover, it is uncontroverted that midazolam's sedative or anesthetic effect is dose-dependent, meaning that the effects of midazolam are stronger and occur more quickly with an increase in the dosage. Dr. Strader could not give an opinion about how long it would take a person to be rendered unconscious after being given a 500 mg dose of midazolam because that is "outside [his] realm of practice."

As to his time gap estimate, Dr. Strader only extrapolated from his clinical practice of 2–5 mg of midazolam as to the onset of both the sedative and hemodynamic effects of 500 mg of midazolam. Arthur is correct that, in certain situations, opinions based on extrapolations from available data are permissible. Glossip, 135 S.Ct. at 2740, 2741 (explaining that "because a 500-milligram dose is never administered for a therapeutic purpose, extrapolation was ***1312** reasonable."). But merely because extrapolation may be reasonable in some

circumstances, does not mean that all extrapolated opinions are reliable.

Simply put, Dr. Strader presented only speculative evidence regarding the first number in his attempt at a time-gap measurement. Indeed, when asked how long it would take to render a patient unconscious using a 500–mg dose of midazolam, he was never able to provide an answer, acknowledging that this was "outside [his] realm of practice." The problem for Arthur is not that Dr. Strader engaged in extrapolation, it is that Dr. Strader did not have sufficient information to extrapolate from. In other words, while an opinion based on extrapolation is allowed, there must be some basis for that extrapolation. While experts "commonly extrapolate from existing data ... nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." Joiner, 522 U.S. at 146, 118 S.Ct. at 519. Rather, the district court is allowed to "conclude that there is simply too great an analytical gap between the data and the opinion proffered." Id.

When carefully analyzed, it is apparent that the methodology Dr. Strader used to reach his opinion regarding the time "gap" between the hemodynamic and sedative effects of midazolam was not reliable, nor was Dr. Strader qualified to testify competently as to these matters. See Kilpatrick, 613 F.3d at 1335. Thus, the district court did not abuse its discretion in ruling that Dr. Strader's ultimate opinion that Arthur was likely to suffer a heart attack upon administration of 500–mg of midazolam before being rendered unconscious was speculative, inadmissible under Daubert, and insufficient to meet Arthur's burden.

Without Dr. Strader's opinion, Arthur had no evidence whatsoever to meet his burden of demonstrating that, as applied to him, Alabama's current lethal injection **protocol** was "sure or very likely to cause serious illness and needless suffering, and give rise to sufficiently imminent dangers." Glossip, 135 S.Ct. at 2737 (emphasis and internal quotation marks omitted). Thus, there was no genuine dispute of material fact on this "as-applied" claim, and the district court properly granted summary judgment for the ADOC.

But even if Dr. Strader's opinion as to the time gap should have been admitted, it does not change the fact that Arthur has not met his burden to show a known and available alternative method of **execution** (for him with his health concerns) that "significantly reduce[s]" a substantial risk of severe pain in Arthur. See id. (internal quotation marks omitted).

XVII. EQUAL PROTECTION CLAIM ABOUT CONSCIOUSNESS ASSESSMENT

[20] Arthur argues that the district court erroneously applied Eighth Amendment law from Baze and Glossip to his distinct Fourteenth Amendment Equal Protection claim. Arthur claims that members of the ADOC's **execution** team (1) did not perform the consciousness assessment properly; and (2) were not medically or adequately trained on the consciousness assessment, which requires they pinch inmates with enough force to "gauge anesthetic depth." Arthur contends that, if Alabama is to use a consciousness assessment as part of its **execution protocol**, the assessment should be performed adequately.

At trial, the parties presented conflicting evidence as to whether the ADOC **execution** ***1313** team had adequately performed the consciousness assessment at past **executions**. The district court made a factual finding that the testimony from ADOC's witnesses were to be afforded more weight and, accordingly, it found that the assessment had been adequately performed "in every instance" based on ample evidence. The district court's findings were not clearly erroneous. [28]

Relying on language from Baze and Glossip, the district court also determined that the Eighth Amendment does not require that "sophisticated" medical training and standards be employed in a consciousness assessment during an **execution**. Summing up, the district court wrote that:

> Arthur's attempt to apply a medical standard of care to **execution** procedures and training for them, in this case, procedures that are not required by the Eighth Amendment, does not state a plausible equal protection claim. This principle is applicable to Arthur's Equal Protection claim challenging the

> "adequacy" of the consciousness assessment and the training therefor, including the force used in the pinch test.

The district court did not err in rejecting the training portion of Arthur's Equal Protection claim. Arthur's arguments ignore the district court's explicit factual finding that "the consciousness assessment has been adequately performed in every instance in which it was required, [and] no deficiency in training, practice, or procedure is found," which led to the court's conclusion of law that the ADOC had not "otherwise deviated substantially from its **execution protocol**." (Emphasis added).

Moreover, we discern no error in the district court's application of Baze and Glossip to Arthur's Equal Protection claim. As we previously explained in our 2012 opinion, the crux of Arthur's Equal Protection claim was whether "Alabama has substantially deviated from its **execution protocol** in a manner that significantly reduces inmate safeguards" and whether this "reduction in safeguards burdens his right to be free from cruel and unusual punishment." Arthur, 674 F.3d at 1263. The district court's conclusions regarding whether Alabama had substantially deviated from its **execution protocol** thus implicates Arthur's right to be free from cruel and unusual punishment. As to this issue, the Equal Protection question necessarily intertwines with Eighth Amendment principles.

To satisfy Arthur, all ADOC **execution** team members must pinch inmates with approximately identical force and pinch as hard as they can because this is the standard used in a medical setting. But this is not what the Constitution requires. In Baze, the petitioners faulted Kentucky's **protocol** for lacking a system to monitor the prisoner's anesthetic depth. 553 U.S. at 58–59, 128 S.Ct. at 1536. Although Kentucky had other safeguards in place, including "visual inspection" by the warden and deputy warden of whether the inmate was unconscious, the petitioners requested that "qualified personnel ... employ monitoring equipment, such as a Bispectral Index (BIS) monitor, blood pressure cuff, or EKG to verify that a prisoner has achieved sufficient unconsciousness before injecting the final two drugs." Id. at 59, 128 S.Ct. at 1536. The petitioners claimed that visual ***1314** inspection by the warden and deputy warden "is an inadequate substitute for the more sophisticated procedures they envision." Id. The Supreme Court rejected the petitioners' argument, writing that "these supplementary procedures, drawn from a different context, are [not] necessary to avoid a substantial risk of suffering." Id. at 60, 128 S.Ct. at 1536.

And in Glossip, the Supreme Court pointed to its conclusion in Baze that "although the medical standard of care might require the use of a blood pressure cuff and an [EKG] during surgeries, this does not mean those procedures are required for an **execution** to pass Eighth Amendment scrutiny." 135 S.Ct. at 2742. Thus, the Glossip Court concluded, "the fact that a low dose of midazolam is not the *best* drug for maintaining unconsciousness during surgery says little about whether a 500–milligram dose of midazolam is *constitutionally adequate* for purposes of conducting an **execution**." Id.

We leave for another day the question of whether an additional safeguard such as Alabama's consciousness assessment is constitutionally required under the Eighth Amendment. It is enough that the district court found that Alabama does conduct the consciousness assessment as part of its lethal injection **protocol**, and the Supreme Court has made clear that the safeguards implemented during an **execution** need not match a medical standard of care. See Baze, 553 U.S. at 58–60, 128 S.Ct. at 1536; Glossip, 135 S.Ct. at 2742. Thus, whether the **execution** team at Holman pinches inmates with the same level of force used during medical practice is not dispositive of this claim. In other words, because a medical-grade pinch is not required under the Constitution, there can be no Equal Protection claim that such a medical-grade pinch is not uniformly performed. Thus, the district court's rejection of Arthur's Equal Protection claim is due to be affirmed.

XVIII. FIRING SQUAD CLAIM

Arthur argues that the district court improperly denied him leave to amend his Second Amended Complaint to plead the firing squad as an alternative method of **execution**. Arthur made this request in August 2015, four years after he filed this third § 1983 action back in 2011 and 13 years after Alabama adopted lethal injection as its method of **execution**.

[21] **[22]** The district court's operative order did not expressly state that its denial was based either on futility (as Arthur claims) or on prejudice and undue delay (as the State contends), although it listed all of these as reasons that it could deny leave to amend under the law. Instead, the district court concluded that "**execution** by firing squad is not permitted by [Alabama] statute and, therefore, is not a method of **execution** that could be considered either feasible or readily implemented by Alabama at this time." Even under a de novo standard of review, [29] we affirm the district court's denial of leave to amend, but on ***1315** multiple grounds, including futility, as Arthur never showed Alabama's current lethal injection **protocol**, per se or as applied to him, violates the Constitution.

Again, under controlling Supreme Court precedent, Arthur had the burden to plead and prove both that (1) Alabama's current three-drug **protocol** is "sure or very likely to cause serious illness and needless suffering, and give rise to sufficiently imminent dangers"; and (2) there is an alternative method of **execution** that is feasible, readily implemented, and in fact significantly reduces the substantial risk of pain posed by the state's planned method of **execution**. Glossip, 135 S.Ct. at 2737 (quoting Baze, 553 U.S. at 50, 128 S.Ct. at 1520) (internal quotation marks and emphasis omitted). Arthur has not satisfied either prong.

Because Arthur did not satisfy the first prong as to midazolam, that means his firing-squad claim fails in any event. Indeed, as outlined in great detail above, Arthur has not carried his heavy burden to show that Alabama's current three-drug **protocol**—which is the same as the **protocol** in Glossip—is "sure or very likely to cause" Arthur serious illness, needless suffering, or a substantial risk of serious harm. See id. at 2737 (internal quotation marks and emphasis omitted). The district court stayed Arthur's **execution** and then waited for Glossip to be decided. Both the Supreme Court and this Court have upheld the midazolam-based **execution protocol** that Arthur challenges here. See Glossip, 135 S.Ct. at 2739–40; Brooks, 810 F.3d at 818–19; Chavez, 742 F.3d at 1269, 1273. And even as applied to Arthur individually, Arthur did not present any admissible evidence or carry his burden to show that his **execution** under Alabama's lethal injection **protocol** would cause him to suffer a substantial risk of serious harm.

[23] As an alternative and independent ground, even if Arthur had proved midazolam may likely cause him harm, which he has not done, Arthur's proposed amendment failed to show that **execution** by firing squad is a feasible, readily implemented, and significantly safer alternative method of **execution** when compared to Alabama's planned lethal-injection method of **execution** that has been repeatedly approved by the courts and successfully carried out in the past. See Glossip, 135 S.Ct. at 2734, 2740–46.

Alabama's **execution** statute is Ala. Code § 15–18–82.1. By way of review, that statute allows all persons sentenced to death to choose between two methods of **execution**, providing that death sentences "shall be **executed** by lethal injection, unless the person sentenced to death affirmatively elects to be **executed** by electrocution." Ala. Code § 15–18–82.1(a) (emphasis added). Only if "electrocution or lethal injection is held to be unconstitutional by the Alabama Supreme Court ... [or] the United States Supreme Court ..., or if the United States Supreme Court declines to review any judgment holding a method of **execution** to be unconstitutional ... made by the Alabama Supreme Court or the United States Court of Appeals that has jurisdiction over Alabama" can the ADOC carry out Arthur's **execution** by "any constitutional method of **execution**." Id. § 15–18–82.1(c). And, finally, "[i]n any case in which an **execution** method is declared unconstitutional, the death sentence shall remain in force until the sentence can be lawfully **executed** by any valid method of **execution**." Id. § 15–18–82.1(h).

Arthur's main argument has three parts: (1) that under the Alabama statute, Alabama can **execute** him by "any constitutional method of **execution**," (2) that a firing ***1316** squad is still today a constitutionally valid method of **execution**, and (3) that Alabama cannot prevent him from electing to have a firing squad as his preferred constitutional method. This claim misreads the text of the Alabama statute and Supreme Court case law and fails for multiple reasons.

First, it is undisputed that a firing squad is not a currently valid or lawful method of **execution** in Alabama. Therefore, an Alabama state trial court would be without any authority to order Arthur to be **executed** by firing squad, just as the ADOC would be without authority to **execute** Arthur by that method, without the Alabama legislature fundamentally rewriting the state's method-of-**execution** statute or one of the courts named in the

statute already striking down as unconstitutional either electrocution or lethal injection. But neither electrocution nor lethal injection has been declared unconstitutional by this Court, the Alabama Supreme Court, or the United States Supreme Court.

In this § 1983 suit, Arthur brings a narrow challenge to two aspects of Alabama's lethal injection **protocol** (midazolam and the consciousness assessment) and does not argue or even suggest that lethal injection is per se unconstitutional —in fact, the main premise of his attack on the midazolam **protocol** is that it is more painful than the prior Alabama **protocol** using pentobarbital. Also, Arthur does not challenge the constitutionality of death by electrocution, or allege any facts establishing that electrocution involves a substantial risk of severe pain. [30] No court has held that lethal injection (or electrocution) as applied to Arthur in this case violates the Constitution. Therefore, the ADOC would not be able to carry out Arthur's preferred death sentence without the Alabama legislature fundamentally rewriting its method-of-**execution** statute.

Arthur argues, nevertheless, that Glossip does not "require" that alternative methods of **execution** be statutorily authorized. In his proposed allegations, Arthur points to the fact that another state, Utah, has conducted three **executions** by firing squad since 1976, the most recent taking place in 2010. Arthur implies that, since the Utah legislature has approved death by firing squad, the Alabama legislature could easily do the same. But Arthur misunderstands the state's obligation under the Eighth Amendment. States that continue to have capital punishment are free to choose any method of **execution** they deem appropriate, so long as they conform to the requirements of the United States Constitution, and more particularly, to the constraints found in the Eighth Amendment. This recognition—that states are constrained by the United States Constitution—is wholly consonant with the plain language of the Supremacy Clause. See U.S. Const. art. VI, cl. 2 ("[The Constitution] shall be the supreme Law of the Land ... Laws of any State to the Contrary notwithstanding."). Alabama has chosen ***1317** death by lethal injection or electrocution; the petitioner is not free to simply disregard those methods (and substitute his own) without satisfactorily establishing that those methods violate the constitutional command barring cruel and unusual punishment. To be clear, states remain subject to the Constitution, and the Constitution requires states to select a constitutional method of **execution**. But the state is not required to use Arthur's chosen method (the firing squad) unless Arthur shows the methods the state selected are unconstitutional.

We do recognize that, in contrast to Alabama, Utah has a state statute that, while it prescribes lethal injection as the primary method of **execution**, allows the state to use a firing squad if (1) "a court holds that a defendant has a right to be **executed** by a firing squad," (2) "a court holds that **execution** by lethal injection is unconstitutional on its face" or "as applied," or (3) "the sentencing court determines the state is unable to lawfully obtain the substance or substances necessary to conduct an **execution** by lethal intravenous injection." Utah Code Crim. Proc. § 77–18–5.5(1)–(4). Similarly, Oklahoma law provides for firing squad as the quaternary option for carrying out an **execution**, making it available only after **execution** by lethal injection, nitrogen hypoxia, and electrocution are all declared unconstitutional. See Okla. Stat. tit. 22, § 1014 (2016).

Utah and Oklahoma are the only states that have statutes contemplating **execution** by firing squad, and lethal injection is still the primary method of **execution** in both of those states, as it is in every state that allows for capital punishment. Thus, to the extent that Arthur relies on dicta from Glossip [31] concerning "other acceptable, available methods," Oklahoma law expressly allowed both the firing squad and electrocution. Okla. Stat. tit. 22, § 1014 (2015). [32] As we noted in Brooks, a prisoner must identify an alternative that is "known and available" to the state in question to meet the requirements in Baze and Glossip. 810 F.3d at 820 (explaining that petitioners must show that "there is now a source for pentobarbital that would sell it to the ADOC for use in **executions**" (emphases added)).

Arthur argues, nevertheless, that a state could "legislatively exempt" itself from Eighth Amendment review simply by adopting a narrow method of **execution** without any prescribed alternatives, thereby preventing challengers from identifying a statutorily authorized alternative method. But the Alabama legislature has authorized ***1318** two methods of **execution**—lethal injection in any form and electrocution—and neither of its authorized methods has been deemed unconstitutional by a court, either per se or even as applied to Arthur. See Ala. Code. § 15–18–82.1(a), (c), (h). Arthur is not entitled to veto the Alabama legislature's constitutional choice as to

how Alabama inmates will be **executed** because there may still be other statutorily authorized (and unchallenged) methods available. As for the dissent's argument that the state's legislative choices should not affect whether an alternative could be feasible and readily implemented, the dissent refuses to acknowledge that the Alabama statute is not simply the result of the state's "will," but it is also very much constrained by the United States Constitution. Absent a showing that Alabama's chosen methods of **execution** present an unconstitutional risk of severe pain, Alabama is under no obligation to deviate from its widely accepted, presumptively constitutional methods in favor of Arthur's retrogressive alternative.

Moreover, the Supreme Court has recognized that requiring a state to amend its method-of-**execution** statute or to authorize a variance from that statute "impos[es] significant costs on the State and the administration of its penal system." See Nelson v. Campbell, 541 U.S. 637, 644, 124 S.Ct. 2117, 2123, 158 L.Ed.2d 924 (2004). That is particularly true where, as here, the necessary legislation would retreat from a method of **execution** that is employed by the overwhelming majority of states that still authorize the death penalty and is widely considered the "most humane available," and would replace it with a method of **execution** that has long been abandoned by almost every state in this country.[33] See Baze, 553 U.S. at 62, 128 S.Ct. at 1537. As the Supreme Court has recognized, "[t]he firing squad, hanging, the electric chair, and the gas chamber have each in turn given way to more humane methods [of **execution**], culminating in today's consensus on lethal injection." Id. at 62, 128 S.Ct. at 1538; see also id. at 42, 128 S.Ct. at 1526–27 ("A total of 36 States have now adopted lethal injection as the exclusive or primary means of implementing the death penalty, making it by far the most prevalent method of **execution** in the United States."). The dissent's suggestion that our decision nullifies Arthur's right to a "humane **execution**" by preventing his access to **execution** by firing squad is peculiar, and, moreover, flatly contradicted by the Supreme Court.

In considering whether Arthur's proposed alternative is "feasible" and "readily implemented," it is also important to note that the firing squad is a vastly different method of **execution** from electrocution and lethal injection, which are the only methods of **execution** that Alabama has employed in the past ninety years. As far as we can tell, Alabama has never carried out an **execution** by firing squad or statutorily recognized it as a method for carrying out **executions**. Indeed, Arthur does not say that any ADOC employee would have the first idea about how to carry out an **execution** by this method, and, undeniably, doing so would require a lot more than merely buying some new supplies for the ADOC to begin carrying out **executions** by this new method. The firing squad has not been used even in Utah since 2010. ***1319** This sits in stark contrast to the numerous **executions** by lethal injection that were carried out across the country during the past decade or so. The fact that a few other states could theoretically carry out an **execution** by firing squad without violating their own laws tells us nothing about whether that method is, in fact, readily implementable for use in actual **executions** in Alabama today.

As we see it, our dissenting colleague errs in claiming that our opinion contravenes Baze and Glossip. Our dissenting colleague writes that, under our analysis, "if a state legislatively rejects an alternative, the alternative is not feasible and readily implemented. ... State opposition ... has no bearing on the 'feasible and readily implemented' inquiry as set forth in Baze and Glossip." This is not at all what we have said. What we say is (1) Alabama has chosen two constitutional methods of **execution**, (2) Arthur has not shown that they are, or that either one is, unconstitutional (per se or as applied to him), and (3) Arthur is not entitled to veto the Alabama legislature's choice of two constitutional methods of **execution**. Furthermore, by requiring Arthur to show a feasible, readily implementable, and significantly safer alternative, we are abiding by the rules set forth in the Supreme Court's Baze and Glossip opinions, and also giving credence to Alabama's prerogative to choose any constitutional method of **execution** it deems appropriate. It is true that neither Baze nor Glossip held that an **execution** alternative must be statutorily authorized as that, of course, was not the issue. But those opinions did not direct that we ignore constitutional state laws in employing constitutional methods of **execution**.

We are also unpersuaded by the concerns forwarded by Arthur and the dissent that giving this deference to states will effectively cut off inmates' ability to advocate for more humane alternative methods of **execution**, as contemplated by Baze and Glossip. We see no merit to the dissent's hypothesis that a state could, for example, offer the gas chamber as its method of **execution**. It seems clear that if a state's sole method of **execution**

is deemed unconstitutional, while other methods remain constitutional (even if they are not authorized by the state statute), our inquiry into whether those other options are feasible and readily implemented would be a different one. Among other things, Alabama's statute plainly allows for other options if its statutory methods are declared unconstitutional, making those other options more feasible and readily implementable. But that is not the case here. Alabama's two methods of **execution** have not been declared unconstitutional, nor has Arthur even argued that they are.

Furthermore, our dissenting colleague is concerned that our opinion will foreclose all but lethal-injection-alternative challenges and that inmates can never win such suits due to the secrecy surrounding **executions** and states' admitted challenges in locating sources for the drugs. These practical constraints do not rob the State of Alabama, or any other state, of its right to choose the method of **execution** it wishes to use, so long as the state complies with the requirements of the United States Constitution. These constraints should also be weighed against the practical problems of instituting an untested (in Alabama) **protocol** for **execution** by firing squad. While Arthur points to Utah as an exemplar, the reality is that formulating a new **protocol** and locating the people and resources necessary to carry out such an alternative (even if feasible, readily implementable, and significantly safer), would ***1320** take considerable time and would, inevitably, lead to an entire new round of legal challenges regarding the details of the **protocols** for constitutionally conducting an **execution** by firing squad. Arthur's own nine-year history of § 1983 litigation well proves that point. [34]

Arthur's strategy here to avoid **execution** is to claim that the ADOC should employ a profoundly different method of **execution** that is not legal in Alabama and has long been abandoned by states seeking to employ the "most humane" method of **execution** available, lethal injection. See Baze, 553 U.S. at 62, 128 S.Ct. at 1537. Arthur's strategic choice left him with a steep hill to climb, requiring him to show that this method of **execution** that is beyond the ADOC's statutory authority somehow could be feasible and readily implemented by the ADOC. He failed to surmount that obstacle.

For these reasons, the firing squad is not an alternative method of **execution** that is available, feasible, or readily implemented by the ADOC and, thus, the district court did not err in disallowing this third amendment to Arthur's complaint. And furthermore, absent a showing that the methods chosen by the Alabama legislature pose an unconstitutional risk of pain, either per se or as applied to Arthur, the Constitution does not compel Alabama to search for a new method. Accordingly, we find that amending Arthur's Second Amended Complaint to add the firing squad as an alternative method of **execution** would have been futile, and affirm the district court's denial of leave to amend. [35]

XIX. CONCLUSION

The district court did not err in entering final judgment in favor of the ADOC and against Arthur on all claims. Accordingly, we affirm.

Given that this Court has determined Arthur's appeal lacks merit, the Court denies Arthur's motion to stay his November 3, 2016 **execution** for failure to show a ***1321** likelihood of success on the merits of his claims. "It is by now hornbook law that a court may grant a stay of **execution** only if the moving party establishes that: (1) he has a substantial likelihood of success on the merits; (2) he will suffer irreparable injury unless the injunction issues; (3) the stay would not substantially harm the other litigant; and (4) if issued, the injunction would not be adverse to the public interest." Brooks, 810 F.3d at 818 (citation omitted) (internal quotation marks omitted). Because Arthur has not satisfied the first requirement for a stay, we need not reach the other three requirements.

AFFIRMED.

WILSON, Circuit Judge, dissenting:

Under the Majority's decision, state law can dictate the scope of the Constitution's protections. Thomas Arthur raises a method-of-**execution** claim proposing the firing squad as an **execution** alternative, and the Majority finds that state law defeats this constitutional claim. By misreading an Alabama statute, the Majority creates a conflict between the claim and state law. The Majority then resolves that faux conflict in favor of state law, taking the unprecedented step of ascribing to states the power to legislatively foreclose constitutional relief. These missteps

nullify countless prisoners' Eighth Amendment right to a humane execution.

I. INTRODUCTION

The Eighth Amendment guarantees a death row prisoner the right to relief when he faces a method of execution that is "*sure or very likely* to cause serious illness and needless suffering" and there is a "feasible" and "readily implemented" alternative that "significantly reduce[s] a substantial risk of severe pain." *Baze v. Rees*, 553 U.S. 35, 50–52, 128 S.Ct. 1520, 1531–32, 170 L.Ed.2d 420 (2008) (plurality opinion) (internal quotation marks omitted); *Glossip v. Gross*, 576 U.S. ——, ——, 135 S.Ct. 2726, 2737, 192 L.Ed.2d 761 (2015). Arthur seeks to vindicate this right. He asserts that Alabama's current three-drug lethal injection protocol is sure or very likely to cause him severe pain, and he seeks to amend his complaint to propose the firing squad as an execution alternative. [1] The firing squad is a well-known, straightforward procedure that is regarded as "relatively quick and painless." [2] *See Glossip*, 135 S.Ct. at 2739 (internal quotation marks omitted), *Baze*, 553 U.S. at 48, 128 S.Ct. at 1530. And one state has recently used the firing squad to execute a prisoner. *See* Kirk Johnson, *Double Murderer Executed by Firing Squad in Utah*, N.Y. Times (June 18, 2010), www.nytimes.com/2010/06/19/us/19death.html?_r=0.

Arthur should be permitted to amend his complaint to include the firing squad as an execution alternative to Alabama's lethal ***1322** injection protocol. The firing squad is a potentially viable alternative, and Arthur may be entitled to relief under *Baze* and *Glossip* based on that method of execution.

Arthur requested to amend his complaint shortly after the Supreme Court confirmed in *Glossip* that prisoners must plead and prove an execution alternative to obtain method-of-execution relief. [3] The district court denied Arthur's request on futility grounds, finding that the "firing squad is not permitted by [an Alabama] statute and, therefore, is not a method of execution that could be considered either feasible or readily implemented by Alabama at this time."

The Majority now affirms that finding. The Majority determines that the firing squad is not feasible and readily implemented because § 15–18–82.1 of the Alabama Code does not authorize the firing squad. Thus, according to the Majority, a state can restrict a prisoner's access to Eighth Amendment relief by legislatively rejecting a viable execution alternative.

The Majority's analysis of Arthur's request to amend his complaint is legally flawed and has unacceptable consequences for death row prisoners throughout this circuit. [4] First, the Majority misreads § 15–18–82.1; that statute is not a barrier to Arthur relying on the firing squad. The plain language of § 15–18–82.1 permits Alabama to turn to the firing squad under the circumstances presented here.

Section 15–18–82.1 states, in relevant part:

> (c) If electrocution or lethal injection is held to be unconstitutional by ... the United States Supreme Court under the United States Constitution, or if the United States Supreme Court declines to review any judgment holding a method of execution ***1323** to be unconstitutional under the United States Constitution made by ... the United States Court of Appeals that has jurisdiction over Alabama, all persons sentenced to death for a capital crime shall be executed by any constitutional method of execution.
>
> ....
>
> (h) No sentence of death shall be reduced as a result of a determination that a method of execution is declared unconstitutional under the Constitution of Alabama of 1901, or the Constitution of the United States. In any case in which an execution method is declared unconstitutional, the death sentence shall remain in force until the sentence can be lawfully executed by any valid method of execution.

Ala. Code § 15–18–82.1 (2002). The Majority concludes that Alabama cannot deviate from a prisoner's designated method of execution unless electrocution or lethal injection is declared per se unconstitutional. [5] Because no court has declared electrocution or lethal injection per se unconstitutional, the Majority holds that § 15–18–82.1 forbids the firing squad.

This interpretation of § 15–18–82.1 does not pass muster. Subsection (h) allows Alabama to turn to the firing squad —a "valid method of execution"—in "case[s]" where our

court declares Alabama's planned "**execution** method" for a prisoner unconstitutional. *See* § 15–18–82.1(h). Alabama's planned "**execution** method" for Arthur is Alabama's three-drug lethal injection **protocol**, and Arthur claims that the **protocol** is unconstitutional. *See id.* If our court agreed with him, then subsection (h) would allow Alabama to utilize the firing squad to enforce Arthur's death sentence. Because this case could implicate subsection (h) and open the door to the firing squad, § 15–18–82.1 is not a barrier to Arthur relying on the firing squad. Arthur's firing-squad claim thus conflicts only with the Majority's flawed interpretation of Alabama law, not Alabama law itself.

Second, even if § 15–18–82.1 did not permit the firing squad here, the Majority's conclusion that the statute precludes Arthur from relying on the firing squad would *still* be erroneous. The Majority contravenes *Baze* and *Glossip*, as well as the Supremacy Clause, in relying on a state statute to limit Arthur's access to Eighth Amendment relief. Under *Baze* and *Glossip*, a state cannot make an **execution** alternative not feasible and readily implemented by legislatively rejecting the alternative. A state's rejection of an **execution** alternative is irrelevant to the "feasible and readily implemented" inquiry. Moreover, in holding that a state can dictate that inquiry and foreclose an **execution** alternative, the Majority infringes the Supremacy Clause. The Majority's holding affords states the power to thwart viable method-of-**execution** claims. That is unprecedented. States cannot render an **execution** alternative not feasible and readily implemented—and thereby insulate themselves from constitutional scrutiny—by opposing the alternative through legislation or any other means. The Supremacy Clause precludes that type of state incursion on the Eighth Amendment.

Finally, the practical consequences of the Majority's mistakes are deeply troubling. ***1324** The Majority's decision nullifies countless prisoners' right to a humane **execution**. Based on the Majority's approach to § 15–18–82.1, Alabama prisoners such as Arthur must rely on lethal-injection-based **execution** alternatives[6] to obtain method-of-**execution** relief. A myriad of Florida prisoners are likewise limited to lethal-injection-based alternatives because Florida has a statute that is identical to § 15–18–82.1, *compare* Ala. Code § 15–18–82.1, *with* Fla. Stat. § 922.105 (2005). However, due to the scarcity of and secrecy surrounding lethal injection drugs, identifying an available lethal-injection-based alternative is a Sisyphean task. Consequently, relief under *Baze* and *Glossip* is now a mirage for prisoners across Alabama and Florida.

II. THE PLAIN LANGUAGE OF § 15–18–82.1 PERMITS THE FIRING SQUAD.

Arthur's request to die by the firing squad is not at odds with Alabama law. The plain language of § 15–18–82.1 permits Alabama to turn to the firing squad under the circumstances presented here. The Majority erroneously concludes that the statute bars Alabama from using the firing squad to **execute** Arthur. The Majority's misreading of the statute not only creates a faux conflict with Arthur's firing-squad claim but also impairs Alabama's ability to enforce the death penalty.

Section 15–18–82.1 states:

> (a) A death sentence shall be **executed** by lethal injection, unless the person sentenced to death affirmatively elects to be **executed** by electrocution.
>
> (b) A person convicted and sentenced to death for a capital crime at any time shall have one opportunity to elect that his or her death sentence be **executed** by electrocution. The election for death by electrocution is waived unless it is personally made by the person in writing and delivered to the warden of the correctional facility within 30 days after the certificate of judgment pursuant to a decision by the Alabama Supreme Court affirming the sentence of death or, if a certificate of judgment is issued before July 1, 2002, the election must be made and delivered to the warden within 30 days after July 1, 2002.
>
> (c) If electrocution or lethal injection is held to be unconstitutional by the Alabama Supreme Court under the Constitution of Alabama of 1901, or held to be unconstitutional by the United States Supreme Court under the United States Constitution, or if the United States Supreme Court declines to review any judgment holding a method of **execution** to be unconstitutional under the United States Constitution made by the Alabama Supreme Court or the United States Court of Appeals that has jurisdiction over Alabama, all persons sentenced to death for a capital crime shall be **executed** by any constitutional method of **execution**.

....

(f) Notwithstanding any law to the contrary, a person authorized by state law to prescribe medication and designated by the Department of Corrections ***1325** may prescribe the drug or drugs necessary to compound a lethal injection. Notwithstanding any law to the contrary, a person authorized by state law to prepare, compound, or dispense medication and designated by the Department of Corrections may prepare, compound, or dispense a lethal injection.

....

(h) No sentence of death shall be reduced as a result of a determination that a method of **execution** is declared unconstitutional under the Constitution of Alabama of 1901, or the Constitution of the United States. In any case in which an **execution** method is declared unconstitutional, the death sentence shall remain in force until the sentence can be lawfully **executed** by any valid method of **execution**.

Ala. Code § 15–18–82.1. Alabama enacted this section in 2002 when it first changed its default method of **execution** from electrocution to lethal injection. In doing so, Alabama shrewdly expected challenges to the constitutionality of lethal injection and its administration of lethal injection. Section 15–18–82.1 not only prescribes lethal injection as the default method of **execution** but also establishes contingency plans in the event that: (1) lethal injection is declared per se unconstitutional or (2) Alabama's lethal injection **protocol** is declared unconstitutional.

Subsections (a) and (b) of § 15–18–82.1 designate lethal injection as Alabama's primary method of **execution**, while affording prisoners a one-time opportunity to choose electrocution as their designated method in lieu of lethal injection. And subsections (c) and (h) afford Alabama the flexibility to deviate from a prisoner's designated method of **execution** and specific **execution** **protocol** if either is declared unconstitutional. Those subsections serve as complementary safety valves, ensuring that Alabama can fulfill its goal of carrying out **executions**. Subsection (c) guarantees Alabama flexibility by providing that Alabama can utilize "any constitutional method of **execution**" if lethal injection or electrocution is struck down as per se unconstitutional. § 15–18–82.1(c). Subsection (h) complements subsection (c), as it protects Alabama's ability to carry out an **execution** when a prisoner successfully attacks the specific lethal-injection or electrocution **protocol** that Alabama plans to use to kill him. That subsection states that Alabama can turn to "any valid method of **execution**" in "any case" in which its planned "**execution** method is declared unconstitutional." § 15–18–82.1(h).

Arthur's designated method of **execution** is lethal injection, as he did not opt for electrocution during the time period allotted in subsection (b). *See* § 15–18–82.1(a), (b). Pursuant to subsection (f), the Alabama Department of Corrections has elected to carry out Arthur's lethal injection using a three-drug, midazolam-based **protocol**. Arthur asserts that this planned "**execution** method" violates the Eighth Amendment. *See* § 15–18–82.1(h). If our court agreed with Arthur, then Alabama would be able to resort to "any valid method of **execution**," including the firing squad, to fulfill its goal of **executing** Arthur. *See id.*; *Glossip*, 135 S.Ct. at 2732 (noting that the firing squad is a presumably valid, constitutional method of **execution**). As such, through this litigation, § 15–18–82.1(h)'s safety valve could be implicated, thereby opening the door to the firing squad. The firing squad is a plausible **execution** alternative in Alabama.

However, the Majority departs from the plain language of § 15–18–82.1 and concludes ***1326** that the statute bars the firing squad here. The Majority makes a threshold error by determining that Alabama currently authorizes both electrocution and lethal injection as methods of **execution** for Arthur. *See* Maj. Op. at 1316–17 ("Alabama has chosen death by lethal injection or electrocution."). Based on that finding, the Majority suggests that Arthur cannot rely on the firing squad because he has not challenged both lethal injection and electrocution. But the text of subsections (a) and (b) belie the Majority's conclusion that Alabama has "chosen" both lethal injection and electrocution for Arthur. Because Arthur did not opt for electrocution, he "shall be **executed** by lethal injection." *See* Ala. Code § 15–18–82.1 (a), (b). Therefore at this time § 15–18–82.1 authorizes Alabama to kill Arthur only by lethal injection. Alabama has not "chosen" electrocution for Arthur merely because electrocution is mentioned in the statute as a contingency option. If that were the case, then "any valid method of **execution**" would also be "chosen" for Arthur. *See* § 15–18–82.1(h). Moreover, the Majority's suggestion that Arthur was required to attack electrocution *and* lethal

injection to trigger § 15–18–82.1's safety valves is clearly inconsistent with the statute. Neither subsection (c) nor subsection (h) states that lethal injection *and* electrocution must be struck down to trigger its safety valve.

The Majority also erroneously determines that under § 15–18–82.1 Alabama can turn to the firing squad *only* if lethal injection or electrocution is declared per se unconstitutional.[7] *See* Maj. Op. at 1316 (suggesting that Alabama would have authority to use the firing squad if a court struck down "as unconstitutional either electrocution or lethal injection"). And since no court has declared either method per se unconstitutional, the Majority finds that § 15–18–82.1 precludes Alabama from using the firing squad in this case. A proper textual analysis reveals that subsection (h) forecloses this reading of the statute.

As noted above, subsection (h) states:

> In any case in which an **execution** method is declared unconstitutional, the death sentence shall remain in force until the sentence can be lawfully **executed** by any valid method of **execution**.

Ala. Code § 15–18–82.1(h). At first glance, it is possible to read this sentence in a manner consistent with the Majority's interpretation of § 15–18–82.1. That is, the sentence could be interpreted as permitting Alabama to turn to an alternative method of **execution**, such as the firing squad, only if lethal injection or electrocution is declared per se unconstitutional. But because, as the Majority concludes, subsection (c) stands for that exact proposition, interpreting subsection (h) to convey the same message violates an elementary rule of statutory interpretation—that we must give effect to each provision. *See United States v. Butler*, 297 U.S. 1, 65, 56 S.Ct. 312, 319, 80 L.Ed. 477 (1936) ("These words cannot be meaningless, else they would not have been used."). The correct interpretation of subsection (h)—and the only interpretation that avoids surplusage—is that, if the specific "**execution** method" in a "case" is declared unconstitutional, Alabama can resort to "any valid method of **execution**." *See* Ala. Code § 15–18–82.1(h).

This interpretation is also consistent with the subsections immediately preceding ***1327** subsection (h). Subsections (f) and (g) charge the Department of Corrections with the administration of **executions**. *See* § 15–18–82.1(f), (g). Specifically, subsection (f) provides that the Department of Corrections shall designate who selects the drugs used in the administration of lethal injection, and subsection (g) exempts from Alabama's ordinary rulemaking procedure the Department of Corrections's "policies and procedures" for administering **executions**. *See* § 15–18–82.1(f), (g). Immediately following this discussion, subsection (h) is correctly understood to discuss the constitutionality of the Department of Corrections's chosen **execution protocol**. *See* Antonin Scalia & Bryan A. Garner, *Reading Law* 167 (2012) ("Context is a primary determinant of meaning."); *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291, 108 S.Ct. 1811, 1818, 100 L.Ed.2d 313 (1988) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole."). Based on the plain language of § 15–18–82.1, the statute permits Alabama to turn to the firing squad when its planned **execution protocol** for a particular prisoner is declared unconstitutional. The Majority's interpretation clearly fails.

Yet, even assuming that the plain language of § 15–18–82.1 is ambiguous and the Majority's interpretation is plausible, the statute must still be read to permit the firing squad in this case. In the face of such ambiguity, an interpretation that "furthers rather than obstructs [the statutory text]'s purpose should be favored." *See* Scalia, *supra*, at 63; *SEC v. C.M. Joiner Leasing Corp.*, 320 U.S. 344, 350, 64 S.Ct. 120, 123, 88 L.Ed. 88 (1943) ("[C]ourts [sha]ll construe the details of an act in conformity with its dominating general purpose."). This rule of statutory construction militates against the Majority's interpretation of § 15–18–82.1.

The purpose of subsections (c) and (h) is clear: to ensure that Alabama can enforce the death penalty through an alternative form of **execution** when its chosen means of **executing** a prisoner is declared unconstitutional. Under the reading described above, § 15–18–82.1 provides Alabama the authority to (1) turn to an alternative form of **execution** upon a per se finding that lethal injection or electrocution is unconstitutional, *see* Ala. Code § 15–18–82.1(c), *and* (2) employ "any valid method of **execution**" when its specific **execution protocol** is declared unconstitutional, *see* § 15–18–82.1(h). In contrast, the Majority's interpretation affords Alabama the authority

to use an alternative form of **execution** only when lethal injection or electrocution is declared per se unconstitutional. This reading plainly limits Alabama's ability to turn to an alternative form of **execution** in the face of constitutional scrutiny. The interpretation obstructs the purpose of subsections (c) and (h) and impairs Alabama's ability to enforce the death penalty.

The Majority's determination that § 15–18–82.1 precludes Arthur from relying on the firing squad is inconsistent with the plain language of the statute and the purpose underlying subsections (c) and (h). Arthur's firing-squad claim conflicts only with the Majority's flawed interpretation of Alabama law, not Alabama law itself.

III. THE MAJORITY'S RELIANCE ON STATE LAW CONTRAVENES *BAZE*, *GLOSSIP*, AND THE SUPREMACY CLAUSE.

Even assuming that § 15–18–82.1 does not permit the firing squad under the present circumstances, the Majority's dismissal ***1328** of Arthur's claim would *still* be erroneous. The Majority's rejection of the firing squad rests on its determination that, if a state legislatively opposes an **execution** alternative, then the alternative is not feasible and readily implemented and method-of-**execution** relief is foreclosed. State law however is irrelevant to the Eighth Amendment inquiry established by *Baze* and *Glossip*, and more fundamentally, under the Supremacy Clause, state law cannot thwart a viable constitutional claim. In relying on state law to deny Arthur relief, the Majority commits constitutional error. The Majority's decision in effect turns *Baze* and *Glossip*'s method-of-**execution** test—a test designed to protect the Eighth Amendment rights of death row prisoners—into a test that narrows, and in many cases defeats, those rights. This transformation is not only unprecedented, it is completely unmoored from precedent.

A. *Baze* and *Glossip*

1. An Overview of *Baze* and *Glossip*

In *Baze*, the Supreme Court first held that a method-of-**execution** claimant must identify a "feasible" and "readily implemented" **execution** alternative that "significantly reduce[s] a substantial risk of severe pain." *See Baze*, 553 U.S. at 52, 128 S.Ct. at 1532; *Glossip*, 135 S.Ct. at 2737. According to the *Baze* Court, "[i]f a [s]tate refuses to adopt ... an alternative in the face of these documented advantages, without a legitimate penological justification for adhering to its current method of **execution**, then [the] [s]tate's refusal ... can be viewed as 'cruel and unusual.' " *Baze*, 553 U.S. at 52, 128 S.Ct. at 1532. *Baze* neither placed any restrictions on the categories of **execution** alternatives that a claimant can rely on to demonstrate such cruel and unusual conduct, nor limited possible alternatives to those that the claimant's state has approved. *See id.*, 128 S.Ct. at 1532. To satisfy *Baze*, an alternative must simply have the "documented advantages" of being "feasible, readily implemented," and significantly safer than the state's designated **execution** method. *See id.*, 128 S.Ct. at 1532.

Subsequently, *Glossip* confirmed this "**execution** alternative" requirement, stating:

> The controlling opinion [in *Baze*] summarized the requirements of an Eighth Amendment method-of-**execution** claim as follows: ... the condemned prisoner [must] establish[ ] that the [s]tate's [method of **execution**] creates a demonstrated risk of severe pain. And he must show that the risk is substantial when compared to the known and available alternatives.

Glossip, 135 S.Ct. at 2737 (internal quotation marks omitted). Consistent with *Baze*, *Glossip* also indicated that, when attempting to satisfy the "**execution** alternative" requirement, prisoners are neither limited to certain categories of **execution** alternatives nor constrained by state-approved alternatives. *See id.* at 2739 (stating that a prisoner is required only "to plead and prove a known and available alternative"); *id.* (rejecting the dissent's argument that "the methods of **execution** employed before the advent of lethal injection," such as the firing squad, are not permissible **execution** alternatives).

In *Glossip*, the prisoners argued that Oklahoma's lethal injection cocktail posed an unacceptable risk of cruel and unusual punishment. They proposed a different cocktail as an **execution** alternative. However, the Court found that the proposed cocktail was not a "known and available" ***1329** alternative because the record showed

that "despite a good-faith effort," Oklahoma was unable to procure the drugs in the cocktail. *Id.* at 2738. Due to the scarcity of those drugs, it was functionally impossible for Oklahoma to obtain them. *See id.* at 2733–34, 2738.

Our court has applied the "**execution** alternative" requirement on multiple occasions. We have found, in accord with *Glossip*, that a proposed **execution** alternative does not satisfy the requirement when a state is unable to obtain the materials necessary for the alternative. *See, e.g.*, *Brooks v. Warden*, 810 F.3d 812, 820–21 (11th Cir. 2016) (concluding that, due to scarcity, the lethal injection cocktail that the prisoner proposed as an **execution** alternative was not available to Alabama), *cert. denied sub nom. Brooks v. Dunn*, —— U.S. ——, 136 S.Ct. 979, 193 L.Ed.2d 813 (2016); *Chavez v. Fla. SP Warden*, 742 F.3d 1267, 1274 (11th Cir. 2014) (Carnes, C.J., concurring) (rejecting a method-of-**execution** claim in part because the prisoner admitted that the relevant lethal injection drug alternatives were unavailable), *cert. denied sub nom. Chavez v. Palmer*, —— U.S. ——, 134 S.Ct. 1156, —— L.Ed.2d —— (2014). We have never concluded that an **execution** alternative fails to satisfy *Baze* and *Glossip* because a state has rejected the alternative by legislation or some other means.

2. The Majority's Misapplication of *Baze* and *Glossip*

Although neither *Baze* nor *Glossip* holds that an **execution** alternative must be state authorized, the Majority imposes such a requirement on Arthur. The Majority finds that, if a state legislatively rejects an alternative, the alternative is not feasible and readily implemented. But the "feasible and readily implemented" inquiry cannot serve as a vessel for the Majority's novel requirement. State opposition to an **execution** alternative—through legislation or any other means—has no bearing on the "feasible and readily implemented" inquiry as set forth in *Baze* and *Glossip*.

Whether an **execution** is feasible and readily implemented is considered separately from a state's rejection of the alternative. Again, in setting forth the "**execution** alternative" requirement, *Baze* emphasized:

> [An] alternative procedure must be feasible, readily implemented, and in fact significantly reduce a substantial risk of severe pain. If a [s]tate refuses to adopt such an alternative in the face of these documented advantages, without a legitimate penological justification for adhering to its current method of **execution**, then a [s]tate's refusal to change its method can be viewed as "cruel and unusual" under the Eighth Amendment.

Baze, 553 U.S. at 52, 128 S.Ct. at 1532. Hence, in considering a method-of-**execution** claim, we determine whether a proposed alternative has "documented advantages," such as being feasible and readily implemented, and then we consider separately the state's refusal to adopt the alternative. *See id.*, 128 S.Ct. at 1532. Those are clearly distinct inquiries. An alternative can have the "documented advantages" of being "feasible" and "readily implemented" even though a state "refuses to adopt" the alternative. *See id.*, 128 S.Ct. at 1532. A state's decision to embrace or reject an alternative therefore does not bear on the "feasible and readily implemented" inquiry. Yet, under the Majority's reasoning, when a state refuses to adopt an **execution** alternative—by, for example, passing legislation that rejects the alternative and then ***1330** adhering to that legislation—the alternative is ipso facto not feasible and readily implemented. That novel conclusion contravenes *Baze*.

Indeed, *Baze* and *Glossip*'s method-of-**execution** standard would be internally inconsistent if the "feasible and readily implemented" inquiry took into account a state's opposition—via legislation or another means—to an **execution** alternative. A state's refusal to adopt a viable **execution** alternative is the very conduct that gives rise to an Eighth Amendment violation under *Baze* and *Glossip*. *See id.*, 128 S.Ct. at 1532. The Eighth Amendment prohibits states from ignoring an "objectively intolerable risk of harm" when imposing punishment. *See id.* at 49–50, 128 S.Ct. at 1530–31 (internal quotation marks omitted). The method-of-**execution** standard implements this constitutional protection. When a state uses a dangerous method of **execution** and "refuses to adopt" an alternative that is feasible, readily implemented, and significantly safer than the state's method, the state ignores an avoidable risk of harm, thereby violating the Eighth Amendment. *See id.* at 52, 128 S.Ct. at 1532.

The Majority's decision allows this exact conduct to *shield* a state from method-of-**execution** liability. According to the Majority, Alabama has legislatively opposed the firing

squad, and that "refus[al] to adopt" the firing squad defeats Arthur's method-of-execution claim. *See id.* at 52, 128 S.Ct. at 1532. That application of *Baze* and *Glossip* is clearly inconsistent with those precedents. State law cannot render the firing squad not feasible and readily implemented.

B. The Supremacy Clause

Beyond its incongruence with *Baze* and *Glossip*, the Majority's treatment of state law conflicts with the Supremacy Clause. In determining that state law can thwart an execution alternative, the Majority improperly grants states the power to dictate the scope of federal constitutional relief. *See* U.S. Const. art. VI, cl. 2 ("[The Constitution] shall be the supreme Law of the Land ... Laws of any State to the Contrary notwithstanding."). The upshot of this novel allocation of power is that a state statute can abrogate prisoners' Eighth Amendment right to a humane execution.

Under the Majority's decision, § 15–18–82.1 constricts Eighth Amendment relief and protects Alabama from claims that are viable under *Baze* and *Glossip*. The Eighth Amendment guarantees method-of-execution relief when a prisoner identifies any viable alternative. *See Baze*, 553 U.S. at 51–52, 128 S.Ct. at 1531–32; *Glossip*, 135 S.Ct. at 2737–39. However, because the only method of execution that § 15–18–82.1 currently authorizes for Arthur is lethal injection, Arthur must identify a viable lethal-injection-based alternative to obtain method-of-execution relief. Any other type of alternative is not contemplated by § 15–18–82.1 and is not feasible and readily implemented.[8] Section 15–18–82.1 thus severely restricts the circumstances in ***1331** which Arthur can obtain method-of-execution relief. This narrowing of Arthur's access to relief flouts the Supremacy Clause; states cannot override the Constitution's protections. *See Reynolds v. Sims*, 377 U.S. 533, 582–84, 84 S.Ct. 1362, 1392–93, 12 L.Ed.2d 506 (1964) ("When there is an unavoidable conflict between the Federal ... Constitution [and state law], the Supremacy Clause of course controls."); *Cox v. Louisiana*, 348 F.2d 750, 752 (5th Cir. 1965) ("When a [s]tate ... [limits] citizens [in] the exercise of their constitutional rights[,] ... the federal system is imperiled.").

The Majority's state-law determination however does not merely allow states to constrict prisoners' Eighth Amendment rights—it permits states to abrogate such rights. Moving forward, a state can pass legislation requiring all executions to be performed with a certain gas chamber protocol or a certain electrocution protocol, and since the legislation would authorize only those two particular protocols, no other protocol or method of execution would be feasible and readily implemented. As a result, even in the face of evidence that both protocols are excruciatingly painful, condemned prisoners could never obtain relief from the protocols—it would be impossible to meet *Baze* and *Glossip*'s "execution alternative" requirement, and *Baze* and *Glossip* provide the only avenue for method-of-execution relief. The state's legislation would thus nullify prisoners' right to a humane execution.

Although this example is merely a hypothetical, it underscores the troubling constitutional issues that arise from the Majority's decision. The decision allows state law to trump the Eighth Amendment's basic guarantee against cruel and unusual punishment.[9] *Contra* U.S. Const. art. VI, cl. 2.

IV. THE MAJORITY'S DECISION FORECLOSES RELIEF FOR PRISONERS ACROSS THIS CIRCUIT WHO ARE DESIGNATED TO DIE BY LETHAL INJECTION.

Prisoners in Alabama and Florida[10] who, like Arthur, are designated to die by lethal injection must now identify a viable lethal-injection-based alternative to obtain method-of-execution relief. But given the "difficult realities" surrounding lethal injection drugs, that is not practicable. *See* Brief of Defendant–Appellee at 10, *Arthur v. Comm'r, Ala. Dept. of Corr.*, 840 F.3d 1268, No. 16-15549 (11th Cir. Oct. 11, 2016) ***1332** (noting the practical barriers to identifying a viable lethal-injection-based alternative). Due to the scarcity of and secrecy surrounding lethal injection drugs, it is all but impossible for a prisoner to set forth a viable lethal-injection-based alternative. The Majority's decision therefore checkmates countless Alabama and Florida prisoners, nullifying their constitutional right to a humane execution.

Many condemned prisoners have attempted to propose lethal injection drug alternatives in method-of-execution cases but those attempts have been futile because lethal injection drugs are extremely scarce. *See, e.g.*,

Glossip, 135 S.Ct. at 2738 (rejecting a method-of-**execution** claim after finding that "Oklahoma has been unable to procure [two formerly widely-used lethal injection] drugs despite a good-faith effort to do so"); *Brooks*, 810 F.3d at 820–21; *Chavez*, 742 F.3d at 1274 (Carnes, C.J., concurring) (discussing the scarcity of lethal injection drugs); *Sepulvado v. Jindal*, 729 F.3d 413, 416 (5th Cir. 2013) ("Since 2010, the first drug in [Louisiana's former lethal injection] procedure—sodium thiopental—has been unavailable."); *cf. Wood v. Ryan*, 759 F.3d 1076, 1097 (9th Cir. 2014) (Bybee, J., dissenting) (remarking that "Tennessee recently reauthorized the use of the electric chair as an alternative method of **execution**" due to concerns about the unavailability of "the drugs necessary to perform a lethal injection"), *vacated*, —— U.S. ——, 135 S.Ct. 21, 189 L.Ed.2d 873 (2014); Distanislao, Note, 49 U. Rich. L. Rev. at 804–05 ("[A]mid ... widespread drug shortages, capital punishment is losing its position as a functional element of American society."). In fact, Arthur himself proffered to the district court two alternative lethal injection drug compounds, but the district court rejected those proposed alternatives after discovery, finding them unavailable to Alabama. *See Arthur v. Dunn* (*Dunn I*), No. 2:11–cv–438–WKW–TFM, slip op. at 19–21, 2016 WL 1551475 (M.D. Ala. Apr. 15, 2016); Brief of Defendant–Appellee at 10, *Arthur*, No. 16–15549. And the Majority now affirms that finding. *See* Maj. Op. at 1301, 1306.

Furthermore, to the extent that some limited supply of viable, alternative lethal injection drugs exists, prisoners cannot gather the information needed to use those drugs in a method-of-**execution** claim because details about lethal injection drugs and their suppliers are heavily concealed. *See, e.g.*, *Arthur v. Thomas*, 674 F.3d 1257, 1263 (11th Cir. 2012) (per curiam) (noting "the veil of secrecy that surrounds Alabama's **execution protocol**"); *Terrell v. Bryson*, 807 F.3d 1276, 1281 (11th Cir. 2015) (Martin, J., concurring) (discussing Georgia's lethal injection "secrecy rules"). This veil of secrecy is evident here. Arthur was stonewalled in his attempts to gather information about the availability of the drugs in his proposed lethal injection compounds. According to testimony from an expert witness who asked members of the drug community about the availability of one of the compounds, "none of the pharmacists" that he spoke to "provided [him] permission to share their names [or] contact information." *See Arthur v. Dunn* (*Dunn II*), No. 2:11–cv–438–WKW–TFM, slip op. at 41, —— F.3d ——, 2016 WL 3912038 (M.D. Ala. July 19, 2016). Another expert witness also spoke to the secrecy surrounding the compound, stating, "I have no knowledge of where any state has [in the past] secured [the compound]." *See Dunn I*, slip op. at 11 n.5.

The scarcity of and secrecy surrounding lethal injection drugs make it basically impossible to identify a "feasible" and "readily ***1333** implemented" lethal-injection-based alternative that "significantly reduce[s] a substantial risk of severe pain." *See Baze*, 553 U.S. at 52, 128 S.Ct. at 1532; *Glossip*, 135 S.Ct. at 2737. This bears out in our case law. Based on my research, no prisoner has ever successfully challenged his method of **execution** relying on a lethal-injection-based alternative.

Accordingly, the Majority's decision all but forecloses method-of-**execution** relief for a myriad of Alabama and Florida prisoners. [11] This case is telling. Arthur proffered an **execution** alternative that was not lethal-injection-based, but the Majority's interpretation of § 15–18–82.1 thwarted that potentially safe and available alternative, leaving Arthur with no choice but to rely solely on lethal-injection-based alternatives. Arthur attempted to identify such an alternative but was stymied by the limited supply of lethal injection drugs and the secrecy surrounding such drugs. Checkmate.

V. CONCLUSION

The Majority misinterprets Alabama law, reads a new restriction into *Baze* and *Glossip* that is directly at odds with those decisions, and empowers states to thwart constitutional claims. Taken together, these errors have jarring practical consequences; relief under *Baze* and *Glossip* is now a mirage for prisoners across this circuit.

Arthur is entitled to amend his complaint and proceed with his method-of-**execution** claim proposing the firing squad. [12] I respectfully dissent.

APPENDIX

In offering the firing squad as an **execution** alternative, Arthur's proposed complaint states:

Alternative # 3—Firing Squad

134. A third potential alternative is the firing squad. The Supreme Court has held that the firing squad is a constitutionally permissible form of **execution**. *See Wilkerson v. Utah*, 99 U.S. 130, 134–35, 25 L.Ed. 345 (1879) (upholding sentence of death by firing squad). Indeed, as recently as 2010 Utah **executed** an inmate by firing squad. On March 23, 2015, Utah Governor Gary Herbert signed into law an amendment providing that firing squads will serve as the backup method of **execution** if lethal injection drugs are not available.

135. **Protocols** for **execution** by firing squad, which has been carried out at ***1334** least three times since 1976 without apparent incident, are known and available. For example, under Utah's recent law, the prisoner is seated in a chair set up between stacked sandbags to prevent the bullets from ricocheting. A target is pinned over the inmate's heart. Five shooters are set up approximately 25 feet from the chair where the prisoner is seated, with .30 caliber Winchester rifles pointing through slots in the wall. The gunmen are chosen from a pool of volunteer officers. (Utah Rep. Paul Ray, the sponsor of the firing squad bill, has said that there are always more volunteers than spots on the firing squad. Upon information and belief, the same would be true in Alabama and/or the State would otherwise be able to supply officers to carry out an **execution**.) The shooters' identities are kept anonymous, and one rifle is loaded with a blank so that no one knows which officer killed the inmate.

136. The firing squad is a known and available alternative in the state of Alabama. Upon information and belief, there are numerous people employed by the State who have the training necessary to successfully perform an **execution** by firing squad. The State already has a stockpile of both weapons and ammunition.

137. Moreover, **execution** by firing squad, if implemented properly, would result in a substantially lesser risk of harm than the State's continued use of a three-drug **protocol** involving midazolam. Evidence and recent experience strongly suggest that the firing squad is "significantly more reliable than other methods." *Glossip*, 135 S.Ct. at 2796 (Sotomayor, J., dissenting). A recent study, which analyzed the contemporaneous news reports of all **executions** in the United States from 1900 to 2010, found that 7.12% of the 1,054 **executions** by lethal injection were "botched" and that 0 of the 34 **executions** by firing squad had been botched.

138. Accordingly, if implemented properly, an **execution** by firing squad is a known and available alternative method of **execution** that presents a substantially lower risk of pain and suffering than the current [Alabama Department of Corrections] **protocol** described above.

Motion for Leave to File Third Amended Complaint, Exhibit A at 43–44, No. 2:11–CV–438–WKW–TFM (M.D. Ala. Aug. 25, 2015), ECF No. 256–1 (footnotes omitted).

All Citations

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Footnotes

1 In May 2012, Arthur filed a motion pursuant to Rule 60(b)(6) of the Federal Rules of Civil Procedure, seeking relief from the district court's order dismissing his § 2254 petition as untimely. Arthur, 739 F.3d at 626–27. The district court denied Arthur's motion, and this Court affirmed. Id. at 627, 633.

2 Alabama previously scheduled Arthur's **execution** for (1) April 27, 2001; (2) September 27, 2007, which was reprieved by the governor until December 6, 2007; (3) July 31, 2008; (4) March 29, 2012; and (5) February 19, 2015.

3 Arthur has, in fact, filed five § 1983 cases in total. In addition to his three method-of-**execution** challenges, he has also brought claims under § 1983 seeking (1) access to physical evidence for DNA testing in a bid to uncover exonerating evidence; and (2) an injunction barring a post-mortem autopsy of his body. (CM/ECF for the U.S. Dist. Ct. for the S.D. Ala., case no. 1:08–cv–441, docs. 1, 11, 12); (CM/ECF for the U.S. Dist. Ct. for the M.D. Ala., case no. 2:07–cv–319, docs. 1, 14,15).

4 The Alabama Supreme Court had set Arthur's **execution** date for February 19, 2015. On February 13, 2015, six days before his then-scheduled **execution**, Arthur sought a stay of **execution**. On February 17, the district court granted a stay "pending a trial and final decision on the merits." Defendants appealed, but this Court dismissed the appeal, finding that there was no abuse of discretion. With the issuance of the district court's July 19, 2016 final judgment in favor of the State, that district court stay is no longer in effect. Accordingly, Alabama has now set an **execution** date for November 3, 2016.

5 The district court carried these motions into the trial and resolved them as moot in light of its April 15, 2016 order.

6 Dr. Zentner's November 16, 2015, declaration and his December 3, 2015, deposition—which reflect opinions and testimony essentially identical to the testimony he offered at the January 2016 trial—were admitted into evidence and considered by the district court.

7 Arthur's counsel deposed Hill three times in this case. Hill also **executed** an affidavit, offering substantially the same testimony she provided at trial.

8 Although Dr. Zentner's list included 19 pharmacies, two of the pharmacies were simply two locations of the same entity.

9 Two of the attorneys testified about the **execution** of Eddie Powell in 2011, and the other attorney testified about the **execution** of Michael Jeffrey Land in 2010. Blocker testified to the **executions** of seven other inmates from 2009 until 2011.

10 Dr. Kaye's November 16, 2015, declaration and his December 10, 2015, deposition—which reflect opinions and testimony essentially identical to the testimony he offered at trial—were admitted into evidence and considered by the district court.

11 The district court rejected Arthur's contention that the State had the burden to prove his requested alternative of compounded pentobarbital was unavailable. But the district court also found that the State in fact had proven its inability to obtain compounded pentobarbital.

12 On May 16, 2016, Arthur appealed the district court's April 15, 2016, order to this Court. This Court later granted Arthur's motion to dismiss this appeal as premature, without prejudice to Arthur's refiling a timely notice of appeal upon entry of final judgment in the district court.

13 Presumably, Dr. Strader is referring to the January 2009 EKG.

14 We note that Arthur moved to have Dr. Buffington's declaration excluded from the evidence, but the district court never granted that motion. Ultimately, we do not need to rely on this declaration, but we include it for completeness.

15 Grayson v. Dunn, Case No. 2:12–cv–316 (M.D. Ala.), a consolidated action known as the "Midazolam Litigation." This Court has explained that this "group of cases began as one lawsuit [filed in April 2012] when an Alabama death row inmate sued pursuant to 42 U.S.C. § 1983 to challenge the constitutionality of Alabama's lethal injection **protocol**.... [The lawsuit] evolved along with the state's new **protocol**, and now is known as the 'Midazolam Litigation.' Since 2012, cases brought by four other Alabama death row inmates have been consolidated into the Midazolam Litigation." Brooks, 810 F.3d at 817. Petitioner Brooks himself also successfully intervened in the Midazolam Litigation. Id. Five additional inmates joined the suit after this court decided Brooks. Brooks was **executed** on January 21, 2016. A search of the ADOC prison records reveals that all 10 remaining plaintiffs are currently on Holman's death row, although the State has set a December 8, 2016 **execution** date for one of the plaintiffs.

16 In his Third Amended Complaint, Arthur alleged that, because of his age and an "anxiety disorder," there is a high likelihood that he will suffer a "paradoxical reaction" to midazolam. Arthur offered absolutely no proof on this subject, and the district court rightly considered it abandoned.

17 Arthur had filed a declaration from Dr. Kaye who opined that midazolam would not work during the **execution**, whether as a large or small dose. Even in a 500–mg dose, Dr. Kaye's opinion is that midazolam is "incapable of holding an inmate in an unconscious state through the administration of the second and third lethal injection drugs." Dr. Kaye admitted that midazolam is useful to induce unconsciousness and that he had used it for this purpose "many, many times," but that it is not effective to keep a patient unconscious. Dr. Kaye opined that this is because of midazolam's "ceiling effect," such that it stops being effective above a certain dose.

18 Although it is not entirely clear, it appears that the petitioner in Brooks was arguing that compounded (not commercially manufactured) pentobarbital was a known and available alternative method of **execution**. See Brooks, 810 F.3d at 819 & n.2. Arthur's allegation that Alabama's supply of commercially manufactured pentobarbital expired on or around November 2013 also supports this presumption.

19 The Brooks Court also rejected a midazolam-only alternative. 810 F.3d at 821–22.

20 In this appeal, Arthur has not resurrected his claim regarding a one-drug **protocol** of sodium thiopental as a feasible alternative method of **execution**. Accordingly, we will not address it.

21 Arthur's claim is only about "compounded pentobarbital," and he makes no claim that the ADOC has access to commercially manufactured pentobarbital. Nor could he. In Glossip, the Supreme Court observed that Oklahoma in December 2010 became the first state to **execute** an inmate using pentobarbital, and states "gradually shifted to pentobarbital as their supplies of sodium thiopental ran out." 135 S.Ct. at 2733. Pentobarbital was used in all 43 **executions** carried out in 2012. Id. As the Supreme Court noted, "[b]efore long, however, pentobarbital also became unavailable" because "[a]nti-death-penalty advocates lobbied the Danish manufacturer of the drug to stop selling it for use in **executions**." Id. "That manufacturer opposed the death penalty and took steps to block the shipment of pentobarbital

for use in **executions** in the United States." Id. The Supreme Court added, "Oklahoma eventually became unable to acquire the drug through any means." Id.

As Arthur points out in his reply brief, more than a dozen inmates (to date, seven in Texas, seven in Georgia, and one in Missouri) have been **executed** in 2016 using a single-drug pentobarbital **protocol**. See **Execution** List 2016, DEATH PENALTY INFORMATION CENTER, http://www.deathpenaltyinfo.org/**execution**-list-2016. Given Glossip, these states presumably used compounded pentobarbital in these **executions**.

22 In support of his argument, Arthur points us to language from Baze that a state's refusal to change its method of **execution** "in the face of these documented advantages, [and] without a legitimate penological justification for adhering to its current method of **execution**" can violate the Eighth Amendment. Baze, 553 U.S. at 52, 128 S.Ct. at 1532. But this language would apply only where the death-sentenced petitioner has already met his burden of proof and established an available alternative method of **execution** that " 'significantly reduce[s] a substantial risk of severe pain,' " which Arthur did not do here. See Glossip, 135 S.Ct. at 2737.

23 We review a district court's ruling on summary judgment de novo. Mathews v. Crosby, 480 F.3d 1265, 1268 (11th Cir. 2007). Summary judgment is appropriate only when the evidence before the court demonstrates that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The evidence must be viewed in the light most favorable to Arthur as the nonmoving party. Mathews, 480 F.3d at 1269.

24 Arthur failed to specifically plead, or request, a modification of the midazolam **protocol** in his Second or Third Amended Complaints. The district court would have been well within its discretion to dismiss any such putative claim. See Glossip, 135 S.Ct. at 2739 (conferring on petitioners the burden to plead and prove a known and available alternative). But since the district court addressed the claim on the merits, we do too.

25 Rule 9.7.3 of the American Medical Association's ("AMA") Code of Medical Ethics provides that "a physician must not participate in a legally authorized **execution**," with "participation" defined as, inter alia, the "[r]endering of technical advice regarding **execution**." AMA Code of Medical Ethics Rule 9.7.3 (2016).

26 Ironically, Dr. Kaye, Arthur's other expert, opined that midazolam was "fundamental[ly] unsuitab[le] ... as the first drug in the ADOC **protocol**" because it was "incapable" of maintaining unconsciousness through administration of the second and third drug. The district court found that this evidence was "wholly inconsistent" with Arthur's latest position that gradual administration of small doses of midazolam could be a feasible, readily available, and safer alternative. For this reason, the district court found that "Arthur cannot credibly propose the use of midazolam in any argument for a remedy [i.e., an alternative method], based upon his own evidence." The district court did not see how Arthur can argue that midazolam in small doses can be used to painlessly render him unconscious and, in the same breath, say that the drug ought not to be used at all in any dose because it will not render him insensate during the administration of the second and third drugs. See Brooks, 810 F.3d at 822 (noting a similar "fundamental tension" in the petitioner's argument that a midazolam-only **protocol** was a known and available alternative).

As an independent and alternative ground, this testimony by Arthur's own expert witness also demonstrates that the district court did not clearly err in finding that Arthur did not meet his burden to show a known, available, and substantially safer alternative, as he was required to do in his as-applied claim. Glossip, 135 S.Ct. at 2737; Gissendaner, 803 F.3d at 568–69.

27 We recognize that Dr. Buffington stated in his rebuttal declaration that a rapid infusion of midazolam could result in induction of anesthesia in as little as 30 seconds. We need not rely on his testimony, however, because Dr. Strader has no expertise in doses of midazolam for anesthesia or anesthesia at all.

28 To the extent that Arthur argues that the ADOC employees disagreed on how the results of a consciousness check should have been communicated to the warden, the point is immaterial because the ADOC-employee witnesses testified that an inmate never gave a reaction after the consciousness assessment was performed.

29 The parties dispute whether we should review Arthur's firing-squad claim de novo or merely for an abuse of discretion. We generally review the denial of a motion for leave to amend a complaint for abuse of discretion. McKinley v. Kaplan, 177 F.3d 1253, 1255 (11th Cir. 1999). But a district court's decision to deny leave to amend based on futility is a legal conclusion, and we review such decisions de novo. Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1236 (11th Cir. 2008). We need not resolve this standard-of-review issue because Arthur's firing-squad arguments on appeal lack merit under even de novo review.

30 The dissent admits that Arthur did not opt for death by electrocution because he did not opt for it under the statute during the allotted time frame. See Ala. Code § 15–18–82.1(b) ("The election for death by electrocution is waived unless it is personally made by the person in writing and delivered to the warden of the correctional facility within 30 days after the certificate of judgment pursuant to a decision by the Alabama Supreme Court affirming the sentence of death....").

But neither has Arthur claimed that **execution** by electrocution is unconstitutional, nor that the 30–day limit makes it unconstitutional. Thus, for purposes of the constitutional inquiry Arthur has raised, we cannot say that electrocution would not be a "feasible and readily implemented" alternative to lethal injection.

31 While the dissent claims that the firing squad is a "valid" alternative, the Supreme Court majority in Glossip did not opine about whether a firing squad remains a constitutional alternative to lethal injection, as that was not the issue before the Court in Glossip. The Glossip majority noted only that, back in 1879, the Supreme Court upheld a sentence of death by firing squad, citing Wilkerson v. Utah, 99 U.S. 130, 25 L.Ed. 345 (1879). Glossip, 135 S.Ct. at 2732. The principal dissent in Glossip "goes out of its way to suggest that a State would violate the Eighth Amendment if it used one of the methods of **execution** employed before the advent of lethal injection." Id. at 2739. But, as the majority in Glossip pointed out, if States cannot use one of the "more primitive" methods used in the past and also cannot use certain drugs to carry out an **execution** by lethal injection, "the logical conclusion is clear. But we have time and again reaffirmed that capital punishment is not per se unconstitutional." Id. Here, we need not reach any issue about the constitutionality of a firing squad.

32 Oklahoma later added nitrogen hypoxia as another authorized form of **execution**. Okla. Stat. tit. 22, § 1014 (2016).

33 This wide adoption of lethal injection also serves to undermine Arthur's argument that the district court's holding "will result in state-by-state variation in federal constitutional rights."

34 The dissent isolates Arthur's firing-squad claim (first made in 2015) from the rest of his § 1983 case and complains that Arthur has not had any chance for discovery or a trial on that claim. But this argument wholly ignores that Arthur's complaint challenging Alabama's three-drug lethal injection **protocol** was filed in 2011, and Alabama changed the first drug to midazolam back in 2014. Thus, Arthur has had literally years of discovery and even a 2016 evidentiary hearing to demonstrate that the midazolam drug **protocol** is, either per se or as applied, unconstitutional. But Arthur has never sustained his heavy burden. Arthur's firing-squad claim fails under both prongs of Glossip.

35 As an alternative and independent ground, we also conclude Arthur's firing-squad claim is barred by laches. See Williams v. Allen, 496 F.3d 1210 (11th Cir. 2007) (upholding dismissal of § 1983 method-of-**execution** action based on unreasonable delay); Jones v. Allen, 485 F.3d 635 (11th Cir. 2007) (denying a stay). The Supreme Court made clear in 2008—three years before Arthur filed this § 1983 case in 2011—that a petitioner-inmate had the burden to show that a proffered alternative was "feasible, readily implemented, and in fact significantly reduce[d] a substantial risk of severe pain," such that the state's failure to adopt that alternative constituted cruel and unusual punishment under the Eighth Amendment. Baze, 553 U.S. at 41, 52, 128 S.Ct. at 1526, 1532. Despite this language, Arthur nevertheless waited until August 2015 before seeking to add this firing-squad alternative method to his § 1983 complaint. Such dilatory filing "leaves little doubt that the real purpose behind his claim is to seek a delay of his **execution**, not merely to effect an alteration of the manner in which it is carried out." Jones, 485 F.3d at 640. In light of this delay, there was no error in the district court's denying Arthur leave to amend to add his firing-squad claim in August 2015.

1 Arthur's proposed allegations about the firing squad are attached as an appendix.

2 In recent years, several scholars have advocated for wider use of the firing squad. *See* Deborah W. Denno, *The Firing Squad As "A Known and Available Alternative Method of **Execution**" Post*-Glossip, 49 U. Mich. J. L. Reform 749 (2016); P. Thomas Distanislao, III, Note, *A Shot in the Dark: Why Virginia Should Adopt the Firing Squad As Its Primary Method of **Execution***, 49 U. Rich. L. Rev. 779 (2015); Alexander Vey, Note, *No Clean Hands in a Dirty Business: Firing Squads and the Euphemism of "Evolving Standards of Decency"*, 69 Vand. L. Rev. 545 (2016). One such scholar concluded that "the firing squad is the most viable 'known and available [**execution**] alternative'.... Indeed, [it] is the only current form of **execution** involving trained professionals, and it delivers a swift and certain death." Denno, 49 U. Mich. J. L. Reform at 753 (quoting *Glossip*, 135 S.Ct. at 2731).

3 Given that Arthur requested to amend his complaint immediately after the Supreme Court's decision in *Glossip*, the Majority's conclusion that the request is barred by laches is unavailing. Indeed, in a similar case, the same district court judge who presided over Arthur's proceedings rejected the Majority's position. In *Boyd v. Myers*, the prisoner—a few weeks after the *Glossip* decision—sought to amend his complaint to include the firing squad, and the State argued that the request was untimely. *See* No. 2:14–cv–1017–WKW, slip op. at 6–7, 2015 WL 5852948 (M.D. Ala. Oct. 7, 2015). The district court judge concluded that, because "*Glossip* clarified" the "**execution** alternative" requirement and the prisoner made his request shortly after *Glossip*, the request was timely. *See id.* at 6, 10.

4 As an initial matter, the Majority appears to confuse the posture of Arthur's firing-squad claim. Arthur has only moved to add to his complaint the firing-squad claim. He has not been provided an opportunity to proceed to discovery, summary judgment, or trial on the claim. Evidence and proof therefore have no relevance in the discussion of whether the district court erred in denying Arthur relief on this issue. However, in arguing the futility of Arthur's request, the Majority

emphasizes Arthur's failure to "present any admissible evidence"—a feat that Arthur is expected to accomplish in the absence of the amended pleading and corresponding discovery.

Although a district court has discretion in whether to grant a request to amend the complaint, the court in denying the request must articulate a valid reason for the denial. *See* 3-15 Moore's Federal Practice § 15.15 (Matthew Bender 3d ed.) ("[A] trial court must provide a reason for denying a motion to amend."); Fed. R. Civ. P. 15(a)(2) ("The court should freely give leave [to amend a pleading] when justice so requires."). The Majority claims that the district court could have listed several reasons for its denial here, but the court offered only one reason: futility due to an Alabama statute. We review a finding of futility de novo. *Mizzaro v. Home Depot, Inc.*, 544 F.3d 1230, 1236 (11th Cir. 2008). And this dissent argues that under de novo review, the Majority's finding of futility based on Alabama law is erroneous.

5 The Majority however muddies this finding, as it also appears to reach a contradictory conclusion: that Alabama cannot turn to a non-designated method of **execution** unless a prisoner attacks both electrocution *and* lethal injection.

6 Lethal injection is not a unitary form of **execution**; it is a category of **execution** that can be carried out using a variety of methods. I use the term "lethal-injection-based **execution** alternative" to refer to an **execution** method that falls within that category.

7 Of course, this determination is inconsistent with the Majority's suggestion that Alabama cannot turn to the firing squad absent an attack on both lethal injection *and* electrocution.

8 While concluding that Arthur must rely on an alternative currently authorized by § 15–18–82.1, the Majority indicates that, under its reading of § 15–18–82.1, Arthur could have obtained relief based on an alternative that is not currently authorized if he successfully raised a per se challenge to lethal injection or electrocution. However, that point is a red herring. First, a prisoner such as Arthur who Alabama plans to kill via lethal injection has no standing to challenge electrocution. Second, it strains credulity to suggest that Arthur could, at this time, raise a legitimate argument that lethal injection is per se unconstitutional. Lethal injection is a category of **execution** that can be carried out in a variety of ways. A finding that lethal injection is per se unconstitutional would require a finding that every possible method of lethal injection is unconstitutional. Hence, it was not feasible for Arthur to successfully bring a per se challenge to electrocution or lethal injection. Such challenges do not provide a means for Arthur or others to obtain relief based on a method of **execution** not currently authorized by § 15–18–82.1.

9 These serious constitutional concerns provide yet another reason why the Majority's interpretation of § 15–18–82.1 is improper. Even if the text of the statute is susceptible both to the reading the Majority ascribes and to the one advanced above, because the reading advanced above avoids a clash with the Supremacy Clause, it is the one that must be employed. *See Clark v. Martinez*, 543 U.S. 371, 381, 125 S.Ct. 716, 724, 160 L.Ed.2d 734 (2005).

10 As previously noted, because Florida has a statute that is identical to § 15–18–82.1, the Majority's decision has the same consequences for Florida and Alabama prisoners. *Compare* Ala. Code § 15–18–82.1, *with* Fla. Stat. § 922.105.

11 The Majority's decision may also chill the rights of prisoners outside our circuit. Several states have legislation similar to § 15–18–82.1. *Compare* Ala. Code § 15–18–82.1, *with, e.g.*, Tenn. Code § 40–23–114 (2014); Ky. Rev. Stat. § 431.220–223 (1998).

12 In addition to finding that the firing squad is not feasible and readily implemented, the Majority opines that the district court's denial of Arthur's request to amend was not error because Arthur has failed to prove that Alabama's three-drug lethal injection **protocol** is sure or very likely to cause serious harm. Based on the posture of this case, that is not a proper basis for affirming the district court. The parties have not litigated whether Alabama's **protocol**, as a general matter, is sure or very likely to cause serious harm. The district court dismissed all of Arthur's general method-of-**execution** claims based on the "**execution** alternative" requirement, and Arthur's as-applied challenge did not present the issue of whether the **protocol** is sure or very likely to cause serious harm to prisoners. Because the parties have not litigated that issue, the Majority's reliance on the issue is misplaced.

860 F.3d 881
United States Court of Appeals,
Sixth Circuit.

IN RE: OHIO **EXECUTIONPROTOCOL**.
Angelo Fears, et al., Plaintiffs,
Gary Otte; Ronald Phillips; Raymond Tibbetts, Plaintiffs-Appellees,
v.
Donald Morgan, et al., Defendants-Appellants.

No. 17-3076
|
Argued: June 15, 2017
|
Decided and Filed: June 28, 2017

Synopsis

Background: Death-row inmates brought § 1983 action against state officials and anonymous drug manufacturers, compounders, intermediaries, and others involved in state's **execution** process, challenging state's three-drug lethal-injunction **protocol**, which used midazolam as a sedative, as cruel and unusual punishment in violation of Eighth Amendment. After state announced **execution** date for three inmates, and after the court vacated stay of proceedings as to those inmates, the United States District Court for the Southern District of Ohio, No. 2:11-cv-01016, Michael R. Merz, United States Magistrate Judge, 2017 WL 378690, granted in part and denied in part inmates' motion for preliminary injunction. State officials and other defendants appealed.

Holdings: On rehearing en banc, the Court of Appeals, Kethledge, Circuit Judge, held that:

[1] inmates did not show that the **protocol** would be very likely to leave them conscious enough to feel serious pain;

[2] inmates did not show that a barbiturate-only **protocol** for lethal injections, using pentobarbital, was feasible and could be readily implemented; and

[3] state was not judicially estopped with respect to its change in policy after earlier litigation.

Preliminary injunction vacated.

Karen Nelson Moore, Circuit Judge, filed a dissenting opinion, in which Cole, Chief Judge, and Clay, Stranch, and Donald, Circuit Judges, joined, and White, Circuit Judge, join in part.

Jane B. Stranch, Circuit Judge, filed an opinion concurring in the dissent of Moore, Circuit Judge.

West Headnotes (10)

[1] Sentencing and Punishment
Mode of **execution**

To challenge successfully a State's chosen method of **execution**, as violating the Eighth Amendment's prohibition of cruel and unusual punishment, the challengers must establish that the method presents a risk that is sure or very likely to cause serious pain and needless suffering. U.S. Const. Amend. 8.

4 Cases that cite this headnote

[2] Sentencing and Punishment
Mode of **execution**

Expert testimony offered by state death-row inmates regarding effects of midazolam, which was used as sedative in state's three-drug lethal injection **protocol**, and eyewitness testimony regarding **executions** carried out with midazolam, did not meet inmates' heavy burden of showing that state's **protocol**, which used 500-milligram dose of midazolam, would be very likely to leave them conscious enough to feel serious pain, as would be required for successful claim for violation of Eighth Amendment's prohibition of cruel and unusual punishment. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

1 Cases that cite this headnote

[3] Sentencing and Punishment
Mode of **execution**

Some risk of pain is inherent in any method of **execution**, no matter how humane, and the Eighth Amendment's prohibition of cruel and unusual punishment does not guarantee a pain-free **execution**. U.S. Const. Amend. 8.

4 Cases that cite this headnote

[4] Sentencing and Punishment
Mode of **execution**

Challengers to a State's chosen method of **execution**, as violating the Eighth Amendment's prohibition of cruel and unusual punishment, must prove that an alternative method of **execution** is available, feasible, and can be readily implemented. U.S.Const. Amend. 8.

3 Cases that cite this headnote

[5] Sentencing and Punishment
Mode of **execution**

A barbiturate-only **protocol** for lethal injections, using pentobarbital, was not feasible and could not be readily implemented, and thus, state death-row inmates did not show that state's three-drug lethal-injunction **protocol**, which used midazolam as a sedative, was cruel and unusual punishment in violation of the Eighth Amendment; state could not obtain pentobarbital or its active ingredient with ordinary transactional effort. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

1 Cases that cite this headnote

[6] Criminal Law
Review De Novo

District Court's error, in determining that state death-row inmates had shown that an alternative method of **execution** was available, feasible, and could be readily implemented, was a legal error that was subject to de novo review, on state's appeal from preliminary injunction in favor of inmates, in § 1983 action alleging that state's three-drug lethal-injunction **protocol** was cruel and unusual punishment in violation of the Eighth Amendment; District Court was seriously mistaken as to what "available" and "readily implemented" meant. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

2 Cases that cite this headnote

[7] Estoppel
Claim inconsistent with previous claim or position in general

The judicial estoppel doctrine's purpose is to prevent a party from abusing the judicial process through cynical gamesmanship by changing positions to suit an exigency of the moment.

Cases that cite this headnote

[8] Estoppel
Claim inconsistent with previous claim or position in general

When the judicial estoppel doctrine is invoked against a state, it must be construed narrowly.

1 Cases that cite this headnote

[9] Estoppel
Claim inconsistent with previous claim or position in general

State's change in policy, in using a new three-drug lethal injection **protocol** with midazolam as a sedative, after earlier litigation in which a challenge to state's earlier three-drug lethal injection **protocol**, which used sodium thiopental as a sedative, was found to be moot because state had switched to a one-drug **protocol**, did not involve gamesmanship, and thus, judicial estoppel doctrine was not applicable, in state death-row inmates' § 1983 action alleging that state's new **protocol** was cruel and unusual punishment in violation of Eighth Amendment; state's representation in earlier litigation that there was absolutely no reason to believe that state would reinstate the previous three-drug **protocol** occurred before death-penalty opponents successfully prevented states from obtaining the drugs

necessary for one-drug **protocol**. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

5 Cases that cite this headnote

[10] Estoppel

Claim inconsistent with previous claim or position in general

Judicial estoppel prohibits playing fast and loose with the courts, that is, abusing the judicial process through cynical gamesmanship by changing positions to suit an exigency of the moment.

Cases that cite this headnote

***883** Appeal from the United States District Court for the Southern District of Ohio at Columbus. No. 2:11-cv-01016—Michael R. Merz, Magistrate Judge.

Attorneys and Law Firms

REARGUED EN BANC: Eric E. Murphy, OFFICE OF THE OHIO ATTORNEY GENERAL, Columbus, Ohio, for Appellants. Mark E. Haddad, SIDLEY AUSTIN LLP, Los Angeles, California, for Appellees. ON SUPPLEMENTAL BRIEF: Eric E. Murphy, Peter T. Reed, Hannah C. Wilson, Thomas E. Madden, Jocelyn K. Lowe, Charles L. Wille, Katherine E. Mullin, OFFICE OF THE OHIO ATTORNEY GENERAL, Columbus, Ohio, for Appellants. Mark E. Haddad, Joshua E. Anderson, Alycia A. Degen, Katherine A. Roberts, Collin P. Wedel, Adam P. Micale, SIDLEY AUSTIN LLP, Los Angeles, California, Allen L. Bohnert, Erin G. Barnhart, Adam M. Rusnak, Nadia Wood, OFFICE OF THE FEDERAL PUBLIC DEFENDER FOR THE SOUTHERN DISTRICT OF OHIO, Columbus, Ohio, James A. King, PORTER, WRIGHT, MORRIS & ARTHUR LLP, Columbus, Ohio, Vicki Werneke, FEDERAL PUBLIC DEFENDER, Cleveland, Ohio, Timothy F. Sweeney, LAW OFFICE OF TIMOTHY FARRELL SWEENEY, Cleveland, Ohio, Lisa M. Lagos, OFFICE OF THE OHIO PUBLIC DEFENDER, Columbus, Ohio, for Appellees.

Before: COLE, Chief Judge; BATCHELDER, MOORE, CLAY, GIBBONS, ROGERS, SUTTON, McKEAGUE, GRIFFIN, KETHLEDGE, WHITE, STRANCH, DONALD, and THAPAR, Circuit Judges. [*]

KETHLEDGE, J., delivered the opinion of the court in which BATCHELDER, GIBBONS, ROGERS, SUTTON, McKEAGUE, GRIFFIN, and THAPAR, ***884** JJ., joined, and WHITE, J., joined in the analysis of judicial estoppel. MOORE, J. (pp. 892–909), delivered a separate dissenting opinion in which COLE, C.J. and CLAY, STRANCH, and DONALD, JJ., joined, and WHITE, J., joined in all except part II.C. regarding judicial estoppel. STRANCH, J. (pp. 909–11), delivered a separate concurrence to Judge Moore's dissent.

OPINION

KETHLEDGE, Circuit Judge.

Roughly two decades have passed since the plaintiffs in this case murdered their victims. Ronald Phillips raped a three-year-old girl and beat her so badly that her internal organs ruptured. For two days she suffered intense abdominal pain and vomiting, until her heart collapsed. *See State v. Phillips*, 74 Ohio St.3d 72, 656 N.E.2d 643, 650-52 (1995). Gary Otte entered the home of an Ohio man, robbed him, and then shot him in the head. Two nights later, Otte pushed his way into a woman's home and did the same things to her. After each murder Otte went out partying. *See State v. Otte*, 74 Ohio St.3d 555, 660 N.E.2d 711, 715-16 (1996). Raymond Tibbetts killed an elderly man and his caretaker. Police found the man slumped in his chair with butcher knives protruding from his chest and back. His caretaker lay on the floor in a pool of blood with her skull cracked open and its contents scattered nearby. *See State v. Tibbetts*, 92 Ohio St.3d 146, 749 N.E.2d 226, 237-39 (2001).

Phillips, Otte, and Tibbetts now claim that Ohio's **ExecutionProtocol** would cause them to suffer severe pain in violation of the Eighth Amendment. In a sense the claim is unprecedented: the Supreme Court "has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment." *Glossip v. Gross*, —— U.S. ——, 135 S.Ct. 2726, 2732, 192 L.Ed.2d 761 (2015) (internal quotation marks omitted). The State's chosen procedure here is the same procedure (so far as the combination of drugs is concerned) that the Supreme Court upheld in *Glossip.*

Every other court of appeals to consider that procedure has likewise upheld it, including most recently the Eighth Circuit, which rejected a nearly identical challenge in a procedural posture identical to the one here. *See McGehee v. Hutchinson*, 854 F.3d 488, 492 (8th Cir. 2017) (en banc) (per curiam), *cert. denied*, —— U.S. ——, 137 S.Ct. 1275, 197 L.Ed.2d 746 (2017); *Glossip*, 135 S.Ct. at 2739-40 (collecting cases); *Brooks v. Warden*, 810 F.3d 812, 818-22 (11th Cir. 2016); *cf. Jordan v. Fisher*, 823 F.3d 805, 811-12 (5th Cir. 2016). Yet here the district court thought the same procedure is likely invalid. We respectfully disagree and reverse the court's grant of a preliminary injunction.

I.

The litigation that produced this appeal began in 2004, when death-row inmates challenged Ohio's then-existing three-drug **protocol** under 42 U.S.C. § 1983. That **protocol** called for the injection of sodium thiopental (which anesthetizes the prisoner) followed by pancuronium bromide (which paralyzes the prisoner's muscles) and finally potassium chloride (which stops the prisoner's heart). By 2008, 30 of the 36 states with the death penalty had adopted that three-drug **protocol**. *See Baze v. Rees*, 553 U.S. 35, 42-44, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008). Yet the Ohio inmates argued that the **protocol** created an unacceptable risk that, if the sodium thiopental were improperly administered, inmates would feel the painful effects of the second and third drugs. In 2008, the Supreme Court rejected that argument and upheld Kentucky's nearly identical three-drug **protocol**. *See id.* at 41, 128 S.Ct. 1520.

***885** Nevertheless, the next year, Ohio announced that it was switching to the same one-drug **protocol** favored by the losing plaintiffs in *Baze*: a massive, lethal dose of either sodium thiopental or another barbiturate, pentobarbital. From 2010 to 2013, Ohio **executed** 20 inmates using those barbiturates. Meanwhile, opponents of the death penalty successfully pressured the pharmaceutical companies who make the drugs to stop selling them to states. *See Glossip*, 135 S.Ct. at 2733-35. Ohio's supplies soon ran out, as did other states'. *See id.*; R. 941 at 31942-44.

The shortage led some states with three-drug **protocols** to turn to midazolam, a sedative in the same family of drugs as Valium. *See Glossip*, 135 S.Ct. at 2733-34. In 2014, Oklahoma adopted a **protocol** that called for the administration of 500 milligrams of midazolam—about 100 times the usual therapeutic dose—followed by a paralytic agent (pancuronium bromide, rocuronium bromide, or vecuronium bromide) and potassium chloride. Death-row inmates filed a § 1983 action alleging that Oklahoma's **protocol** violated the Eighth Amendment. As relief, the inmates sought a stay, which the district court denied. The Supreme Court affirmed the denial for two "independent reasons": that the district court "did not commit clear error when it found that midazolam is highly likely to render a person unable to feel pain during an **execution**"; and that Oklahoma was unable to acquire either pentobarbital or sodium thiopental. *Id.* at 2731, 2738-39.

In October 2016, Ohio adopted a lethal-injection **protocol** using the same three drugs that Oklahoma uses. Like the Oklahoma **protocol**, the Ohio **protocol** contains several procedural safeguards to ensure that **executions** are carried out humanely, including guidelines for identifying viable IV sites, detailed requirements for training **execution** team members, and a "consciousness check" after the 500-milligram injection of midazolam. If the prisoner is found to be conscious, a qualified drug administrator can inject another 500 milligrams of midazolam. After confirming that the prisoner is unconscious, the team can then administer the second and third drugs. *See* R. 667-1 at 19828-29.

Ohio planned to use this **protocol** to **execute** Phillips, Otte, and Tibbetts during the first four months of this year. The three inmates then filed complaints and moved for a preliminary injunction, claiming among other things that Ohio's three-drug **protocol** violates the Eighth Amendment's ban on "cruel and unusual punishments." The plaintiffs' theory here is the same one the Court rejected in *Glossip*: that the first drug—a massive dose of midazolam—will not prevent them feeling severe pain after injection of the second and third drugs.

After an evidentiary hearing, the district court found that "use of midazolam as the first drug" in Ohio's three-drug **protocol** would create a "substantial risk of serious harm" under *Baze* and *Glossip*. The court separately held that Ohio was estopped from using the paralytic and heart-stopping drugs because of Ohio's putative representations when it switched from its original three-drug **protocol** to the one-drug **protocol** in 2009. Thus, the court held that the plaintiffs had demonstrated a likelihood of success

on their claims, and stayed the plaintiffs' executions. This appeal followed.

II.

A.

The plaintiffs first argue that Ohio's three-drug protocol violates their Eighth Amendment right to be free from cruel and unusual punishment. As to that claim, we begin with two areas of common ground. First, we agree with the plaintiffs ***886** and the district court that the protocol's second and third drugs—the paralytic and potassium chloride, which stops the inmate's heart—would cause severe pain to a person who is fully conscious. (Hence the need for the first drug—the 500-milligram dose of midazolam.) Second, we reject the State's argument that the Supreme Court's holding in *Glossip* categorically bars the plaintiffs' claim here. The Court's holding—that the district court there "did not commit clear error when it found that midazolam is highly likely to render a person unable to feel pain during an execution [,]" 135 S.Ct. at 2739—is couched expressly in terms of a standard of review that cuts the other way here. But neither, as the plaintiffs suggest, is *Glossip* irrelevant here. Quite the contrary: the Court's opinion contains plenty of reasoning that was not confined to the record there—and which therefore binds us just as much as the reasoning in any other opinion of the Supreme Court.

1.

[1] Yet here the district court's opinion was seriously flawed nonetheless. To begin with, that opinion did not apply the relevant legal standard, which by now the Supreme Court and our court have recited a total of four times. Specifically, to challenge successfully a State's chosen method of execution, the plaintiffs must "establish that the method presents a risk that is *sure or very likely* to cause" serious pain and "needless suffering [.]" *Glossip*, 135 S.Ct. at 2737 (emphasis in original) (internal quotations marks omitted); *see also Baze*, 553 U.S. at 50, 128 S.Ct. 1520 (same); *Cooey v. Strickland (Cooey II)*, 604 F.3d 939, 944 (6th Cir. 2010) (same); *Cooey v. Strickland (Cooey I)*, 589 F.3d 210, 220 (6th Cir. 2009) (same). Instead, the district court addressed only whether Ohio's procedure presents a "substantial risk of serious harm," *Baze*, 553 U.S. at 50, 128 S.Ct. 1520 (internal quotation marks omitted). That standard is correct so far as it goes; but it elides the more rigorous showing—that the method of execution is *sure or very likely* to cause serious pain—that the Supreme Court and our court have repeatedly said is necessary to satisfy the "substantial risk" standard in the particular context present here. *Accord McGehee*, 854 F.3d at 492.

Nor, respectfully, did the district court offer much reasoning in support of its decision. (To some extent that omission is understandable, given the tight timelines applicable here.) The bulk of the court's opinion merely summarized the expert testimony on both sides. The relevant question, to reiterate, is whether the plaintiffs met their "heavy burden," *Baze*, 553 U.S. at 53, 128 S.Ct. 1520, to show that an inmate who receives a 500-milligram dose of midazolam is "sure or very likely" to be conscious enough to experience serious pain from the second and third drugs in the protocol. *Glossip*, 135 S.Ct. at 2737. As to that question the experts offered diametrically opposed conclusions: the plaintiffs' experts argued that serious pain was "highly likely" or a "virtual certainty," while Ohio's experts testified that the risk was "very, very low" or "speculative." *Compare* R. 923 at 30802-03 *and* R. 844-1 at 24944 *with* R. 924 at 31063-64 *and* R. 852-2 at 25831-32. Yet the district court offered virtually no reason for its decision to adopt the conclusions of the plaintiffs' experts wholesale. The court did say, "[w]ithout knowing precisely why," that inmates who are "administered midazolam" (including doses as low as ten milligrams—one fiftieth of the dosage at issue here) "take longer to die and exhibit different bodily behaviors in the process." R. 948 at 32227. The court also noted that "there was little support in the record for the idea that midazolam would be used alone" (again, at doses that are a tiny fraction of the dosage at issue here) "for ***887** surgeries other than those performed on an outpatient basis." *Id.* at 32228. The latter observation has little relevance in light of a passage from *Glossip* that does bind us here: "the fact that a low dose of midazolam is not the *best* drug for maintaining unconsciousness during surgery says little about whether a 500-milligram dose of midazolam is *constitutionally adequate* for purposes of conducting an execution." 135 S.Ct. at 2742 (emphasis in original). And taken even on their own terms, neither of the district court's observations provides much support for the conclusion that a 500-milligram dose of midazolam

is very likely to leave an inmate conscious enough to feel serious pain.

The court also drew what it called "reasonable inferences" from the abandonment of midazolam-based protocols by three states. R. 948 at 32228. First, the district court noted that, in 2014, Ohio abandoned the midazolam-opioid protocol that it used to execute Dennis McGuire. *Id.* But McGuire's dose of midazolam was only 10 milligrams, so again his execution says little about the effectiveness of a 500-milligram dose. Second, the district court found that Florida, "despite having conducted many executions using midazolam, abandoned the drug while this case was in hearing." *Id.* But the court did not explain why Florida changed its protocol or why that decision helps the plaintiffs here. And meanwhile, in *Glossip*, the Supreme Court observed that Florida had used midazolam in 11 executions, apparently "without any significant problems." 135 S.Ct. at 2734, 2746. Third, the district court noted that Arizona had "abandoned midazolam shortly before [the hearing below] as a result of settling litigation over its use." R. 948 at 32228. But Arizona's settlement agreement says nothing about why the State abandoned midazolam, other than that the State had run out of it. *See* R. 976-2 at 36214. None of these states' actions, therefore, provide reason to infer that 500 milligrams of midazolam is sure or very likely to leave an inmate conscious enough to feel serious pain.

Otherwise, the district court merely observed that "there are not now and never will be clinical studies of the effect of injecting 500 mg of midazolam into a person[,]" and that "we certainly cannot ask the executed whether they experienced pain after the injection of midazolam[.]" R. 948 at 32227-28. Those observations are obviously correct, but the district court's reliance on them effectively shifted the burden of proof to the State. Fairly or not, the applicable legal standard requires the plaintiffs to prove their allegations to a high level of certainty; yet the district court based its decision, at best, on uncertainty.

2.

[2] The district court's findings thus provide little support for its conclusion that Ohio's three-drug protocol creates an unconstitutional risk of pain. Since we can affirm the district court's decision on any ground supported by the record, however, we must consider whether the plaintiffs met their burden for reasons the court did not articulate. The plaintiffs' evidence as to risk of pain fell into two main categories: testimony about midazolam's effects, and testimony about executions carried out with midazolam. We address each in turn.

Each side offered testimony from two experts as to midazolam's effects. The plaintiffs offered testimony from Dr. Sergio Bergese, M.D., an anesthesiologist, and Dr. Craig Stevens, Ph.D., a pharmacologist. The State offered testimony from Dr. Joseph Antognini, M.D., an anesthesiologist, and Dr. Daniel Buffington, Ph.D., a pharmacologist.

The experts generally agreed that midazolam ultimately has a "ceiling" above which an increase in dosage will not have ***888** any greater anesthetic effect. (On that point Dr. Buffington was the only dissenter.) Dr. Stevens attempted to estimate the ceiling using two different methods. One method, based on extrapolations from petri-dish experiments, suggested that the ceiling effect occurs at 228 milligrams. R. 923 at 30800. Another method, based on extrapolations from clinical studies, yielded an estimate of 25 milligrams. R. 836-1 at 24827. That Dr. Stevens's estimates vary by a factor of nine, however, underscores that they are highly speculative. Moreover, even Dr. Stevens's estimates suggest that any ceiling effect arrives only at doses five to 45 times greater than the usual therapeutic dose. And in any event the relevant question is not whether the ceiling effect arrives at the equivalent of five doses or 45, but whether, once it arrives, an inmate is sure or very likely to experience serious pain from the second and third drugs. *See Glossip*, 135 S.Ct. at 2743.

As to that point, Dr. Stevens testified that midazolam cannot produce "general anesthesia," the level of unconsciousness appropriate for major surgeries. Studies indicate that midazolam—at doses in the therapeutic range—produces "deep sedation," a level of brain depression just short of general anesthesia. But none of those studies involved the massive doses at issue here. *See id.* at 2742 ("The effect of a small dose of midazolam has minimal probative value about the effect of a 500-milligram dose"). Meanwhile, the experts for both sides agreed that midazolam is sometimes used alone for intubation, a medical procedure in which a tube is inserted into a person's windpipe. Dr. Antognini, one of Ohio's experts, testified that intubation is "incredibly

stimulating." R. 924 at 31052. Dr. Bergese likewise acknowledged that intubation is "very reactive," meaning that "people react to [it] quite a bit." R. 923 at 30900. True, Dr. Bergese asserted in his expert report that the protocol's second and third drugs are more painful than intubation. But Dr. Bergese did not cite any medical evidence to support that assertion. And Dr. Antognini did cite studies showing that injection of the paralytic drug has no effect on a sedated person's level of consciousness as measured by a brain scan, even when the person appears to flinch in response. R. 924 at 31066. Dr. Antognini further testified that midazolam would reduce or remove any sensation of suffocation (commonly referred to as "air hunger") caused by the paralytic. *See id.* at 31072, 31088-89.

Thus, even Dr. Bergese—the plaintiffs' principal expert as to whether Ohio's executionprotocol would cause inmates to experience severe pain—admitted that the science on this issue "could go either way." R. 923 at 30844, 30909. What tipped the balance for him, rather, was "the eyewitness reports" from laymen who attended executions involving midazolam. *Id.* at 30909; *see also id.* at 30870. But that data came with a raft of problems of its own. First, the sample size was small: in his expert report, Dr. Bergese discussed only nine midazolam-based executions. *See* R. 844-1 at 24972-80. Second, most of those accounts came from witnesses who, according to the district court, were likely to be "highly biased"—such as relatives of executed inmates, capital-defense attorneys, and even the inmates' own lawyers. R. 923 at 30869. And none of these witnesses had any medical training. *See*, *e.g.*, R. 922 at 30644, 30713. Thus, as Dr. Bergese himself admitted, "the quality of the data is not there." R. 923 at 30910; *see also id.* at 30869.

The reliability of Dr. Bergese's opinion does not improve when one considers the evidence of the nine executions themselves. Two of them—the execution of Clayton Lockett in Oklahoma and the execution of Joseph Wood in Arizona—are ones that the Supreme Court has specifically said ***889** have "little probative value" because they "did not involve the protocol at issue here." *Glossip*, 135 S.Ct. at 2746. And notwithstanding the plaintiffs' assertion to the contrary, we are not free to disregard that reasoning simply because the plaintiffs' experts have to some extent testified to the contrary here. Moreover, Lockett's IV line was not properly connected. *See* R. 948 at 32147; *Glossip*, 135 S.Ct. at 2734, 2746. A third execution—the McGuire execution in Ohio—involved a dose of 10 milligrams of midazolam rather than 500. And the district court in McGuire's case found that McGuire had a condition that "might make him susceptible to an airway obstruction." R. 948 at 32191 n.26. Hence that execution too has "little probative value[.]" *Glossip*, 135 S.Ct. at 2746.

That leaves six executions that were conducted using the same protocol at issue here. But five of those involved reports only of eyes opening, "head movements," and "foot movements" after the injection of midazolam. R. 844-1 at 24974-80. And the plaintiffs concede that "evidence of slight movements might, in a vacuum, not be compelling evidence of consciousness." Appellee Br. 54. Dr. Bergese likewise testified that minor movements are possible even under general anesthesia. R. 923 at 30834, 30850. Moreover, even in executions involving barbiturates, inmates may have "convulsions" without a paralytic. *Workman v. Bredesen*, 486 F.3d 896, 909 (6th Cir. 2007). We upheld the use of a paralytic in executions for that very reason, finding legitimate a state's concern that "lethal injection without [the paralytic] would typically result in involuntary movement," which "might be misinterpreted as ... an indication of consciousness." *Id.*

That leaves only the execution of Ronald Smith in Alabama. The district court heard testimony about that execution from Spencer Hahn, a federal defender in the Alabama Capital Habeas Unit. According to Hahn, at some point after the injection of midazolam, Smith began coughing, clenching and unclenching his fists, flailing his arms, and moving his lips. R. 922 at 30619. Both sides' experts agreed, however, that people's bodies can move at reduced levels of consciousness. Dr. Antognini explained that surgical patients under anesthesia can respond to noxious stimuli in complex ways, sometimes by thrashing about violently. R. 852-1 at 25792; R. 924 at 31037, 31044, 31063-64. That is why patients' arms are strapped down and their eyes taped shut. R. 924 at 31044. Indeed, as the "Lazarus phenomenon" illustrates, even brain-dead persons can move their limbs and seemingly respond to stimuli. *See id.* at 31036-37. Dr. Stevens agreed that "reflexive withdrawal from a noxious stimulus is not considered a purposeful movement." R. 948 at 32196. Similarly, Dr. Bergese testified that "movement is ... in the spinal cord," so "patients are going to move even when the consciousness is depressed." R. 923 at 30834. And a reporter for the *Columbus Dispatch*, who witnessed 19 executions using barbiturate-based protocols, said that he

had sometimes seen "clenching and unclenching of the hands." R. 922 at 30708.

As for coughing or gasping, neither demonstrates that the inmate is feeling air hunger. Dr. Antognini testified that midazolam, like other anesthetics, can remove the sensation of air hunger by depressing the drive to breathe. R. 924 at 31071-73, 31088-93. Even Dr. Bergese admitted that an inmate who gasps repeatedly during an **execution** might not be conscious, and that involuntary respirations associated with the process of dying are hard to distinguish from purposeful attempts to breathe. *See* R. 923 at 30860-61. Dr. Antognini also testified that patients can cough vigorously while under anesthesia for surgery, though this behavior may ***890** signal that the patient is shifting to a lighter level of anesthesia. R. 924 at 31037, 31043, 31157, 31178.

All that said, Hahn's description of the Smith **execution** is the plaintiffs' best evidence in support of their claim. But that evidence is far from compelling. Some people react differently to drugs than other people do, *see* R. 923 at 30896; and the amount of movement reported in Smith's **execution** appears to be the exception, not the rule, for **executions** with the three-drug **protocol**. More fundamentally, as Dr. Bergese himself explained, consciousness falls on a "spectrum." *Id.* at 30830. Yet he appeared to treat consciousness as binary when he opined that an inmate sedated with 500 milligrams of midazolam would feel pain the same way a conscious person would, simply because the inmate clenches his fists or coughs.

[3] In sum, we will grant that the plaintiffs have shown some risk that Ohio's **executionprotocol** may cause some degree of pain, at least in some people. But some risk of pain "is inherent in any method of **execution**—no matter how humane[.]" *Baze*, 553 U.S. at 47, 128 S.Ct. 1520. And the Constitution does not guarantee "a pain-free **execution**[.]" *Cooey I*, 589 F.3d at 220. Different people may have different moral intuitions as to whether—taking into account all the relevant circumstances—the potential risk of pain here is acceptable. But the relevant legal standard, as it comes to us, requires the plaintiffs to show that Ohio's **protocol** is "sure or very likely" to cause serious pain. *Glossip*, 135 S.Ct. at 2737, 2745. The district court did not meaningfully apply that standard here. And the plaintiffs have fallen well short of meeting it.

B.

[4] **[5]** That shortcoming by itself is sufficient to defeat the plaintiffs' claim under *Glossip*. But the district court also erred in its analysis of *Glossip*'s second prong—which requires the plaintiffs to prove that an alternative method of **execution** is "available," "feasible," and can be "readily implemented," among other things. *Id.* at 2737. The court found this requirement met as to one of the plaintiffs' proposed alternatives, namely a one-drug, barbiturate-only method using either sodium thiopental or pentobarbital. The court acknowledged, however, that Ohio no longer has any supplies of these drugs, that "Ohio's efforts to obtain the drug from other States and from non-State sources have not met with success[,]" and that Ohio is "not likely" to overcome these obstacles anytime soon. R. 948 at 32229. Yet the court concluded that barbiturates are "available" to Ohio because "there remains the possibility" that Ohio can obtain the active ingredient of pentobarbital and have it made into injectable form by a compounding pharmacy. *Id.*

[6] The district court was seriously mistaken as to what "available" and "readily implemented" mean. (For that reason the district court's error is legal, and thus subject to de novo review. *See Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, —— U.S. ——, 134 S.Ct. 1744, 1748, 188 L.Ed.2d 829 (2014).) To obtain pentobarbital or its active ingredient, Ohio would need to receive an import license from the Drug Enforcement Administration. R. 948 at 32229. Ohio's application for that license has been pending, without apparent action by the DEA, for more than four months. *See* R. 966-13 at 34506-10; R. 966-14 at 34512-17. Ohio does not know whether the DEA will approve its application, or even when that decision might be made. R. 948 at 32229. And even if that application is approved, Ohio might not be able to locate a willing supplier or manufacturer, for reasons the Supreme Court explained at some length in *Glossip*.*See*135 S.Ct. at 2733. As ***891** the district court acknowledged, even the plaintiffs' expert, Dr. Stevens, "was unable to identify any manufacturers or suppliers of thiopental and/or pentobarbital who were willing to sell those drugs, or even those drugs' active pharmaceutical ingredients, to Ohio for the purposes of conducting lethal injection **executions**." R. 948 at 32163. The plaintiffs, for their part, rely on Dr. Buffington's testimony about

an affidavit he filed in a prior Alabama case, in which he stated that he believed "there are pharmacists in the United States that are able to compound pentobarbital for use in lethal injections because other states have been reported to have obtained compounded pentobarbital for use in executions." R. 925 at 31440-41. But that is quite different from saying that any given state can actually locate those pharmacies and readily obtain the drugs. And Dr. Buffington testified that he personally contacted 15 pharmacies to that end without success. *Id.* Indeed, in the very case in which Dr. Buffington submitted his affidavit, the Eleventh Circuit rejected the claim that pentobarbital was available to Alabama. *Arthur v. Comm'r, Ala. Dep't of Corr.*, 840 F.3d 1268, 1296 (11th Cir. 2016), *cert. denied sub nom. Arthur v. Dunn*, —— U.S. ——, 137 S.Ct. 725, 197 L.Ed.2d 225 (2017). Meanwhile, Ohio itself contacted the departments of correction in Texas, Missouri, Georgia, Virginia, Alabama, Arizona, and Florida to ask whether they would be willing to share their supplies of pentobarbital. All refused. *See* R. 905-1 at 30313-14. Granted, for the one-drug protocol to be "available" and "readily implemented," Ohio need not already have the drugs on hand. But for that standard to have practical meaning, the State should be able to obtain the drugs with ordinary transactional effort. Plainly it cannot. The reality is that the barbiturate-only method is no more available to Ohio than it was to Oklahoma two years ago in *Glossip*, for precisely the same reasons.

C.

That leaves the district court's determination that Ohio is judicially estopped from returning to a three-drug protocol. The plaintiffs ask us to review that determination for an abuse of discretion, citing the Supreme Court's reference to judicial estoppel as an "equitable doctrine" in *New Hampshire v. Maine*, 532 U.S. 742, 750, 121 S.Ct. 1808, 149 L.Ed.2d 968 (2001). But we have twice rejected that argument and "continue[d] to apply de novo review." *Mirando v. U.S. Dep't of Treasury*, 766 F.3d 540, 545 n.1 (6th Cir. 2014); *Lorillard Tobacco Co. v. Chester, Willcox & Saxbe, LLP*, 546 F.3d 752, 757 (6th Cir. 2008). And here, as in a recent Second Circuit case, "the choice between the two standards is immaterial, for under either," the doctrine of judicial estoppel "is inapplicable[.]" *Chevron Corp. v. Donziger*, 833 F.3d 74, 128 (2d Cir. 2016).

[7] **[8]** The doctrine's purpose is to prevent a party "from abusing the judicial process through cynical gamesmanship" by changing positions "to suit an exigency of the moment." *Mirando*, 766 F.3d at 545. And when, as here, the doctrine is invoked against a state, it must be "construed narrowly." *See United States v. Owens*, 54 F.3d 271, 275 (6th Cir. 1995).

[9] According to the plaintiffs, Ohio's plan to use a three-drug protocol contradicts Ohio's statements in 2009 that it was switching to a one-drug protocol and that "going forward, pancuronium bromide [the paralytic drug] no longer will be used as part of the lethal injection process." R. 718-3 at 22390. Ohio also stated in a motion for summary judgment that a then-pending challenge to its prior three-drug protocol was moot—because Ohio was no longer using it. R. 966-2. The district court never granted Ohio's motion, but our court soon held that any challenge to Ohio's old three-drug protocol (using sodium thiopental) ***892** was "now moot." *Cooey v. Strickland*, 588 F.3d 921, 923 (6th Cir. 2009) (per curiam). Thus, the plaintiffs argue, Ohio prevailed by "permanently" renouncing the paralytic and potassium chloride—a promise on which Ohio has putatively now reneged.

The argument is meritless. As an initial matter, the plaintiffs nowhere explain how they have been harmed in the current litigation, or how the State has been helped, by the fact that the parties in the prior litigation did not have a trial about the sodium-thiopental three-drug protocol in 2009. To the contrary, by all appearances, the absence of that trial has made zero difference in this litigation. The effects of the two drugs that the old and new protocol share (namely, the paralytic and the heart-stopping drug) are undisputed. What is disputed, rather, is the effects of midazolam; and there is no reason to think that a trial about sodium thiopental would have affected that issue one way or the other.

More to the point, Ohio represented in 2009 that it was switching to a one-drug protocol in the context of a particular case involving particular named plaintiffs, which apparently do not include the named plaintiffs here. Ohio then proceeded to execute 20 death-row inmates with the new one-drug protocol, which should be proof enough of the State's truthfulness in making those representations. Ohio did argue in support of its summary-judgment motion (which the State itself later withdrew) that "[t]here

is absolutely no reason to believe that defendants will reinstate the previous 'three-drug **protocol**' if the plaintiffs' suits were dismissed." R. 966-2 at 34329. But that was before death-penalty opponents successfully prevented Ohio (along with other states) from obtaining the drugs necessary to use the one-drug **protocol**. *See Glossip*, 135 S.Ct. at 2733-34. Ohio then ceased **executions** altogether for about three years, before switching to the three-drug **protocol** that the Supreme Court had recently upheld in *Glossip*.

[10] A state's change in policy in response to unforeseen circumstances like these is hardly the kind of inconsistency that warrants estoppel. *See New Hampshire*, 532 U.S. at 749-50, 121 S.Ct. 1808; *Owens*, 54 F.3d at 275. Judicial estoppel prohibits "playing fast and loose with the courts"—that is, "abusing the judicial process through cynical gamesmanship" by changing positions "to suit an exigency of the moment." *New Hampshire*, 532 U.S. at 749-50, 121 S.Ct. 1808; *Mirando*, 766 F.3d at 545. Suffice it to say that, if any gamesmanship led us to this pass, it was not gamesmanship by the State.

* * *

The plaintiffs have failed to demonstrate a likelihood of success on their claims. That failure is "dispositive." *Cooey II*, 604 F.3d at 946. We therefore vacate the district court's January 26, 2017 preliminary injunction.

DISSENT

KAREN NELSON MOORE, Circuit Judge, dissenting. There is a narrow question before this court: Should Gary Otte, Ronald Phillips, and Raymond Tibbetts have a trial on their claim that Ohio's **executionprotocol** is a cruel and unusual punishment, or should Ohio **execute** them without such a trial? The majority has concluded that there is no need for a trial on the merits of Plaintiffs' constitutional claim. I disagree.

There is no dispute that the second and third drugs in Ohio's **executionprotocol** cause immense pain. There is significant evidence that the first drug, midazolam, cannot prevent someone from feeling that pain. After a five-day hearing on Plaintiffs' motion for a preliminary injunction, the district court determined that there should ***893** be a full trial on the merits of Plaintiffs' claim that Ohio's use of midazolam as the first drug in a three-drug **executionprotocol** creates a constitutionally unacceptable risk of pain. Despite the deferential standard of review that this court should apply, the majority casts aside the district court's determination that Plaintiffs should have a trial before the state **executes** them. The majority also determines that despite Defendants' unequivocal sworn testimony that they would no longer use pancuronium bromide or potassium chloride in **executions**, judicial estoppel does not prevent their renewed attempt to use those drugs. For the reasons discussed below, I would hold that Plaintiffs should have a trial on their Eighth Amendment and judicial-estoppel claims, and I respectfully dissent.

I. BACKGROUND

Because a key issue in this case is whether the district court made the requisite findings of fact to support a preliminary injunction, I begin by discussing the evidence presented to the district court and the district court's findings of fact based on that evidence. Over the course of the five-day hearing, the district court heard testimony from four experts: Dr. Craig Stevens, PhD., a Professor of Pharmacology at Oklahoma State University who testified as an expert witness for Plaintiffs; Dr. Sergio Bergese, M.D., a Professor of Anesthesiology and Neurological Surgery and practicing anesthesiologist at The Ohio State University Wexner Medical Center who testified as an expert witness for Plaintiffs; Dr. Joseph Antognini, M.D., a retired anesthesiologist and faculty member at University of California, Davis who testified as an expert witness for Defendants; and Dr. Daniel Buffington, Pharm.D, a pharmacologist in private practice who testified as an expert witness for Defendants. The district court also heard testimony from: Edwin Voorhies, the Managing Director of Operations for the Ohio Department of Rehabilitation and Correction; Gary Mohr, the Director of the Ohio Department of Rehabilitation and Correction; and two Ohio Department of Rehabilitation and Correction **Execution** Team members (who testified anonymously). A reporter, Alan Johnson, testified as an eyewitness to the **execution** of Dennis McGuire by the State of Ohio. Five legal professionals testified as eyewitnesses to out-of-state **executions** in which midazolam was part of a multi-drug **executionprotocol**.

In his 119-page Decision and Order Granting in Part and Denying in Part Plaintiffs' Motions for Preliminary Injunction, the magistrate judge discussed this testimony and set out his findings of fact. First, the district court discussed the testimony of three eyewitnesses to Ohio's execution of Dennis McGuire: ODRC Director Gary Mohr, Execution Team Member No. 10, and reporter Alan Johnson. All three testified that after McGuire appeared to be unconscious, McGuire's stomach began repeatedly to knot up and then relax, and McGuire began to snort. Decision & Order at 20–21. According to Johnson, "McGuire began coughing, gasping, choking in a way that I had not seen before at any execution." *Id.* at 21. Johnson also testified that McGuire gasped "in a way that almost seemed to be choking," clenched and unclenched his hands, and "attempted to kind of lift up off the table." *Id.* Johnson testified that McGuire gasped fifteen or sixteen times, and that the gasping or choking went on for twelve to thirteen minutes. *Id.* Johnson has witnessed twenty Ohio executions, and had never previously seen anything like the intensity or duration of McGuire's reaction. *Id.* Mohr has overseen eleven executions, and testified that he had not previously seen a reaction like McGuire's. *Id.* at 20.

***894** Next, the district court discussed the testimony of five eyewitnesses to midazolam-involved executions that took place outside of Ohio. Two of these out-of-state executions occurred after the Supreme Court's *Glossip* decision. Spencer Hahn, an Assistant Federal Defender in the Capital Habeas Unit in the Middle District of Alabama, witnessed the December 8, 2016 execution of Ronald Smith by the State of Alabama. Like Ohio's current executionprotocol, the protocol used to execute Smith called for 500 milligrams of midazolam. It also called for a 600-milligram dose of a paralytic drug, and 240 milliequivalents of potassium chloride. Decision & Order at 22. Hahn testified that "[t]here were two periods in which [Smith] appeared to rest somewhat briefly" but then he began "coughing, heaving, flailing, or attempting to flail arms, clenching and unclenching of fists, movement of lips ... and then doing this asthmatic cough, barking-type cough." *Id.* at 22. Terry Alang, an attorney employed as an investigator in the Capital Habeas Unit in the Middle District of Alabama, witnessed the January 20, 2016 execution of Christopher Brooks by the State of Alabama. Alabama used the same executionprotocol that it used in the Smith execution, most notably 500 milligrams of midazolam. According to Alang's testimony, after the execution team members administered midazolam, Brooks's chest began heaving. *Id.* at 24.

The district court also discussed testimony about three executions that occurred before the Supreme Court's *Glossip* decision. *Id.* at 22. First, Sonya Rudenstine, a Florida lawyer who specializes in capital post-conviction work, witnessed the execution of Paul Howell by the State of Florida. Like Ohio's current executionprotocol, the protocol used to execute Howell called for 500 milligrams of midazolam in two separate injections of 250 milligrams each. *Id.* at 23. The protocol then called for 200 milligrams of vecuronium bromide in two 100-milligram injections, followed by 240 milliequivalents of potassium chloride. *Id.* Rudenstine observed Howell open his eyes after the consciousness check. *Id.*

Second, Dale Baich, a supervisor in the Federal Defender Capital Habeas Unit in Arizona, witnessed the execution of Joseph Wood by the State of Arizona. *Id.* The protocol used to execute Wood called for injection of a mixture of 50 milligrams of midazolam and 50 milligrams of hydromorphone. *Id.* During Wood's execution, the State injected this mixture fifteen separate times. *Id.* "Wood continued to gasp and try to breathe until his death ... almost two hours after the process began." *Id.* In a settlement agreement entered on December 19, 2016, Arizona agreed to "never again use midazolam, or any other benzodiazepine, as part of a drug protocol in a lethal injection execution." R. 976-2 (Stipulated Settlement Agreement at 2) (Page ID #36214); *see also id.* at 23.

Third, Dean Sanderford, an Assistant Federal Defender in Colorado, witnessed the execution of Clayton Lockett by the State of Oklahoma. Decision & Order at 24. The protocol used to execute Lockett called for 100 milligrams of midazolam followed by a paralytic agent and potassium chloride. *Id.* According to Sanderford, three or four minutes after the administration of the paralytic, Lockett began writhing and attempted to speak. *Id.*

The district court then discussed, at great length, the testimony of the four expert witnesses. Dr. Stevens discussed sedation and general anesthesia. He explained that there are different levels of sedation: minimal sedation (i.e., the sedation that would be appropriate for a root canal); moderate sedation; and deep sedation. General anesthesia is beyond the deepest level of sedation, and

is the state appropriate for surgery. Only at the level of general anesthesia is someone unconscious. ***895** Dr. Stevens explained that midazolam can bring someone to the state of deep sedation, but not to general anesthesia or unconsciousness. Decision & Order at 78. Similarly, Dr. Bergese testified that he would never use midazolam alone as an anesthetic. He also testified that when midazolam is used as an anesthetic, it is for relatively minor procedures, such as colonoscopies, as opposed to more invasive surgeries. *Id.* at 47.

To explain why midazolam cannot render someone unconscious, Dr. Stevens explained midazolam's ceiling effect. *Id.* at 31–32. Midazolam acts on a receptor called $GABA_A$ (GABA is short for gamma-aminobutyric acid), and can decrease neural activity only when $GABA_A$ is present. Once there is no $GABA_A$ left for midazolam to act on, midazolam cannot decrease neural activity anymore and the drug reaches its maximum potency, or ceiling. At this point, administering more midazolam does not increase midazolam's effect.

Dr. Stevens explained that midazolam's reliance on $GABA_A$, and consequential ceiling effect, is a distinction between midazolam and barbiturates like thiopental sodium. *Id.* at 31–32. Midazolam is a benzodiazepine, whereas thiopental sodium is a barbiturate. Although both benzodiazepines and barbiturates work on the central nervous system and can be used as sedatives, barbiturates can decrease neural activity without $GABA_A$ present. According to Dr. Stevens, because barbiturates do not depend on $GABA_A$, they do not have a ceiling effect. Dr. Bergese agreed generally that midazolam has a maximum impact, but he emphasized that his main concern is that midazolam is simply the wrong drug to use. *Id.* at 87.

In response to Dr. Stevens's discussion of ceiling effects, Dr. Antognini testified that midazolam's ceiling effect is not germane. In his view, a 500-milligram dose of midazolam is sufficient to render a person unconscious. Whatever ceiling effect midazolam may have beyond the amount necessary to render someone unconscious is irrelevant. Decision & Order at 70. He also testified that data on midazolam's ceiling effect is unclear. *Id.* at 71. Taking an entirely different tack, Dr. Buffington disputed that midazolam has a ceiling effect at all. *Id.* at 93. However, he also testified that when midazolam is used alone, it is usually in situations where general anesthesia is not required, such as resetting bones, vasectomies, or placement of tubes or implanted devices. *Id.* at 92.

Dr. Antognini and Dr. Stevens disagreed strongly about whether midazolam possesses any analgesic (painkilling) properties. Dr. Antognini testified that midazolam does possess some analgesic properties, at least in massive doses. Dr. Stevens, by contrast, was adamant that midazolam does not treat pain. *Id.* at 75. Dr. Bergese agreed with Dr. Stevens. *Id.* at 47. Without addressing midazolam's analgesic properties, Dr. Buffington said that midazolam would sedate someone sufficiently to render them insensate to the pain caused by a paralytic and potassium chloride. *Id.* at 94. Dr. Antognini testified that the risk that someone would experience pain after receiving a 500-milligram dose of midazolam is "very, very low." *Id.* at 66. Dr. Stevens, by contrast, concluded that " 'the use of midazolam as the first drug in a three-drug **protocol** is highly likely to cause intolerable pain and suffering,' stemming from the administration of the second and third drugs." *Id.* at 40. Again, Dr. Bergese agreed with Dr. Stevens. *Id.* at 47. The testimony of Dr. Stevens and Dr. Bergese that midazolam does not eliminate pain is unequivocal.

II. DISCUSSION

A. Legal Standards

"A plaintiff seeking a preliminary injunction must establish that he is likely to ***896** succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Glossip v. Gross*, —— U.S. ——, 135 S.Ct. 2726, 2736, 192 L.Ed.2d 761 (2015). "The preliminary injunction posture of the present case thus requires petitioners to establish a likelihood that they can establish both that [Ohio's] lethal injection **protocol** creates a demonstrated risk of severe pain and that the risk is substantial when compared to the known and available alternatives." *Id.* at 2737.

An appellate court must review a district court's decision granting or denying a preliminary injunction for an abuse of discretion. *Ashcroft v. Am. Civil Liberties Union*, 542 U.S. 656, 664, 124 S.Ct. 2783, 159 L.Ed.2d 690 (2004). "Under this standard, the court reviews the district court's legal conclusions de novo and its factual findings for

clear error." *Babler v. Futhey*, 618 F.3d 514, 520 (6th Cir. 2010); *see also Glossip*, 135 S.Ct. at 2739. "[A] finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Anderson v. City of Bessemer City*, 470 U.S. 564, 573, 105 S.Ct. 1504, 84 L.Ed.2d 518 (1985) (quoting *United States v. United States Gypsum Co.*, 333 U.S. 364, 395, 68 S.Ct. 525, 92 L.Ed. 746 (1948)). The clearly erroneous standard "plainly does not entitle a reviewing court to reverse the finding of the trier of fact simply because it is convinced that it would have decided the case differently." *Id.* In particular, "when a trial judge's finding is based on his decision to credit the testimony of one of two or more witnesses, each of whom has told a coherent and facially plausible story that is not contradicted by extrinsic evidence, that finding, if not internally inconsistent, can virtually never be clear error." *Id.* at 575, 105 S.Ct. 1504.

Recently, the Supreme Court reiterated the deference owed to a district court's findings of fact, even when other trial courts have made different findings. "The rule that we review a trial court's factual findings for clear error contains no exception for findings that diverge from those made in another court. Whatever findings are under review receive the benefit of deference, without regard to whether a court in a separate suit has seen the matter differently." *Cooper v. Harris*, —— U.S. ——, 137 S.Ct. 1455, 1468, 197 L.Ed.2d 837 (2017) (citing Fed. R. Civ. P. 52(a)(6); *Hernandez v. New York*, 500 U.S. 352, 369, 111 S.Ct. 1859, 114 L.Ed.2d 395 (1991) (plurality opinion)). The Supreme Court continued by explaining that an appellate court "must ask not which court ... had the better view of the facts, but simply whether the court below's view is clearly wrong." *Id.* "[T]he very premise of clear error review is that there are often 'two permissible'—because two 'plausible'—'views of the evidence.' Even assuming [another] court's findings capture one such view, the District Court's assessment may yet represent another. And the permissibility of the District Court's account is the only question before [an appellate court]." *Id.* (quoting *Anderson*, 470 U.S. at 574, 105 S.Ct. 1504).

Finally, the Supreme Court has also instructed appellate courts to err on the side of allowing trials in cases raising constitutional questions. "If the underlying constitutional question is close," the Supreme Court instructs, an appellate court "should uphold the injunction and remand for trial on the merits." *Ashcroft v. Am. Civil Liberties Union*, 542 U.S. at 664–65, 124 S.Ct. 2783.

This last instruction is perhaps the most significant for this case. But the majority ***897** heeds neither the instruction to review district court findings of fact deferentially, nor the instruction to err on the side of allowing trials in cases raising constitutional questions. The majority has decided to forego a trial on the merits of Plaintiffs' constitutional claims and to allow the State of Ohio to **execute** Plaintiffs without such a trial. More egregiously, the majority has decided to forego a trial even though the district court, which has the better view of the evidence, determined that Plaintiffs should have a trial because they are likely to succeed on the merits of their constitutional claim.

B. Eighth Amendment *Baze*/*Glossip* Claim

1. Likelihood of success on the merits

I would affirm the district court's judgment that Plaintiffs were likely to succeed on the merits of their Eighth Amendment *Baze*/*Glossip* claim, which the district court supported with factual findings that, first, Plaintiffs established that Ohio's midazolam three-drug **protocol** creates a substantial risk of severe pain and, second, Plaintiffs presented an available alternative method.

a. Substantial risk of severe pain

Under *Glossip*, to establish that a method of **execution** violates the Eighth Amendment, prisoners must first "establish that the method presents a risk that is '*sure or very likely* to cause serious illness and needless suffering, and give rise to sufficiently *imminent* dangers.' To prevail on such a claim, 'there must be a substantial risk of serious harm[.]' " *Glossip*, 135 S.Ct. at 2737 (quoting *Baze v. Rees*, 553 U.S. 35, 50, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality opinion)) (emphasis in original).

The majority is certainly correct that plaintiffs must meet a "heavy burden" to make the "rigorous showing" that a method of **execution** creates a substantial risk of serious harm. Maj. Op. at 886–87 (quoting *Baze*, 553 U.S. at 53, 128 S.Ct. 1520). The majority and I disagree about whether the determination that a method of **execution** creates a substantial risk of serious harm is a factual finding reviewed for clear error or a legal conclusion

reviewed less deferentially. The majority characterizes the determination as application of a "legal standard" and reviews it without deference. Maj. Op. at 885–86. My view that this determination is a factual finding that must be reviewed for clear error comes directly from the language of the Supreme Court. In *Glossip*, the Supreme Court said that the Oklahoma district court "did not commit clear error when it found that the prisoners failed to establish that Oklahoma's use of a massive dose of midazolam in its **executionprotocol** entails a substantial risk of severe pain." *Glossip*, 135 S.Ct. at 2731. This statement is explicit that a district court's determination as to whether midazolam entails a substantial risk of severe pain must be reviewed for clear error.

In this case, the magistrate judge—relying on his "superior[ ] ... position to make determinations of credibility" and "experience" in "the determination of fact"—evaluated evidence from scientific experts, eyewitnesses to **executions**, and ODRC employees discussing Ohio's current **executionprotocol**. *Anderson*, 470 U.S. at 574, 105 S.Ct. 1504. Based on this evidence, the district court found that Plaintiffs were likely to succeed on their claim that the use of midazolam as the first drug in a three-drug **protocol** creates a substantial risk of severe pain. Decision & Order at 104–05. The district court found "from both the expert opinions and the lay descriptions comparing **executions** with a barbiturate as the first drug and midazolam as the first drug that the drugs do not ***898** produce the same effects in those being **executed**.... [T]hose administered midazolam ... take longer to die and exhibit different bodily behaviors in the process." *Id.* at 104. Evaluating the evidence presented to it during the hearing, including the eyewitness testimony and the opposing viewpoints presented by the experts, the district court "conclude[d] that use of midazolam as the first drug in Ohio's present three-drug **protocol** will create 'a substantial risk of serious harm.' " *Id.* at 105.

For several reasons, the district court's determination was not clearly erroneous. First of all, the district court did not base its opinion on uncertainty, as the majority asserts. Plaintiffs' experts testified unequivocally that Ohio's midazolam three-drug **protocol** is highly likely to cause intolerable pain. *Id.* at 40, 43, 47, 55. The district court was in the position to make credibility determinations about the competing experts' testimony, and the district court's discussion of the experts' testimony indicates that it found Plaintiffs' experts to be more credible than Defendants'. *See* Decision & Order at 103–05.

For example, the district court recognized that Defendants' experts did not agree with each other about whether midazolam has a ceiling effect, and Dr. Buffington did not appear to agree with Dr. Antognini that midazolam has analgesic properties (only that it would sedate someone sufficiently to make them insensate to pain, which is distinct from actually eliminating pain). *Id.* at 71–75, 93–94. By contrast, Plaintiffs' experts were in agreement that midazolam does not have analgesic properties, and, although he was less adamant, Dr. Bergese generally agreed with Dr. Stevens that midazolam has a ceiling effect. *Id.* 31, 87. The specific points of disagreement between Defendants' experts support the district court's determination that Plaintiffs' experts were more convincing.

It is also noteworthy that the district court in this case evaluated evidence that was not available to the Oklahoma district court in *Glossip*. The district court heard testimony from eyewitnesses to five **executions**. Two of those, the **execution** of Christopher Brooks and the **execution** of Ronald Smith, occurred after the *Glossip* decision. In addition to providing the district court with information about additional midazolam-involved **executions**, these recent **executions** also shed new light on earlier midazolam-involved **executions**. In *Glossip*, the Supreme Court noted that neither Lockett nor Wood received the dose of midazolam at issue in the case before it, and that there were problems with the Lockett **execution** that were not attributable to the drugs used (namely, "the **execution** team's inability to obtain an IV access site"). *Glossip*, 135 S.Ct. at 2746. Taking into account these differences, the Supreme Court said that "[w]hen all of the circumstances are considered, the Lockett and Wood **executions** have little probative value for present purposes." *Id.* This conclusion may have been reasonable given the circumstances at the time, but new circumstances entitle a district court to come to a different conclusion. The Brooks **execution**, and particularly the Smith **execution**, in which Smith coughed, flailed, and heaved for several minutes, cast the problems observed in the Lockett and Wood **executions** in a new light. Unlike Lockett and Wood, both Smith and Brooks were **executed** using 500 milligrams of midazolam followed by a paralytic drug and potassium chloride (like Ohio's current **protocol**). Like Lockett and Wood, witnesses testified

that Smith and Brooks moved and heaved during their executions. Witnesses' testimony that Brooks was heaving and that Smith was heaving, coughing, and flailing could suggest that Lockett's writhing and Wood's gasping were attributable to midazolam's ***899** inability to prevent the pain caused by paralytic drugs and potassium chloride, rather than to other circumstances.

The district court made the specific finding that these eyewitnesses were credible, even though many "were from legal practices devoted to representing capital clients." *Id.* at 24. The district court noted that "their testimony was carefully confined to observations rather than opinions," in "contrast [ ] with some press characterizations of some of these executions as 'botched,' 'horrendous,' 'barbaric,' and so forth. These witnesses were carefully professional in not adding advocatory characterizations to their observations." *Id.* at 24–25.

The majority argues that the district court did not offer enough reasoning in support of its decision. Maj. Op. at 886–87. I agree that ideally the district court would have offered more reasoning in support of its findings. But it is clear that the district court's specific findings were meant to be read in conjunction with its lengthy discussion of the testimony. And I do not agree that the district court's 119-page opinion, which included a discussion of the testimony and specific findings of fact, did not provide sufficient reasoning to be entitled to the deference that we must give to district courts' findings of fact. (The majority recognizes that the district court produced its opinion under tight timelines, but fails to acknowledge that these timelines were imposed by the State of Ohio.) In my view, the district court's finding that "use of midazolam as the first drug in Ohio's present three-drug protocol will create 'a substantial risk of serious harm,' " Decision & Order at 105, was not clearly erroneous, and we are bound by this finding.

b. Availability of an alternative

To succeed on their Eighth Amendment claim, Plaintiffs must also show that there is "an alternative that is 'feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain.' " *Glossip*, 135 S.Ct. at 2737 (quoting *Baze*, 553 U.S. at 52, 128 S.Ct. 1520) (alteration in original). *Glossip* explicitly states that whether an alternative method of execution is available is a "factual finding" subject to the "clearly erroneous" standard of review. *Glossip*, 135 S.Ct. at 2738. Other than defining "availability" as a factual finding, the Supreme Court provides little guidance as to the definition of "availability." As the district court observed, "In *Baze* and *Glossip*, the Supreme Court did not attempt to quantify how available the alternative method must be to qualify." Decision & Order at 107.

Plaintiffs proposed two alternative execution methods. For different reasons, each of these alternatives warrants a remand for a trial on the merits. As to the first alternative, a one-drug protocol using compounded pentobarbital, the district court found that by proposing compounded pentobarbital, "Plaintiffs have met their burden to identify a sufficiently available alternative method of execution to satisfy *Baze* and *Glossip*." Decision & Order at 107. Ohio does not currently have pentobarbital on hand and it cannot purchase pentobarbital to use in executions directly from drug manufacturers. However, according to the district court, Ohio has taken key steps toward acquiring compounded pentobarbital, including passing secrecy statutes "to protect the anonymity of potential suppliers and compounders," and applying for the import license necessary to purchase pentobarbital's active ingredient. *Id.* This court resolved litigation over the secrecy statutes and entry of a protective order in Ohio's favor. *See In re: Ohio* ***ExecutionProtocol*** *Litig. (Fears v. Kasich)*, 845 F.3d 231, 240 (6th Cir. 2016); *Phillips v. DeWine*, 841 F.3d 405, 420 (6th Cir. 2016). These favorable resolutions facilitate the State's access to compounded ***900** pentobarbital. The district court also noted that Dr. Buffington, who helped develop Ohio's current executionprotocol and who testified about the content of an affidavit he submitted in an Alabama case, "stated in his affidavit in that case that since other states had been able to procure compounded pentobarbital for their executions, he believed it could be obtained." Decision & Order at 95.

Because Defendants' own expert testified that compounded pentobarbital could be obtained, because Ohio succeeded in passing secrecy statutes and securing a protective order for the specific purpose of obtaining compounded pentobarbital, and because Ohio is currently undertaking the steps necessary to secure compounded pentobarbital, I am not "left with the definite and firm conviction" that the district court erred when it found that compounded pentobarbital is an available alternative.

Anderson, 470 U.S. at 573, 105 S.Ct. 1504 (quoting *United States Gypsum Co.*, 333 U.S. at 395, 68 S.Ct. 525). I would defer to the district court's finding that compounded pentobarbital is available.

For the second alternative, Plaintiffs proposed a two-drug **protocol** using midazolam and potassium chloride without a paralytic drug. Having decided that compounded pentobarbital is an available alternative, the district court did not make a finding as to whether the second alternative is available, or as to the more difficult question whether the second alternative would "significantly reduce[ ] a substantial risk of severe pain." *Glossip*, 135 S.Ct. at 2737 (quoting *Baze*, 553 U.S. at 52, 128 S.Ct. 1520). Particularly if the majority is correct that compounded pentobarbital is not an available alternative, Plaintiffs are entitled to a finding as to whether the second alternative satisfies the *Baze*/*Glossip* standard. Instead, the majority has determined that Plaintiffs should be **executed** with Ohio's three-drug **protocol** without a court ever deciding whether their proposed two-drug **protocol** would significantly reduce the substantial risk of severe pain.

There may be other possible **execution** methods that, if given a trial, Plaintiffs could prove are available and significantly reduce a substantial risk of severe pain. As anyone who reads the newspaper knows, the nation, and Ohio in particular, is in the midst of a virulent drug-death epidemic. *See, e.g.*, Kristine Phillips, *Drugs Are Killing So Many People in Ohio That Cold-Storage Trailers Are Being Used As Morgues*, Wash. Post (Mar. 16, 2017), http://wapo.st/2mNjFEp?tid=ss_mail&utm_term=.e29b9f46cfc8 ("As with much of the United States, Ohio is in the throes of a heroin and opioid epidemic that shows no signs of abating.... The drug epidemic also has caused [Stark] county to spend roughly $75,000 a year in toxicology tests alone.... 'We're just spending all kinds of money on lab work because there's so many different drugs,' [Stark County investigator Rick Walters] said."); Kimiko de Freytas-Tamura, *Amid Opioid Overdoses, Ohio Coroner's Office Runs Out of Room for Bodies*, N.Y. Times (Feb. 2, 2017), https://nyti.ms/2k0DV2Z ("On Thursday, only two days into February, the coroner's office in Dayton, Ohio, had already handled 25 deaths—18 caused by drug overdoses. In January, the office processed 145 cases in which the victims' bodies had been destroyed by opioids."); Katharine Q. Seelye et al., *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, N.Y. Times (Jan. 6, 2017), https://nyti.ms/2k21*l*F0 ("Public health officials have called the current opioid epidemic the worst drug crisis in American history, killing more than 33,000 people in 2015. Overdose deaths were nearly equal to the number of deaths from car crashes. In 2015, for the first time, deaths from heroin alone surpassed gun homicides."); Courtney Astolfi, ***901** *Report: Ohio Ground-Zero for Opioid Overdose Deaths*, Cleveland.com (Dec. 1, 2016), http://s.cleveland.com/OlL8JFD ("The Buckeye State topped the list of opioid overdose deaths among all 50 states, racking up 2,106 deaths in 2014."). Given these reports, there are obviously multiple drugs that could be used to **execute** people.

The district court's findings in this case were not clearly erroneous. The district court did not clearly err by finding that Ohio's current three-drug **protocol** creates a substantial risk of severe pain, and it did not clearly err by finding that alternative **protocols** are available. Not only did the district court not clearly err in its factual finding that compounded pentobarbital is an available alternative, but there are other possible alternative **protocols** that no court has ruled on. Plaintiffs proposed a two-drug **protocol**, and the district court did not rule on this alternative. Moreover, there may be other drug **protocols** that Plaintiffs would propose if given an opportunity to litigate this case fully. Therefore, Plaintiffs have satisfied the first requirement for a preliminary injunction by demonstrating a substantial likelihood of success on their Eighth Amendment claim.

2. Likelihood of irreparable harm, balance of equities, and public interest

Having determined that Plaintiffs failed to show a likelihood of success on the merits of their Eighth Amendment claim, the majority does not assess whether Plaintiffs have satisfied the other requirements for a preliminary injunction. Because in my view Plaintiffs did show a likelihood of success on the merits, I address the other three requirements. Plaintiffs satisfy each one.

Plaintiffs would suffer irreparable harm if **executed** by a drug **protocol** later determined to be unconstitutional. "The key word in this consideration is irreparable." *Babler*, 618 F.3d at 523–24 (quoting *Sampson v. Murray*, 415 U.S. 61, 90, 94 S.Ct. 937, 39 L.Ed.2d 166 (1974)). "A plaintiff's harm from the denial of a preliminary

injunction is irreparable if it is not fully compensable by monetary damages." *Obama for Am. v. Husted*, 697 F.3d 423, 436 (6th Cir. 2012) (quoting *Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp.*, 511 F.3d 535, 550 (6th Cir. 2007)). Being **executed** by a method of **execution** that is later determined to be unconstitutional is quintessentially an injury that is not fully compensable. Or, as the district court noted, "[t]he irreparable harm to the named Plaintiffs if temporary injunctive relief is not granted is patent"; "[w]hether or not Plaintiffs' claims survive their deaths, the injury would be irreparable." Decision & Order at 116.

For the same reason, the balance of the equities favors Plaintiffs. Although "a State retains a significant interest in meting out a sentence of death in a timely fashion," *Nelson v. Campbell*, 541 U.S. 637, 644, 124 S.Ct. 2117, 158 L.Ed.2d 924 (2004), the harm from a delay in meting out a death sentence is not an irreparable harm. As a result, balancing the equities counsels in favor of delaying **executions** until a full trial on the merits can be held on the method of **execution**.

Finally, the public interest favors Plaintiffs. The public has an interest in sentences being carried out, but it also has an interest in ensuring that those sentences are carried out in a constitutional manner. "[I]t is always in the public interest to prevent violation of a party's constitutional rights." *Deja Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson Cty.*, 274 F.3d 377, 400 (6th Cir. 2001) (quoting *G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994)). As the district court stated, "[o]n balance, the public interest weighs in favor ***902** of granting temporary injunctive relief, but maintaining a fast track approach to adjudicating Plaintiffs' claims on the merits." Decision & Order at 118.

C. Judicial Estoppel

I would also hold that the district court did not err by deciding that Defendants were judicially estopped from reverting to an **executionprotocol** that includes pancuronium bromide (a paralytic agent) and potassium chloride (which stops the heart). I begin by reviewing in detail the facts relevant to Plaintiffs' judicial-estoppel claim.

Litigation challenging Ohio's lethal injection **protocol** commenced in 2004. The first events relevant to Plaintiffs' judicial-estoppel claim occurred in 2009. On October 19, 2009, the district court entered a stay of Kenneth Biros's **execution**. R. 965-16 (10/19/2009 Order at 1–4) (Page ID #34294–97). A trial had been scheduled for November 2, 2009, and Biros's **execution's** date had been set for December 8, 2009. *Id.* at 1–2 (Page ID #34294–95). As of October 19, 2009, there was outstanding discovery, including discovery concerning the failed attempt to **execute** Romell Broom and the State's consideration of a new **executionprotocol**. *Id.* Because of the outstanding discovery, the district court postponed the trial date and entered a "stay of [Biros's] **execution**." *Id.* at 1–3 (Page ID #34294–6). The district court reasoned that "[g]iven the issues involved and the instruction of the appellate court, Biros is ... entitled to a stay affording him time for discovery and to be heard at trial on the merits of his claims." *Id.* at 3 (Page ID #34296).

On October 27, 2009, the State filed a Notice of Appeal "from the Court's Opinion and Order granting an injunction to intervenor Kenneth Biros, which was filed on October 19, 2009." R. 965-18 (Notice of Appeal at 1) (Page ID #34304). Also on October 27, the State filed a motion asking this court to vacate the district court's order delaying Biros's **execution**, which the State variously referred to as a stay and a preliminary injunction. R. 965-19 (Defs-Appellants' Mot. to Vacate Prelim. Inj. Granted to Biros at 1–9) (Page ID #34307–15). In its motion, the State took issue with the district court making the determination that outstanding discovery necessitated a stay of **execution** without considering Biros's likelihood of success on the merits. The State argued that "[a] condemned prisoner cannot obtain a stay of **execution** ... absent a finding by the court that the prisoner is likely to succeed on the merits of his claims." *Id.* at 6 (Page ID #34312). Because "a party seeking a preliminary injunction must demonstrate, among other things, a likelihood of success on the merits[,] ... [w]here a condemned prisoner seeks a stay of **execution** to permit litigation of a claim that the state's method of **execution** will violate the Eighth Amendment, the likelihood or lack thereof of the prisoner's success on the merits is not only a necessary consideration, but may well be sufficient to resolve the matter." *Id.*

On October 29, 2009, the district court issued a second order which, "[i]n light of Defendants' characterization

of [the district court's] actions and in an effort to assist the Sixth Circuit Court of Appeals in considering the appeal, ... further memorialize[d] the substance of the October 19, 2009 conference." R. 966 (10/29/2009 Order at 1) (Page ID #34318). In the order, the district court noted that Defendants "helped develop, along with Plaintiffs' counsel, proposed language to be included in the October 19, 2009 Order. In fact, Defendants' counsel asked the Court not to characterize the stay as an injunction and explained that they did not want the court to make a finding of unconstitutionality in regard to the stay." *Id.* at 1–2 (Page ID #34318–19). The district court surmised ***903** that Defendants did not want it to make a finding as to Biros's likelihood of success on the merits of his constitutional claims because "[s]uch Rule 65 injunctive relief analysis would have necessitated the Court discussing in detail in a written decision its review of the numerous deposition transcripts of witnesses involved in the attempted **execution** of Romell Broom." *Id.* at 2 (Page ID #34319). The court also ordered that "all future conferences, except those dealing with protected discovery material, shall be held in open court and on the record" "[t]o avoid creating an incorrect impression of the events of this litigation and to facilitate clarity as to the parties' public positions." *Id.*

On November 13, 2009, the State announced its intention to change its **executionprotocol** effective no later than November 30, 2009. In its News Release, the State, through ODRC Director Terry Collins, said, " 'The previous method of **execution** included a three-drug **protocol** applied intravenously. The first change to the **execution** procedure includes the adoption of a one-drug **protocol**, using thiopental sodium alone, applied intravenously. Pancuronium bromide and potassium chloride will no longer be used as a part of the process.' " R. 966-1 (11/13/2009 ODRC News Release) (Page ID #34322).

On the same day, the State filed in the district court a motion for summary judgment. In its motion, the State argued that, as a result of changes to the **executionprotocol**, "Defendants have negated all of Plaintiffs' claims" and "Plaintiffs' challenges to defendants' previous 'three-drug **protocol**' are moot." R. 966-2 (Defs.' Second Mot. Summ. J. with Req. Expedited Briefing Sched. at 4) (Page ID #34328). The State explained,

> It is readily apparent here that the recent changes to defendants' **execution** procedures have rendered moot plaintiffs' constitutional challenges to the "three-drug **protocol**" previously used by defendants to **execute** condemned prisoners. The issues presented by plaintiffs' complaints stem from the alleged risk of severe pain which could be caused by the use of pancuronium bromide and potassium chloride, the second and third drugs in the so-called "three-drug **protocol**," in the event that the first drug, thiopental sodium, is not properly administered. In view of the new procedures' elimination of the second and third drugs, the issues presented in plaintiffs' suits are no longer actionable.... Moreover, there is *no* possibility here that the allegedly unconstitutional conduct will reoccur, or that there is any lingering effects of previous allegedly unconstitutional conduct. There is absolutely no reason to believe that defendants will reinstate the previous "three-drug **protocol**" if the plaintiffs' suits were dismissed. And, more importantly, if defendants **execute** plaintiffs using the revised procedures, defendants cannot "go back to their old ways" and **execute** plaintiffs using the prior procedures.

Id. at 5 (Page ID #34329) (emphasis in original). The State attached to its summary-judgment motion an affidavit of Director Collins, in which he swore, "[G]oing forward, pancuronium bromide no longer will be used as part of the lethal injection process. Also, potassium chloride no longer will be used as part of that process." R. 966-3 (Collins Aff. at ¶ 6) (Page ID #34335).

In the summary-judgment motion, the State repeatedly argued that the claims of *all* Plaintiff*s* were moot as a result of the change to the **executionprotocol**, R. 966-2 (Defs.' Second Mot. Summ. J. with Req. Expedited Briefing Sched. at 5) (Page ID #34329), and Collins's affidavit stated that pancuronium bromide and potassium chloride would not be used "going forward," R. 966-3 (Collins Aff. at ¶ 6) (Page ID ***904** #34335). The State sought judgment as a matter of law on the claims of all plaintiffs, not only Biros.

On November 16, 2009, the State filed in this court a reply in support of its October 27 motion to vacate the stay. R. 966-4 (Defs-Appellants' Mem. Reply to Biros' Mem. in Opp'n to Defs' Mot. Vacate District Ct.'s Stay of Biros' **Execution**, Sche'd for Dec. 8, 2009, and Defs' Mem. in Opp. to Biros' Mot. Dismiss Defs' Appeal at 1) (Page ID #34338). In the reply, the State argued that "Biros's lawsuit is moot." *Id.* at 7 (Page ID #34344). The State explained that Collins, "has directed changes in the

procedures used to carry out the execution of condemned prisoners. The changes include the discontinuation of the use of pancuronium bromide and potassium chloride in the execution process." *Id.* The State argued that as a result of this change, "Biros' suit no longer presents a case or controversey [sic], as the 'three-drug protocol' he challenges is no longer used." *Id.*

Unlike in the district court summary-judgment motion, the State's reply in our court argued that "Biros' suit" was moot, but did not address claims of other Plaintiffs. This focus on Biros is in keeping with the narrowness of that appeal, in which the only issue was the stay of Biros's execution, not the underlying merits of Plaintiffs' challenge or any other Plaintiffs' individual procedural claims. However, although the State did not mention the other Plaintiffs in the body of the reply, the State did attach its summary-judgment motion from the district court as an exhibit to the reply. R. 966-4 (Defs.' Second Mot. Summ. J. with Req. Expedited Briefing Sched., filed as Ex. A to Defs-Appellants' Mem. Reply to Biros' Mem. in Opp'n to Defs' Mot. Vacate District Ct.'s Stay of Biros' Execution, Sche'd for Dec. 8, 2009, and Defs' Mem. in Opp. to Biros' Mot. Dismiss Defs' Appeal) (Page ID #34348–59). It also addressed Biros's "suit," as opposed to his claims, which may suggest that it had the entire lawsuit in mind, which involved multiple plaintiffs. As noted above, the summary-judgment motion argued that the claims of all the plaintiffs were moot, and sought judgment as a matter of law on all claims.

On November 25, 2009, a panel of this court vacated the district court's stay of Biros's execution. The panel held that "the district court's stay order must be vacated because any challenge to Ohio's three-drug executionprotocol is now moot." *Cooey v. Strickland*, 588 F.3d 921, 923 (6th Cir. 2009). The panel explained that, "the question at hand is whether Ohio will use the old procedure, or the new one, in executing Biros." *Id.* In response to this question, the panel maintained that "[t]here is no basis in the record or for that matter in common sense for assuming that the State will do anything other than what it has told us in court filings and what it has told the public at large: it has changed its executionprotocol, and it intends to apply the substantially modified protocol to Biros." *Id.*

On December 4, 2009, this court denied rehearing en banc. The concurrence with denial of rehearing en banc posited that, "At a minimum, the new protocol 'likely' moots the old challenge, and that is enough to create a likelihood-of-success problem for Biros when it comes to premising a request for a stay on orders related to a different protocol." *Cooey v. Strickland*, 588 F.3d 924, 925 (6th Cir. 2009) (Sutton, J., concurring in denial of reh'g en banc). Dissents from denial of rehearing en banc pointed out that nothing prevented the State from going back to the prior executionprotocol, which, they explained, fatally undermined the holding that the challenge was moot. *Id.* at 925–26 (Moore, J., dissenting from denial of reh'g en banc) ***905** ("Although there is little indication that the State will continue to use the initially challenged three-drug cocktail now that it has developed a new procedure, in analyzing whether Biros's claim is moot, we must consider whether anything would prevent the State from doing so.... Although we have no reason to doubt Ohio's sincerity, determining mootness based on a litigant's statement that it has no reason to resume the challenged activity, no matter how earnest, is not part of the mootness analysis."); *see also id.* at 928 (Martin, J., dissenting).

Neither the panel opinion nor the concurrence with denial of rehearing en banc clarified the breadth of the court's holding. It is not clear whether the panel held that the challenge to Ohio's lethal injection protocol was moot as to Biros or was moot as to all of the Plaintiffs. It is unclear, first, because in this court the State was ambiguous about whether it was arguing that the claims were moot as to Biros or all Plaintiffs. It is unclear, second, because neither the panel opinion nor the concurrence with the denial of rehearing en banc explicitly stated whether the claims were moot as to Biros or all Plaintiffs.

Subsequently, Biros's execution was again set for December 8, 2009, and Biros challenged the November 30, 2009 one-drug executionprotocol. On December 7, 2009, this court considered Biros's challenge to the new protocol, and, affirming the district court, declined to stay his execution. *Cooey v. Strickland*, 589 F.3d 210, 221, 234 (6th Cir. 2009). The State executed Biros on December 8, 2009.

On December 9, 2009, the district court held a hearing. At that hearing, the district judge "suggest[ed] that all of these motions, as a result of the November 30, 2009, new protocol, are moot and should be withdrawn. I'm talking about the defendants', the plaintiffs' everything; that the

plaintiffs should amend all of their complaints based upon the new protocol and we proceed from that standpoint." R. 966-10 (12/9/2009 Hr'g Tr. at 25–26) (Page ID #34453–54). The district court added, "I actually can't demand that you withdraw something, and wouldn't do that, but I am suggesting that almost everything that's been filed in this case up until now is moot." *Id.* at 26 (Page ID #34456). Addressing this court's decision on mootness, the district court added, "And I'm not going to get into an argument over mootness like the Court of Appeals has done recently. I'm not going to get into that mess, as I'm sure Judge Sutton would not like to get back into that mess." *Id.* Instead, he explained, "I'm trying to suggest a way in which the record can get cleaned up and where we present arguments, present with new arguments, that have anything to do with the new protocol. It just seems to me to be the better way in which to proceed in this case, but, again, it's up to you guys how we decide this." *Id.* After some discussion, attorneys for both sides agreed to withdraw their pending motions, with the understanding that Plaintiffs would file amended complaints challenging the November 30, 2009 protocol. Defendants agreed not to assert a statute-of-limitations defense to Plaintiffs' amended complaints, and the district court granted leave to Plaintiffs to amend their complaints. *Id.* at 43, 46 (Page ID #34471, 34474).

Litigation proceeded, and so did executions. After the execution of Kenneth Biros on December 8, 2009, Ohio executed an additional twenty people until the State halted executions after the Dennis McGuire execution in 2014. However, prior to the McGuire execution, the State replaced the November 30, 2009 protocol with a protocol providing for a single-injection of midazolam and hydromorphone. *See* R. 323 (10/10/2013 Ohio DRC ExecutionProtocol, 01-COM-11 at 1–19) (Page ID ***906** #9568–86). McGuire's execution using the October 10, 2013 protocol prompted questions about midazolam and caused Ohio again to change its protocol, this time to the midazolamprotocol at issue in this case.

The State decided that it would switch to the current midazolam three-drug protocol months before it revealed this switch to Plaintiffs, the district court, or the public. *See* R. 941 (Hr'g Tr. at 800–01) (Page ID #31862–63). Director Mohr admitted that it was a strategic decision to conceal the switch. *Id.* at 803 (Page ID #31865).

The "rule[ ] known as judicial estoppel" provides that "[w]here a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him." *New Hampshire v. Maine*, 532 U.S. 742, 749, 121 S.Ct. 1808, 149 L.Ed.2d 968 (2001). "We review *de novo* a district court's decision regarding the application of judicial estoppel." *Javery v. Lucent Techs., Inc.*, 741 F.3d 686, 697 (6th Cir. 2014). [1] Three factors "typically inform the decision whether to apply the [judicial estoppel] doctrine." *New Hampshire v. Maine*, 532 U.S. at 750, 121 S.Ct. 1808. "First, a party's later position must be 'clearly inconsistent' with its earlier position." *Id.* (quoting *United States v. Hook*, 195 F.3d 299, 306 (7th Cir. 1999)). "Second, courts regularly inquire whether the party has succeeded in persuading a court to accept that party's earlier position, so that judicial acceptance of an inconsistent position in a later proceeding would create 'the perception that either the first or the second court was misled.' " *Id.* (quoting *Edwards v. Aetna Life Ins. Co.*, 690 F.2d 595, 599 (6th Cir. 1982)). "A third consideration is whether the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped." *Id.* at 751, 121 S.Ct. 1808.

The first factor for judicial estoppel is satisfied. The State's earlier position is "clearly inconsistent" with its current position. *Id.* at 750, 121 S.Ct. 1808. The State represented to the district court and this court that it would no longer use pancuronium bromide or potassium chloride for executions. The Director of the ODRC swore that "going forward, pancuronium bromide no longer will be used as part of the lethal injection process" and that "potassium chloride no longer will be used as part of that process." R. 966-3 (Collins Aff. at ¶ 6) (Page ID #34335). In its motion for summary judgment, the State represented to the district court not only that it had "eliminate[ed] ... the second and third drugs" but that "there is *no* possibility here that the allegedly unconstitutional conduct will reoccur." R. 966-2 (Defs.' Second Mot. Summ. J. with Req. Expedited Briefing Sched. at 5) (Page ID #34329). The State's motion explicitly stated that "[t]here is absolutely no reason to believe that defendants will reinstate the previous 'three-drug protocol.' " *Id.* The State's motion also argued that its decision to stop using pancuronium bromide and

potassium ***907** chloride mooted Plaintiffs' claims. At the December 9, 2009 hearing, the State reasserted its promise that it would stop using pancuronium bromide and potassium chloride, and said that because of this promise, "[t]o the extent that the other motions are based on the old **protocol**, we think it's appropriate that they be dismissed as moot or withdrawn." R. 966-10 (12/9/2009 Hr'g Tr. at 43) (Page ID #34471).

The State's representations that there was "*no* possibility" of reverting to a three-drug **protocol** using pancuronium bromide or potassium chloride and Director Collins's sworn statement that the State would not use these two drugs "going forward" are inconsistent with the State's current position. R. 966-3 (Collins Aff. at ¶ 6) (Page ID #34335); R. 966-2 (Defs.' Second Mot. Summ. J. with Req. Expedited Briefing Sched. at 5) (Page ID #34329). The State's current **executionprotocol**, which it is seeking to use in **executing** Otte, Phillips, and Tibbetts, includes pancuronium bromide and potassium chloride. R. 667-1 (Ohio DRC **ExecutionProtocol**, 01-COM-11 at 2) (Page ID #19813). By repeatedly representing that it would no longer use pancuronium bromide or potassium chloride in **executions** but now attempting to **execute** condemned inmates with these very drugs, the State has taken directly contradictory positions.

The second factor, whether the State succeeded in persuading a court to accept its earlier position that it would not use pancuronium bromide or potassium chloride in **executions**, is the most difficult. *See New Hampshire v. Maine*, 532 U.S. at 750–51, 121 S.Ct. 1808. As noted above, this court did not make clear whether its November 25, 2009 decision held that the claims of all Plaintiffs were moot or only Biros's claims were moot. At the December 9, 2009 hearing, the district court expressed its view that all of the motions pending as of December 9, 2009 were moot, but the district court also stated that it was not going to get into the "mess" over mootness, and urged the parties to withdraw their pending motions as a way "the record can get cleaned up." R. 966-10 (12/9/2009 Hr'g Tr. at 26) (Page ID #34454). The State withdrew the November 13, 2009 motion for summary judgment that argued mootness, but it is not clear whether the State withdrew that motion because the motion's argument had already been successful or because the district court was not going to entertain the motion's argument.

If this court held that the claims of all Plaintiffs were moot, then the State's mootness argument was successful, regardless of whether the State withdrew the motion. Similarly, if the district court held that all Plaintiffs' claims were moot, then the State's mootness argument was successful, notwithstanding the fact that as a procedural matter the State withdrew the motion. On the other hand, if this court's holding applied only to Biros and the district court prompted the parties to withdraw their motions because of practical concerns rather than a determination that the claims of all Plaintiffs were moot, then the State's mootness argument was not successful.

Ultimately, it appears that the State succeeded in persuading at least the district court, if not also this court, that the claims of all the Plaintiffs were moot. At the December 9 hearing, the district court repeatedly emphasized its view that all the motions pertaining to the old **protocol** were moot, and encouraged the parties to withdraw their motions for precisely that reason, even if it offered practical reasons as well. R. 966-10 (12/9/2009 Hr'g Tr. at 25–26) (Page ID #34453–54). The State also expressed its view that Plaintiffs should withdraw their motions because they were moot. *Id.* at 43 (Page ID #34471). Based ***908** on the statements of the district court and the State, and after some hesitation, Plaintiffs withdrew their challenge to the three-drug **protocol**. *Id.* at 42, 46 (Page ID #34470, 34474).

Significantly, the Plaintiffs' withdrawal of their challenge to the old **protocol** cleared the way for the State to proceed with **executions**. After Biros's **execution**, the State **executed** twenty other individuals until it halted **executions** in the wake of the McGuire **execution**. The fact that Ohio no longer had to litigate the constitutionality of its three-drug **protocol** and was able to proceed with **executions** beginning in December 2009 using other **protocols** indicates that its mootness argument succeeded. Resuming **executions** was the State's ultimate goal in the litigation, and it achieved that goal by affirmatively stating that it was no longer going to use pancuronium bromide or potassium chloride "going forward." R. 966-3 (Collins Aff. at ¶ 6) (Page ID #34335). If the State were now allowed to revert to using pancuronium bromide or potassium chloride, it would create the perception that the district court, and perhaps this court, had been misled about the abandonment of pancuronium bromide and potassium chloride. Accordingly, the second factor is satisfied.

The third factor, "whether the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped," is also satisfied. *New Hampshire v. Maine*, 532 U.S. at 751, 121 S.Ct. 1808. Earlier in this litigation, by representing that there was "*no* possibility" that it would use pancuronium bromide or potassium chloride "going forward," the State avoided having to litigate the constitutionality of an **executionprotocol** that relied on those drugs. R. 966-3 (Collins Aff. at ¶ 6) (Page ID #34335); R. 966-2 (Defs.' Second Mot. Summ. J. with Req. Expedited Briefing Sched. at 5) (Page ID #34329). Given the possibility that the State would revert to an **executionprotocol** that relies on pancuronium bromide and potassium chloride—as State officials and attorneys represented that the State would *not* do, but as the State has now done—Plaintiffs were entitled to continue litigating the constitutionality of those drugs.

In 2009, by making the unnecessarily broad and, we now know, false representations that there was "*no* possibility" that the State would use pancuronium bromide and potassium chloride "going forward," the State prevented Plaintiffs from having a trial on their claim that an **executionprotocol** including those drugs is unconstitutional. R. 966-3 (Collins Aff. at ¶ 6) (Page ID #34335); R. 966-2 (Defs.' Second Mot. Summ. J. with Req. Expedited Briefing Sched. at 5) (Page ID #34329). In 2016, the State concealed for months its intention to switch from a one-drug to a three-drug **protocol**, and the State has admitted that this was a strategic decision. Since revealing its current midazolam three-drug **protocol**, the State has pushed for this litigation to proceed quickly. Now, the State argues that Plaintiffs are not entitled to trial on their constitutional claims, including their claim that a two-drug **protocol** that does not include a paralytic is an available alternative that will significantly reduce a substantial risk of severe pain. The upshot of the State's behavior—in making unequivocal representations that it would not use pancuronium bromide or potassium chloride in **executions**, seeking to moot Plaintiffs' case based on those representations, acting in contravention of those representations, and now seeking to prevent Plaintiffs from having a trial—has been to thwart Plaintiffs' efforts to litigate the constitutionality of Ohio's use of a three-drug **protocol** or the question whether a two-drug **protocol** is an available alternative that significantly reduces a substantial risk of severe pain. ***909** This court's acquiescence to the State's behavior—by refusing to estop the State from using pancuronium bromide or potassium chloride—means that the State has succeeded in thwarting the Plaintiffs' efforts try their constitutional claim before being **executed**.

The majority's defense of the State's behavior as based on changed circumstances is unconvincing. Even if Ohio changed its position because of changed circumstances, the change in circumstances had no bearing on Ohio's decision to represent to two federal courts that the State would no longer use pancuronium bromide or potassium chloride. Nothing required Ohio to make the sweeping assertions that there was "*no* possibility" it would use potassium chloride "going forward," rather than making a narrower representation to which it could adhere. R. 966-3 (Collins Aff. at ¶ 6) (Page ID #34335); R. 966-2 (Defs.' Second Mot. Summ. J. with Req. Expedited Briefing Sched. at 5) (Page ID #34329).

Additionally, even if changed circumstances mean that Ohio can no longer obtain barbiturates, the unavailability of barbiturates does not require Ohio to revert to pancuronium bromide and potassium chloride, as opposed to using a different drug or combination of drugs. Ohio's previous representations—including representations made under oath, *see* R. 966-3 (Collins Aff. at ¶ 6) (Page ID #34335)—prevent it from reverting to pancuronium bromide and potassium chloride. Given these representations, if barbiturates are not available to Ohio, Ohio should rely on an **executionprotocol** not involving pancuronium bromide or potassium chloride.

Allowing the State to reverse course and use pancuronium bromide and potassium chloride in **executions** not only unfairly advantages the State, it also undermines the integrity of this litigation. The majority asserts that "if any gamesmanship led us to this pass, it was not gamesmanship by the State." Maj. Op. at 892. Whether or not characterized as gamesmanship, there no question that the State has publicly taken inconsistent positions, concealed facts from Plaintiffs to gain strategic advantage, and attempted at every turn to deny Plaintiffs an opportunity to try their constitutional claims. The purpose of judicial estoppel is to ensure that litigants will not be rewarded for such behavior. The majority has ensured that the State will be rewarded. Therefore, reviewing the issue de novo, I come to the same conclusion as the district court. I would hold that the State of Ohio is

judicially estopped from using pancuronium bromide or potassium chloride for **executions**.

* * *

Plaintiffs should not be **executed** before a trial on the constitutionality of Ohio's **execution** method. The district court did not err by finding that Plaintiffs satisfied the requirements for a preliminary injunction or that the State of Ohio should be judicially estopped from using **execution** drugs it swore that it would no longer use. I respectfully dissent.

CONCURRING IN THE DISSENT

JANE B. STRANCH, Circuit Judge, concurring in the dissent.

I concur in Judge Moore's dissenting opinion because its legal analysis applied to the record before us fully supports and explains where the majority opinion errs. I write separately to address other concerns that intertwine with our merits determination. The majority raises one such fundamental concern by recounting the crimes that underlie the death penalty sentences of prisoners involved in this **executionprotocol** challenge. The recitation of these crimes reveals what they are—horrific. But even in the face of such crimes and their powerful provocation to respond in ***910** kind, our American legal system and current experience with the death penalty provide reasons to stay the hand of those implementing this lethal injection **protocol** so that the court may evaluate whether the latest **protocol** complies with the requirements of our Constitution.

In her dissent from the denial of certiorari in *Arthur v. Dunn*, an Alabama case addressing the same issues raised here, Justice Sotomayor explains why the Eighth Amendment requires a "national conversation"—a continuing dialogue between the legislatures and the courts on the meaning of the Amendment's prohibition on cruel and unusual punishments. —— U.S. ——, 137 S.Ct. 725, 731, 197 L.Ed.2d 225 (2017) (Sotomayor, J., dissenting). She reminds us that the meaning of this prohibition is derived from "the evolving standards of decency that mark the progress of a maturing society." *Id.* (quoting *Kennedy v. Louisana*, 554 U.S. 407, 419, 128 S.Ct. 2641, 171 L.Ed.2d 525 (2008)).

This case contains a conversation that implicates that standard. The majority begins and ends its argument with the conclusion that "death-penalty opponents successfully prevented Ohio (along with other states) from obtaining the drugs necessary to use the one-drug **protocol**." Majority at 892; *see also id.* at 884–85. These framing comments grow from an argument made by various states that death-penalty opponents have employed improper means to prevent sale of the **protocol** drugs to states. But that argument ignores the possibility that our national conversation simply may have resulted in an evolution in the standard of decency upon which the Eighth Amendment relies. The refusal of drug companies to sell **execution** drugs may well evidence a recognition of changing societal attitudes toward the death penalty and a conclusion—whether based on principle, profit motivation, or both—that the business in which drug companies engage, selling drugs that improve health and preserve life, is not consistent with selling drugs that are used to put people to death.

This dialogue about the constitutional prohibition on cruel and unusual punishment is closely intertwined with our ongoing national conversation about the American criminal justice system. Woven through both is disquiet about issues such as punishing the innocent, discrimination on the basis of race, and effective deterrence of crime. These concerns are present throughout the criminal justice processes from arrest, to trial, to sentencing, to appeals, and to the final chapter in death penalty litigation such as this.

Such concerns, along with myriad others, have a role in public opinion that impacts "the evolving standards of decency" governing the Eighth Amendment's prohibition on cruel and unusual punishment. *See Kennedy*, 554 U.S. at 419, 128 S.Ct. 2641. A 2015 survey found that a majority of Americans prefer life without parole over the death penalty for people convicted of murder. Robert P. Jones et al., Public Religion Research Institute, *Anxiety, Nostalgia, and Mistrust: Findings from the 2015 American Values Survey* 47 (2015), http://www.prri.org/wp-content/uploads/2015/11/PRRI-AVS-2015-1.pdf. This matches polling in 2016 finding that public support for the death penalty has dropped below 50%, to its lowest level in 45 years. Baxter Oliphant, *Support for death penalty lowest in more than four decades*, Pew Research Center: Fact Tank (Sept. 29, 2016), http://www.pewresearch.org/fact-tank/2016/09/29/

support-for-death-penalty-lowest-in-more-than-four-decades. Our opinion as a people on whether the death penalty is acceptable is a mark of the progress of our maturing society.

I fully agree with the analysis in the dissenting opinion and believe that affirming ***911** the grant of a preliminary injunction would be the correct outcome based on governing precedent and the factual record before us. In light of the majority's determinations, I also write to stress my agreement with Justice Sotomayor that the Eighth Amendment requires a continuing national discussion —a civil, thoughtful conversation among the American people, legislatures, and the courts—on the meaning of the Amendment's prohibition on cruel and unusual punishment.

All Citations

860 F.3d 881

Footnotes

* Judge Cook recused herself from this case.

1 "In several recent cases, this Court has 'questioned the continuing viability of the *de novo* standard for judicial estoppel, noting the Supreme Court's characterization of the doctrine as an equitable remedy 'invoked by the court at its discretion' and recognizing that the 'majority of federal courts' review for abuse of discretion.' " *Javery*, 741 F.3d at 697 (quoting *Kimberlin v. Dollar General Corp.*, 520 Fed.Appx. 312, 313 n.1 (6th Cir. 2013)). Because the en banc court is not bound by prior panel decisions stating that the appropriate standard of review is de novo, the en banc court should consider the continuing validity of the de novo standard in light of the considerations pointed out in *Javery*.

854 F.3d 488
United States Court of Appeals,
Eighth Circuit.

Jason Farrell MCGEHEE; Stacey Eugene Johnson; Marcel Wayne Williams; Kenneth Dewayne Williams; Bruce Earl Ward; Ledell Lee; Jack Harold Jones, Jr.; Don William Davis; Terrick Terrell Nooner, Plaintiffs–Appellees,
v.
Asa HUTCHINSON, Governor of the State of Arkansas, in his official capacity; Wendy Kelley, Director, Arkansas Department of Correction, in her official Capacity, Defendants–Appellants.

No. 17-1804
|
Submitted: April 17, 2017
|
Filed: April 17, 2017

Synopsis

Background: Nine death row inmates brought § 1983 action against State of Arkansas and sought stays of execution. The United States District Court for the Eastern District of Arkansas, Kristine G. Baker, J., 2017 WL 1399554, granted motion. The State of Arkansas moved to vacate stays of execution.

Holdings: The Court of Appeals held that:

[1] inmates' delay in bringing § 1983 method of execution claim was unnecessary;

[2] district court's conclusion concerning the use of midazolam did not apply governing standard and was not adequately supported by the court's factual findings; and

[3] inmates failed to demonstrate a significant possibility of establishing a known and available alternative that would significantly reduce a substantial risk of severe pain.

Vacated.

Kelly, Circuit Judge, filed dissenting opinion.

West Headnotes (8)

[1] **Civil Rights**
Criminal law enforcement;prisons

Death row inmates' delay in bringing § 1983 method-of-execution claim was unnecessary, and thus district court abused its discretion in staying inmates' executions; State legislature had adopted their method of execution two years earlier, and, while some of the inmates had brought an action challenging such method as violative of Eighth Amendment, they later voluntarily dismissed case without prejudice and did not raise claim again until three weeks before first scheduled execution. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

2 Cases that cite this headnote

[2] **Action**
Stay of Proceedings

A court considering a stay must apply a strong equitable presumption against the grant of a stay where a claim could have been brought at such a time as to allow consideration of the merits without requiring entry of a stay.

Cases that cite this headnote

[3] **Civil Rights**
Criminal law enforcement;prisons

District court's conclusion concerning the use of midazolam in the Arkansas execution protocol did not apply governing standard and was not adequately supported by the court's factual findings, and thus district court abused its discretion in staying Arkansas death row inmates' executions based on likelihood of success on merits of Eighth Amendment method-of-execution claim brought under § 1983; district court never determined whether use of midazolam in execution was sure or very likely to cause serious illness and needless suffering, and evidence relating to midazolam was equivocal

in nature. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

5 Cases that cite this headnote

[4] Sentencing and Punishment
Mode of execution

To establish a violation of the Eighth Amendment based on method of execution, prisoners must show that the method of execution is sure or very likely to cause serious illness and needless suffering. U.S. Const. Amend. 8.

7 Cases that cite this headnote

[5] Sentencing and Punishment
Mode of execution

When a method of execution is authorized under state law, a party contending that this method violates the Eighth Amendment bears the burden of showing that the method creates an unacceptable risk of pain. U.S. Const. Amend. 8.

Cases that cite this headnote

[6] Civil Rights
Criminal law enforcement;prisons

Death row inmates failed to demonstrate a significant possibility of establishing a known and available alternative that would significantly reduce a substantial risk of severe pain, and thus district court abused its discretion in staying inmates' executions in § 1983 action alleging Eighth Amendment method-of-execution claim; even assuming a risk of pain from the current method, the availability of alternative methods was speculative. U.S. Const. Amend. 8; 42 U.S.C.A. § 1983.

5 Cases that cite this headnote

[7] Sentencing and Punishment
Mode of execution

In order to establish that alternative methods of execution are known and available, in asserting an Eighth Amendment method of execution claim, State must have access to the alternative and be able to carry out the alternative method relatively easily and reasonably quickly. U.S. Const. Amend. 8.

7 Cases that cite this headnote

[8] Sentencing and Punishment
Mode of execution

Unless an alternative method of execution is feasible and readily implemented in the sense described, the State has a legitimate penological justification for adhering to its current method of execution in order to carry out lawful sentences; when availability or effectiveness of an alternative is more speculative, a State's refusal to discontinue executions under the current method is not blameworthy in a constitutional sense.

2 Cases that cite this headnote

***490** Motion to Vacate Stays of Execution
United States District Court for the Eastern District of Arkansas—Little Rock

Attorneys and Law Firms

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Before WOLLMAN, LOKEN, RILEY, COLLOTON, GRUENDER, BENTON, SHEPHERD, and KELLY, Circuit Judges. [1]

Opinion

PER CURIAM.

The State of Arkansas moves to vacate stays of execution of nine sentences of death entered by the district court on Saturday, April 15, 2017. The first execution is scheduled for today, April 17, at 7:00 p.m. The State moved to vacate the stays at approximately 6:00 p.m. on April 15. The prisoners responded at 1:16 a.m. today, April 17. The State filed a reply at 10:04 a.m. today. Due to the exigency of time, we dispense with a lengthy statement of procedural history and state our conclusions concisely. The judges in regular active service voted to hear the motion initially en banc.

The stays of execution were entered in an action brought by nine Arkansas prisoners under 42 U.S.C. § 1983. The inmates were all convicted of murder and sentenced to death. Governor Hutchinson of Arkansas scheduled executions for eight of the prisoners to occur on April 17, 20, 24, and 27, 2017, two per day. As relevant here, the complaint alleges that use of the State's method of execution, by itself and in combination with the execution schedule, would constitute cruel and unusual punishment that violates the Eighth and Fourteenth Amendments. The State's current lethal injection protocol calls for injection of 500 milligrams of midazolam, followed by 100 milligrams of vecuronium bromide, followed by 240 milliequivalents of potassium chloride. If the prisoner remains conscious after the injection of midazolam, however, the executioner will inject another 500 milligrams of midazolam before injecting vecuronium bromide.

[1] ***491** The district court based its order staying the executions on three principal conclusions: (1) the inmates did not delay unnecessarily in bringing this action, (2) "there is a significant possibility that plaintiffs will succeed in showing that the use of midazolam in the ADC's current lethal injection protocol qualifies as an objectively intolerable risk that plaintiffs will suffer severe pain," and (3) there is a significant possibility that the risk of severe pain arising from Arkansas's proposed method of execution is substantial when compared to known and available alternative methods. The district court conducted a four-day hearing and produced a 101–page order under great time pressure, and we commend the court for its diligence. For the following reasons, however, we conclude that the district court abused its discretion in staying the executions, and we therefore grant the State's motion to vacate the stays.

[2] *First*, "[a] court considering a stay must ... apply 'a strong equitable presumption against the grant of a stay where a claim could have been brought at such a time as to allow consideration of the merits without requiring entry of a stay.' " *Hill v. McDonough*, 547 U.S. 573, 584, 126 S.Ct. 2096, 165 L.Ed.2d 44 (2006) (quoting *Nelson v. Campbell*, 541 U.S. 637, 650, 124 S.Ct. 2117, 158 L.Ed.2d 924 (2004)). The record here shows that the prisoners could have brought their § 1983 method-of-execution claim much earlier and intentionally declined to do so.

The Arkansas legislature adopted the current method of execution in 2015. On April 6, 2015, several of the prisoners sued in Arkansas state court to challenge the constitutionality of the law under both the Arkansas Constitution and the federal Constitution. After the State removed the case to federal court, however, the prisoners voluntarily dismissed the case without prejudice on April 18, 2015. They then filed a new action in Arkansas state court that omitted the federal claims and alleged only violations of Arkansas law. After more than a year of litigation, the Arkansas Supreme Court—applying the same standards that apply under the Eighth Amendment of the federal Constitution—dismissed the prisoners' claim that the method of execution constituted cruel or unusual punishment in violation of the Arkansas Constitution. *Kelley v. Johnson*, 2016 Ark. 268, 496 S.W.3d 346, 357-60 (2016), *cert. denied*, —— U.S. ——, 137 S.Ct. 1067, 197 L.Ed.2d 235 (2017).

On February 27, 2017, six days after the Supreme Court denied certiorari in *Kelley*, the Governor scheduled executions for eight of the inmates to occur in April 2017. Finally, on March 27, 2017, only three weeks before the first scheduled execution, the plaintiffs brought this action to challenge the method of execution under the Eighth Amendment of the federal Constitution.

The prisoners' long delay in pursuing their federal claim should have created a strong equitable presumption against the grant of a stay. The prisoners voluntarily elected to forego their federal claim in April 2015 and chose instead to challenge the method of execution exclusively in state court under the Arkansas Constitution. Only after the Arkansas Supreme Court rejected their state-law claim, the Supreme Court denied certiorari, and the Governor scheduled the executions did the prisoners present a federal claim in federal court. The claim on which the district court based the stays of execution—that the three-drug lethal injection protocol allegedly violates the Eighth Amendment—could have been litigated at the same time as the state constitutional claim beginning in April 2015. Whether or not the claim technically is barred by doctrine of res ***492** judicata or collateral estoppel, the prisoners' use of "piecemeal litigation" and dilatory tactics is sufficient reason by itself to deny a stay. *Hill*, 547 U.S. at 584-85, 126 S.Ct. 2096.

Although the district court said that a risk of pain arising from the lethal-injection protocol is "exacerbated" by the Governor's execution schedule, R. Doc. 54, at 56, the court did not explain why. The alleged risk of pain from the drug protocol is the central basis for the district court's order granting stays. The prisoners could have challenged the protocol beginning in April 2015. We are not convinced that the execution schedule is material to the question whether stays are warranted based on the lethal-injection protocol.

[3] **[4]** *Second*, the district court's conclusion concerning the use of midazolam in the Arkansas execution protocol did not apply the governing standard and was not adequately supported by the court's factual findings. To establish a violation of the Eighth Amendment, prisoners must show that the method of execution is "*sure or very likely* to cause serious illness and needless suffering." *Glossip v. Gross*, —— U.S. ——, 135 S.Ct. 2726, 2737, 192 L.Ed.2d 761 (2015) (quoting *Baze v. Rees*, 553 U.S. 35, 50, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (plurality opinion)). While the district court found a significant possibility that the prisoners could show an "objectively intolerable risk" of severe pain, the court never found that the prisoners had a likelihood of success under the rigorous "sure or very likely" standard of *Glossip* and *Baze*. Although the court recited the "sure or very likely" standard in its preliminary discussion, R. Doc. 54, at 55, the court never applied it when discussing whether stays of execution were justified.

The district court's factual findings would not support a conclusion that the prisoners have a likelihood of success in showing that the execution protocol is sure or very likely to cause severe pain. Much of the district court's order highlights the equivocal nature of the evidence. The court observed that there are no scientific studies conducted in humans about the effects of the dosage of midazolam that would be administered under the protocol. One human study involving smaller doses was "mixed in terms of supporting either side's theory." R. Doc. 54, at 58. The court discussed the alleged "ceiling effect" for midazolam, under which effectiveness levels off at a certain dosage, but concluded that if there is a ceiling effect, the level is unknown. *Id.* at 60. Evidence from executions in other jurisdictions was of "limited relevance." *Id.* at 69; *see In re Ohio Execution Protocol*, No. 17-3076, —— F.3d ——, ——, 2017 WL 1457946, at *22 (6th Cir. Apr. 25, 2017) (Kethledge, J., dissenting). There is no express finding of fact that the prisoners are likely to prove that a 500–milligram injection of midazolam will fail to anesthetize the prisoners during the execution or that use of the lethal-injection protocol is sure or very likely to cause severe pain. Instead, the district court found that "there appears *at least a possibility* that if the midazolam does not operate as defendants predict ..., the inmate may regain some level of consciousness during the process before the second and third drugs are administered." R. Doc. 54, at 72-73.

The district court appeared to acknowledge that there was no "well-established scientific consensus" that the use of midazolam in conjunction with the other two drugs was very likely to cause severe pain. *Id.* at 68-69. But the district court thought this standard—urged by Justice Alito in *Baze* to avoid "embroil[ing] the States in never-ending litigation concerning the adequacy of their execution procedures," ***493** 553 U.S. at 63, 67, 128 S.Ct. 1520 (Alito, J., concurring)—"seems like a high bar to reach and level of certainty to achieve based on the evidence of which the Court is aware at this stage of the

proceeding and the limitations of human study at 500 mg, 1,000 mg, or higher doses of midazolam." R. Doc. 54, at 69.

[5] "When a method of execution is authorized under state law, a party contending that this method violates the Eighth Amendment bears the burden of showing that the method creates an unacceptable risk of pain." *Glossip*, 135 S.Ct. at 2741. If there is no scientific consensus and a paucity of reliable scientific evidence concerning the effect of a lethal-injection protocol on humans, then the challenger might well be unable to meet this burden. The equivocal evidence recited by the district court falls short of demonstrating a significant possibility that the prisoners will show that the Arkansas protocol is "sure or very likely" to cause severe pain and needless suffering.

[6] **[7]** *Third*, we disagree with the legal standard that the district court applied in determining whether alternative methods of execution are known and available. We do not say that an alternative method must be authorized by statute or ready to use immediately, but we concur with the Eleventh Circuit that the State must have access to the alternative and be able to carry out the alternative method relatively easily and reasonably quickly. *Arthur v. Comm'r, Ala. Dep't of Corr.*, 840 F.3d 1268, 1300 (11th Cir. 2016), *cert. denied*, —— U.S. ——, 137 S.Ct. 725, 197 L.Ed.2d 225 (2017).

[8] The district court thought this standard places an "impossible burden" on the prisoners. We think it is necessary to conform to the Eighth Amendment. Unless an alternative is feasible and readily implemented in the sense described, the State has a legitimate penological justification for adhering to its current method of execution in order to carry out lawful sentences. *See Baze*, 553 U.S. at 52, 128 S.Ct. 1520 (plurality opinion). When availability (or effectiveness) of an alternative is more speculative, a State's refusal to discontinue executions under the current method is not blameworthy in a constitutional sense. *See Baze*, 553 U.S. at 67, 128 S.Ct. 1520 (Alito, J., concurring). The "reasonable possibility" standard urged by the prisoners based on *In re Ohio Execution Protocol*, —— F.3d at ——, 2017 WL 1457946, at *9, is insufficient to establish that an alternative method is available, feasible, and readily implemented. *See id.* at —— – ——, 2017 WL 1457946, at *23-24 (Kethledge, J., dissenting).

Under our view of the correct legal standard, we cannot agree with the district court that the prisoners have demonstrated a significant possibility of establishing a known and available alternative that would significantly reduce a substantial risk of severe pain. Even assuming a risk of pain from the current method, the availability of the several methods cited by the district court is too uncertain to satisfy the rigorous standard under the Eighth Amendment.

The possibility that Arkansas could acquire pentobarbital for use in executions is too speculative to justify stays of execution. Arkansas made at least three unsuccessful inquiries about obtaining barbiturates in 2015, and the difficulty of obtaining drugs for use in lethal injection is well documented. Sevoflurane gas and nitrogen hypoxia have never been used to carry out an execution. With no track record of successful use, these methods are not likely to emerge as more than a "slightly or marginally safer alternative." *Glossip*, 135 S.Ct. at 2737; *see* ***494** *Baze*, 553 U.S. at 41, 128 S.Ct. 1520 (discussing "untried and untested alternatives"). The firing squad has been used by only one State since the 1920s. It requires trained marksmen who are willing to participate and is allegedly painless only if volleys are targeted precisely. The record comes short of establishing a significant possibility that use of a firing squad is readily implemented and would *significantly reduce* a substantial risk of severe pain.

For these reasons, the stays of execution entered on April 15, 2017, R. Doc. 54, are vacated.

KELLY, Circuit Judge, dissenting.

This case is not only about midazolam. Any increased risk of pain from midazolam in this case is compounded here by the compressed execution schedule and Arkansas' execution procedures. Together, these factual elements fully support the district court's conclusion that using midazolam to execute eight men over an eleven day period with limited contingency procedures creates a substantial risk of serious harm. I would hold that the district court did not err in concluding that the appellees' midazolam claim, standing alone, supports a grant of preliminary injunction. But, more significantly, the district court did not clearly err in concluding that, in combination, the risks inherent in the state's procedure likely violate the Eighth Amendment. See Lopez v. Brewer, 680 F.3d 1068, 1074 (9th Cir. 2012) ("The relevant inquiry ... is

whether [the sequence of events], either individually or in combination, lead to an objectively intolerable risk of pain."); Valle v. Singer, 655 F.3d 1223, 1228 (11th Cir. 2011) (addressing petitioner's claim that the "replacement of sodium thiopental with pentobarbital when combined with Florida's history and the deficiencies in its procedures subjects him to a substantial risk of serious harm").

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Glossip v. Gross, ––U.S. ––––, 135 S.Ct. 2726, 2736, 192 L.Ed.2d 761 (2015) (quoting Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7, 20, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008)). We review a district court's grant of preliminary injunction and stay of execution for abuse of discretion. Nooner v. Norris, 491 F.3d 804, 807 (8th Cir. 2007). "An abuse of discretion occurs when the district court bases its decision on an erroneous application of the law or a clearly erroneous finding of fact." See Taylor Corp. v. Four Seasons Greetings, LLC, 403 F.3d 958, 967 (8th Cir. 2005).

Contrary to the court's conclusion, the district court based the preliminary injunction at least in part on appellees' combined claim that midazolam, the compressed execution schedule, and Arkansas' execution procedures violate the Eighth Amendment. (Prelim. Inj. Order at 22–28, 37–45, 53, 56; id. at 73–74 ("[T]he schedule imposed on these officials ... causes concern. For these reasons, the Court finds that there is a significant possibility that plaintiffs will succeed on the merits under the first prong of *Baze*/ *Glossip*."')). The compressed execution schedule is a crucial component of the combined claim. The appellees could not have brought this claim until the Governor set their execution dates on February 27, 2017. By filing their complaint in federal court on March 27, 2017, they diligently and timely pursued their combined claim.

Because the midazolam method of execution claim is integral to both Eighth Amendment claims, I address the state's midazolam-related arguments first. I then ***495** turn to the ultimate issue: whether the district court abused its discretion in granting a preliminary injunction on the combined method of execution claim ("combined claim") that the use of midazolam together with the expedited execution schedule and Arkansas' execution protocols violates the Eighth Amendment. Finally, I consider the claim appellees raised in their cross appeal that the state's compressed execution schedule violates the nation's evolving standards of decency.

I. Midazolam Method of Execution Claim

To bring an Eighth Amendment challenge to a method of execution, a plaintiff must establish "that the State's lethal injection protocol creates a demonstrated risk of severe pain. [And] [h]e must show that the risk is substantial when compared to the known and available alternatives." Glossip, –– U.S. ––––, 135 S.Ct. 2726, 2737, 192 L.Ed.2d 761 (2015) (alteration in original) (quoting Baze v. Rees, 553 U.S. 35, 61, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008)). "The preliminary injunction posture of the present case thus requires petitioners to establish a likelihood that they can establish both" of those prongs. Id. The state argues that the appellees have failed to prove both prongs of the Glossip test, because they have not shown that midazolam creates a demonstrated risk of severe pain, or that a readily available alternative execution method exists.

1. Substantial risk of serious harm

The state argues that the district court erred in entering the preliminary injunction because the appellees failed to establish that Arkansas' midazolam protocol presents a substantial risk of serious harm. Under Glossip, the determination of whether a particular method of execution presents a substantial risk of serious harm is a finding of fact, which we review under the deferential clear error standard. See Glossip, 135 S.Ct. at 2731 ("[T]he District Court did not commit clear error when it found that the prisoners failed to establish that Oklahoma's use of a massive dose of midazolam in its execution protocol entails a substantial risk of severe pain.").

The court asserts that the "equivocal nature of the evidence" fails to demonstrate that midazolam is sure or very likely to cause severe pain. But the clear-error standard "does not entitle us to overturn a finding 'simply because [we are] convinced that [we] would have decided the case differently.' " Id. at 2739 (alterations in original) (quoting Anderson v. Bessemer City, 470 U.S. 564, 573, 105 S.Ct. 1504, 84 L.Ed.2d 518 (1985)). Rather, "[w]here there are two permissible views of the evidence,

the factfinder's choice between them cannot be clearly erroneous." Anderson, 470 U.S. at 574, 105 S.Ct. 1504. Thus, to the extent the court believes the evidence in this case is equivocal—a belief I disagree with—it is required to uphold the district court's findings.

Initially, the court concludes that the district court applied the incorrect legal standard. In its view, Glossip requires prisoners to show that a method of execution is "sure or very likely to cause serious illness and needless suffering." Though the district court quoted this language, the court believes that in fact the district court found only that the appellees showed the Arkansas' midazolam protocol presented an "objectively intolerable risk of severe pain." The distinction the court draws is not supported by Glossip. Glossip explains:

> The controlling opinion in Baze first concluded that prisoners cannot successfully challenge a method of execution unless they establish that the method presents a risk that is " 'sure or very likely to cause serious illness and needless suffering,' ***496** and give rise to 'sufficiently imminent dangers.' " To prevail on such a claim, "there must be a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment.' "

Glossip, 135 S.Ct. at 2737 (citations and quotations omitted). As this paragraph demonstrates, the "sure or very likely to cause serious illness and needless suffering" standard is identical to the "objectively intolerable risk of harm" standard, as well as the "substantial risk of serious harm" standard. These are not different standards; they are different ways of describing the same standard. Indeed, all three phrasings are used interchangeably throughout both Glossip and Baze. See, e.g., id. at 2731, 2739, 2745; Baze, 553 U.S. at 50, 57, 128 S.Ct. 1520. My discussion will use the phrasing "substantial risk of serious harm."

In finding that Arkansas' midazolam protocol presents a substantial risk of serious harm, the district court engaged in a lengthy analysis of evidence presented over the course of a four-day hearing. The district court discussed in detail scientific studies, expert witness testimony, and anecdotal evidence regarding other executions conducted with midazolam. Ultimately, the district court concluded that both the scientific and anecdotal evidence was more consistent with the appellees' theory of the case. The state argues that the district court's finding was in error because it "ignores" various pieces of evidence that support the state's view that midazolam induces general anesthesia, because it erroneously relied on evidence regarding midazolam's "ceiling effect," and because anecdotal evidence of executions in other states was irrelevant. Thus, in the state's view, the district court relied only on "speculation, conjectures, and assumptions" in finding that Arkansas' midazolam protocol presents a substantial risk of severe harm.

a. "Ignored" evidence

To begin with, the state points to several pieces of "undisputed" evidence that, it claims, the district court ignored in finding that midazolam presents a substantial risk of severe harm. First, the state contends the district court ignored evidence that the Food and Drug Administration's (FDA's) package insert for midazolam states that midazolam can be used to induce general anesthesia. On the contrary, the district court's order did discuss the insert, and did not find it to be persuasive evidence that midazolam alone can induce general anesthesia for two reasons. First, it noted that the insert "is not entirely internally consistent in its language, especially in regard to use of midazolam as an induction agent or as a sole agent for anesthesia." Indeed, as appellees' expert Dr. Craig Stevens pointed out, certain portions of the insert indicate that midazolam can be used to induce general anesthesia only when followed by "other anesthetic agents." He testified that this language was consistent with the usual practice of using midazolam together with other medications for induction of anesthesia. The district court also pointed out that the report of the state's expert witness, pharmacologist Dr. Daniel Buffington, explained that an FDA insert can be modified over time based on clinical uses, and that physicians sometimes use drugs "off-label," which the district court noted "seems to contradict a reliance on the label." Further, other evidence in the case consistently demonstrated that midazolam is effective to induce anesthesia only as one medication among several. One of the plaintiffs' experts, Dr. Jonathan Groner, testified that it is used as a "component" of anesthesia, and the appellees' ***497** anesthesiology expert Dr. Joel Zivot testified that inducing anesthesia involves more than a single drug. Dr. Stevens and Dr. Groner also both testified that midazolam alone cannot induce

general anesthesia. In light of the entire record, it cannot be said that the district court's well-reasoned decision to give limited weight to the FDA's package insert gave rise to clear error.

Next, the state contends that Dr. Zivot conceded midazolam can be used for induction of anesthesia and as the sole anesthetic for painful surgeries. The state misrepresents the testimony it cites. When asked if midazolam could be used for that purpose, Dr. Zivot testified, "[W]e could also just give them saline. I don't know what you're asking me. Could we? I mean, you can do a lot of things. So you could give it, but it would be insufficient." He also stated, "I could practice poor medicine in a number of ways, and that would be one of them." In short, Dr. Zivot's testimony does not indicate that he concedes midazolam would, by itself, induce general anesthesia. Additionally, as discussed above, several witnesses testified that midazolam cannot by itself induce general anesthesia. Dr. Groner also testified that midazolam is not an analgesic, meaning that it does not alleviate pain, and an authoritative textbook, Miller's Anesthesia, states that benzodiazepines (the class of drugs to which midazolam belongs) lack analgesic properties. Thus, the district court's failure to rely on Dr. Zivot's "concession" does not suggest that its finding that Arkansas' midazolam protocol presents a substantial risk of serious harm is clearly erroneous.

According to the state, the district court also ignored the fact Dr. Stevens co-authored a pharmacology textbook that listed anesthesia as one of the uses of midazolam. But again, the district court did not ignore this evidence: it acknowledged "that plaintiffs' witness Dr. Stevens was cross examined effectively as to the table from the textbook he co-authored." However, it found that Dr. Stevens regained credibility in other portions of his testimony, in which he discussed the mechanism by which midazolam works to support his view that midazolam cannot, by itself, induce general anesthesia. Furthermore, Dr. Stevens explained that his textbook was a general introduction to pharmacology, which did not go into great detail, and pointed out that his textbook did not state midazolam could induce general anesthesia *by itself*. In light of these circumstances, the district court was justified in finding Dr. Stevens' detailed testimony regarding the mechanism by which midazolam functions credible despite his textbook's brief reference to its uses as an anesthetic. See Prince v. Sargent, 960 F.2d 720, 720–21 (8th Cir.1992) (explaining that under clear-error review, "the appellate court should give particular deference to findings based upon credibility determinations").

The state also points out that its anesthesiology expert Dr. Joseph Antognini testified that a 20 to 30 milligram dose of midazolam will induce general anesthesia in a 200–pound man, that a 40 to 60 milligram dose will induce general anesthesia in a 400–pound man, and that a 500 milligram dose would be much more than necessary to anesthetize a person and render him insensate to pain. But, as the district court noted, there were several reasons not to fully credit Dr. Antognini's testimony on this point: some of the studies he relied on for his opinion that midazolam could induce general anesthesia by itself used a spinal injection rather than an IV to administer the midazolam; he could not recall if he had ever previously used midazolam as the sole agent to induce general anesthesia; and he gave an evasive answer to the question of whether midazolam can be used as the sole anesthetic even for ***498** "short, painful" procedures. Given its estimation of Dr. Antognini's credibility, as well as other evidence in the record demonstrating that midazolam cannot induce general anesthesia by itself, the district court's rejection of Dr. Antognini's testimony did not give rise to clear error.

Finally, the state contends the district court ignored two studies that were discussed during the hearing. But the district court's opinion evaluated the studies at length, and found that both were "mixed in terms of supporting either side's theory of this case." In one study, researchers gave midazolam to 26 subjects and measured the depth of anesthesia achieved using bispectral analysis. Dr. Stevens testified that a bispectral analysis score between 40 and 60 indicates general anesthesia, and Dr. Buffington testified that a score of 60 is the industry definition of general anesthesia. As the district court noted in its order, only a few of the subjects in the study appear to have achieved a bispectral analysis score below 60. The district court was therefore justified in concluding the study did not lend great support to the state's theory. In the other study, researchers gave subjects doses of midazolam between 4.5 and 20 milligrams. According to the state, some of the subjects demonstrated bispectral analysis scores under 60, and "to the extent patient scores were above 60, Appellee's expert concedes these monitors often are not reliable." Even accepting the state's characterization of the study results, it is hard to see how it undermines

the district court's conclusion that the study did not support either side's theory of the case. The fact that unreliable monitors may have shown that midazolam induced general anesthesia in some (but not all) subjects does not undercut the district court's finding that its use in Arkansas' execution protocol would create a substantial risk of severe harm by failing to properly anesthetize the inmates.

In short, the district court did not ignore the evidence the state cites; rather, it discussed each piece of it in detail and explained its reasons for finding the evidence supporting the appellees' case more persuasive. Though the state might have preferred the district court to resolve the conflicting evidence differently, this does not render the district court's finding that midazolam cannot by itself induce general anesthesia clearly erroneous.

b. Ceiling effect

Next, the state contends that the district court erred in concluding that midazolam has a "ceiling effect." First, the state points out that Dr. Stevens' opinion as to the ceiling effect relied on data from *in vitro* and animal studies, rather than studies conducted on human subjects. The state conclusorily asserts this type of evidence is unreliable and violates Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 592, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). To the extent we may review the reliability of an expert opinion under Daubert at this stage, we do so under the abuse-of-discretion standard. See Glossip, 135 S.Ct. at 2745. The state cites no authority for the proposition that an expert's opinion is unreliable solely because it is based on *in vitro* or animal studies. In fact, Dr. Stevens pointed out that the FDA usually requires both types of studies in evaluating pharmaceuticals for human use. And, as the district court noted in its opinion, the state's own anesthesiology expert also cited an animal study. Furthermore, other evidence supported the district court's conclusion that midazolam has a ceiling effect. Dr. Antognini—who was a witness of the state — acknowledged that he had previously testified that midazolam had a ceiling effect, which he expected would occur at a dose of about 20 to 25 milligrams. As such, the district court's ***499** conclusions regarding the ceiling effect support its finding that midazolam cannot by itself induce general anesthesia, and that finding was not clear error.

c. Anecdotal evidence

Finally, the state argues that the district court should not have relied on anecdotal evidence of executions in other states, because those states used different execution protocols than Arkansas plans to use. In particular, the state notes that the execution of Clayton Lockett in Oklahoma failed not because of the midazolam used, but because his IV line dislodged. However, the district court specifically "recognize[d] that evidence of other executions using different lethal injection protocols has limited relevance to the Court's inquiry in this case." Thus, it considered the evidence only for the limited purpose of "assessing the scientific opinions offered by the parties' experts."

The district court concluded that the testimony of lay witnesses who had witnessed executions using midazolam was "more consistent with plaintiffs' theory of this case," especially with respect to "plaintiffs' arguments regarding the ceiling effect and articles about the synergistic effects on midazolam and opoids." It was not clear error for the district court to rely on the lay witness testimony for this limited purpose; nor does the fact that other states use different protocols significantly undermine the relevance of the lay testimony to demonstrate that midazolam is not by itself sufficient to induce general anesthesia.

The district court also considered Dr. Zivot's testimony regarding autopsies performed on inmates who had been executed in Florida using midazolam. Dr. Zivot testified that the autopsy reports showed death was not instantaneous, but occurred slowly, and would have caused the inmate to feel as though his lungs were filling with fluid. The district court acknowledged that unlike Arkansas' protocol, Florida's protocol requires the "very quick administration" of the paralytic drug after midazolam is administered. However, it noted that Dr. Zivot's description of the autopsy reports was not dissimilar to the lay witnesses' descriptions of executions where the paralytic drug was not administered as quickly. Thus, contrary to the state's assertions, the district court did not rely on anecdotal evidence of executions in other states without considering the differences in execution protocols. Rather, the district court recognized the "limited relevance" of the anecdotal evidence, and considered the possible effect different protocols might

have had on the outcome of other executions. This evidence therefore does not undermine the district court's finding that midazolam presents a substantial risk of serious harm.

Accordingly, the district court did not clearly err in finding that the appellees demonstrated that Arkansas' midazolam protocol presents a substantial risk of serious harm. This conclusion is not inconsistent with the Supreme Court's holding in Glossip that the district court did not clearly err in finding that midazolam did *not* present a substantial risk of serious harm. The evidence and witnesses in this case differ from the evidence and witnesses before the district court in Glossip. More importantly, the clear-error standard itself contemplates that two courts may reach contrary conclusions without either having clearly erred. See Anderson, 470 U.S. at 574, 105 S.Ct. 1504 ("Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.").

2. Alternative methods

The state also argues that the district court erred in finding that the appellees ***500** established a likelihood of success on their midazolam claim because the appellees failed to identify "a known and available alternative [ ]" method of execution that is "feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain." Glossip, 135 S.Ct. at 2736–37 (quoting Baze, 553 U.S. at 52, 61, 128 S.Ct. 1520). Though it established the availability requirement, Glossip provided little guidance as to when an alternative method of execution is "available," and instead simply noted that the record demonstrated "that Oklahoma has been unable to procure t[he] drugs despite a good-faith effort to do so." Id. at 2738.

In its order granting the appellees' request for a preliminary injunction, the district court highlighted two interpretations of Glossip's availability requirement: the Eleventh Circuit's more demanding standard, articulated in Arthur v. Commissioner, Ala. Department of Corrections, 840 F.3d 1268 (11th Cir. 2016), cert. denied sub. nom., Arthur v. Dunn, —— U.S. ——, 137 S.Ct. 725, 197 L.Ed.2d 225 (2017), and the Sixth Circuit's definition, announced in In re Ohio Execution Protocol, No. 17-3076, —— F.3d ——, 2017 WL 1457946 (6th Cir. 2017). Despite the fact that our court has yet to fully address what it means for an alternative method to be available under Glossip in the circumstances present here, the court adopts the Eleventh Circuit's iteration of the standard at the state's urging. But given the expedited timeline in the instant matter, I would decline to formally adopt an answer to this weighty legal question at this time. Instead, because I think that the appellees meet the more demanding standard articulated by the Eleventh Circuit, I assume for purposes of this motion that the Eleventh Circuit's availability standard applies in this case.

In Arthur, the Eleventh Circuit affirmed the district court's denial of the plaintiff's motion for a preliminary injunction. It held that in order to establish a known available alternative method of execution, a plaintiff must establish that "(1) the State actually has access to the alternative; (2) the State is able to carry out the alternative method of execution relatively easily and reasonably quickly; and (3) the requested alternative would 'in fact significantly reduce [ ] a substantial risk of severe pain' relative to the State's intended method of execution." Arthur, 840 F.3d at 1300 (alteration in original) (quoting Glossip, 135 S.Ct. at 2737). Reviewing the district court's factual findings for clear error, see Glossip, 135 S.Ct. at 2738, I believe the facts as found by the district court establish known and available alternatives to midazolam.

The district court noted several potential alternative methods of execution, including, *inter alia*, manufactured or compounded pentobarbital (a barbiturate), and sevoflurane (a lethal gas).[2] First, the district court's findings support a conclusion that the appellees are likely able to demonstrate that the state "actually has access" to these alternatives. Arthur, 840 F.3d at 1300. With respect to manufactured or compounded pentobarbital, evidence established that other states currently utilize this drug in performing executions. For example, Missouri executed one person using FDA-approved manufactured pentobarbital as recently as January 31, 2017. Additionally, Texas and Georgia together have executed 20 people in 2016 and so far in 2017 using manufactured or compounded ***501** pentobarbital. The state's expert, Dr. Buffington, testified that he believes Arkansas could acquire compounded pentobarbital for use in executions, though he could not identify a specific supplier—an unsurprising fact in light of Arkansas' laws securing anonymity for execution-drug suppliers. See In re Ohio Execution Protocol, No. 17-3076, —— F.3d ——, 2017 WL 1457946 (6th Cir. 2017) (considering similar

testimony, also from Dr. Buffington, in finding that alternatives were available under different standard for "available"). These facts support a conclusion that the appellees are likely able to demonstrate that the state actually had access to a barbiturate.

Furthermore, the alleged defects the state highlights in appellees proof of its ability to obtain pentobarbital—namely, that it does not currently have it on hand or have a supplier lined up—wane in the context of the appellees' evidence regarding sevoflurane. The appellees specifically identified by name one supplier willing to sell lethal gas to the ADC for use in executions. And the appellees presented evidence that lethal gas is available through online suppliers. Tr. 212–16; cf. Johnson v. Lombardi, 809 F.3d 388, 391 (8th Cir. 2015) (noting that, in the context of a motion to dismiss, a "threadbare assertion that lethal gas is *legally* available in Missouri is not the same as showing that the method is a feasible or readily implementable alterative method of execution." (emphasis in original)).

Glossip makes clear that a state's "good faith effort" to obtain an alternative may be relevant to determining whether an alternative is available. Glossip, 135 S.Ct. at 2738. The district court found that the state made little effort to obtain alternative execution drugs. Mr. Griffin, the current Deputy Director of Healthcare and Programs at the ADC, and ADC Director Wendy Kelley are solely responsible for obtaining execution drugs. Arkansas law permits Director Kelley to choose execution drugs "approved by the [FDA] and made by a manufacturer approved by the [FDA]" or drugs "obtained by a compounding pharmacy that has been accredited by a national organization that accredits compounding pharmacies." Ark. Code Ann. 5-4-617(d). Director Kelley testified that she would prefer to use a barbiturate, but she explained she is not aware of any source from which she could obtain one. However, the last time Director Kelley attempted to obtain a barbiturate was after the Arkansas legislature amended the Arkansas MEA in 2015. Director Kelley asked three sources for a barbiturate, but all refused.

Likewise, Mr. Griffin has made no efforts to obtain a barbiturate since October 2015. In 2015, as a result of litigation in Arkansas state court, the Arkansas Attorney General provided Mr. Griffin with a list of drug manufacturers and their phone numbers in an effort to allow Mr. Griffin to investigate possible sources. While the district court was unclear about whether Mr. Griffin contacted anyone on the list, it found that Mr. Griffin did not hear back from or follow up with any company or individual identified on the list. Mr. Griffin has not talked to any compounding pharmacies about providing the ADC with execution drugs, and Mr. Griffin made clear that he has not attempted to acquire pentobarbital because he "ha[s] the drugs [he] need[s] to conduct the execution. So, no, [he hasn't] tried to get another one." Tr. P. 872. While the state's failure to make a good faith effort to procure alternative drugs is not determinative of their availability in isolation, see Arthur, 840 F.3d at 1303 (declining to impose an affirmative burden to make a good faith effort to obtain other execution drugs, and finding, in the alternative, that Alabama had made ***502** such an effort by contacting 29 potential drug sources), these factual findings are not clearly erroneous and support the district court's conclusion that the appellees are likely able to establish that pentobarbital and lethal gas are available to the defendants. Glossip, 135 S.Ct. at 2738.

The district court's factual findings also support the conclusion that the appellees can likely prove that the state is able to perform executions using one of these alternative methods. Pentobarbital is utilized in the same manner as other lethal injection drugs, and therefore poses little problem with respect to the state's ability to use this alternative in a "relatively quick [ ] and easy[ ]" manner. Arthur, 840 F.3d at 1300. And, unlike execution by lethal injection, which requires some participants to have training in the placement and delivery of a drug by IV, medical expertise is not required to operate the equipment used to perform an execution by lethal gas. The equipment required to implement execution by lethal gas is relatively inexpensive, and is available for as little as $2,000. These factual findings are not clearly erroneous, and support the conclusion that the state could implement these alternatives with relative ease.

Finally, the district court cited ample evidence that barbiturates are a more effective sedative and would in fact significantly reduce the risk of harm posed by midazolam. As discussed above, the district court found that ample scientific and anecdotal evidence supported the conclusion that midazolam alone does not effectively induce general anesthesia. In contrast, the district court cited evidence that barbiturates like pentobarbital possess undisputed analgesic properties and may alone be an effective general anesthetic. The appellees presented

evidence that they could likely establish that a barbiturate would adequately anesthetize them to the pain associated with the second and third drugs utilized in the Arkansas protocol.

The district court found that sevoflurane has the same mechanism action as barbiturate drugs and, like barbiturates, may cause death on its own. What's more, the district court noted the conclusion of the appellees' expert, Dr. Stevens, that sevoflurane and other lethal gases are more potent than barbiturates, and, in large doses, produce a "rapid and painless death." The fact that use of sevoflurane in executions is uncommon or novel does not preclude a finding that the appellees may prove this method significantly reduces their risk of suffering. As an aside, I note that Arkansas has also never performed an execution according to its current midazolam protocol. But, the frequency with which a method of execution has been utilized has no bearing on its viability. The Supreme Court made clear that a procedure's novelty does not render it violative of the Eighth Amendment; such a rule "would hamper the adoption of new and potentially more humane methods of execution and would prevent States from adapting to changes in the availability of suitable drugs." Glossip, 135 S.Ct. at 2745.

The district court's factual findings are not clearly erroneous, and those factual findings support a conclusion that the appellees have demonstrated "a likelihood that they can establish" that there are known and available alternatives to the state's use of midazolam. Glossip, 135 S.Ct. at 2737. Because the appellees presented evidence that they would likely be able to establish an alternative method of execution that is "feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain," Glossip, 135 S.Ct. at 2736–37 (quoting Baze, 553 U.S. at 52, 61, 128 S.Ct. 1520), I would affirm the district court's preliminary injunction ***503** based on the appellees' Eighth Amendment midazolam claim.

II. Combined Claim

The core of the appellees' complaint is not that Arkansas' use of midazolam, alone, supports the grant of preliminary injunction. It is the use of midazolam combined with the compressed execution schedule and insufficient execution procedures that present a novel set of circumstances. Eight of the appellees are scheduled to be executed over an eleven-day period beginning tonight. Two executions are set to occur back-to-back on four nights with the first execution at 7:00 pm and the second at 8:15 pm. The Governor scheduled the appellees' execution dates 49 days before the date set for the first execution. The only reason the state has given for its schedule is "to exhaust the State of Arkansas's supply of midazolam before it expires."

The two executions set for this evening will be the first executions Arkansas has carried out since 2005. The state's last double execution was in 1999. Neither Director Kelley nor Deputy Griffin has ever participated in an execution. Of the current ADC employees who testified, only Dale Reed, the Chief Deputy Director, has ever participated in an execution; even though he has presided over 23 executions, he has never participated in eight executions over eleven days. Tonight will mark the first time that Arkansas has carried out an execution using its midazolam protocol.

Since 1997, no state has attempted this many executions within a month. No state has conducted two executions within one day since 2000. In 2014, Oklahoma attempted a double execution of Clayton Lockett and Charles Warner. However, complications arose during Lockett's execution: he awoke during the administration of the second and third drugs, and the execution was halted, but he died 40 minutes later. Warner's execution did not go forward that night. Oklahoma conducted an investigation into Lockett's execution which concluded that, going forward, "executions should be spaced at least seven days apart." Similarly, Missouri adopted a rule which limits executions to one per month.

The record supports the conclusion that a compressed execution schedule increases the stress on the prison administrators and staff. Oklahoma's investigation determined that the warden, paramedic, and all staff experienced "extra stress" because two executions had been carried out on the same day. Jennie Lancaster, a former North Carolina warden who supervised 23 executions during her career, testified that it would "essentially be professional malpractice" for Arkansas prison officials to carry out the executions as scheduled. She opined that each execution is "immensely stressful for everyone involved," equating it to the physical and mental stress of driving in torrential rain. After just one execution, staff involved in the executions experience

"physical and mental fatigue" because they perform duties that require acute attention to detail and precise timing. Director Kelley agreed that there is stress inherent in the preparation of and events leading up to an execution. Lancaster testified that the stress and fatigue of performing eight executions over eleven days creates "a risk of human error."

Aside from the stress-related risks, Lancaster testified that the "logistical issues" of such a compressed schedule "present challenges that have never been experienced or planned for before." One of the logistical concerns is that with so many executions in such a short period there is insufficient time for the "essential" debriefing process, in which the staff ***504** involved in an execution assess the process, correct deficiencies, receive remedial training, and air concerns about their own ability to conduct the next execution. Oklahoma recommended spacing out its executions in part to allow sufficient time for all involved personnel to discuss their concerns and recommendations for improving the process. The ADC Director before Kelley conducted mandatory debriefing sessions with all staff involved in the executions. Mr. Reed confirmed that given the abbreviated execution schedule, there would not be debriefings between the 7:00 pm and 8:15 pm executions on each of the four nights. Instead, there would only be one debriefing on the morning following the double executions.

Director Kelley also testified that her staff engages in "weeks of preparation" leading up to an execution. This preparation involves meetings with all the agencies and staff involved in the execution, during which the warden reviews each participant's role. Then, all of the staff involved in the execution would conduct approximately twelve practice sessions in which they simulated the entire execution process with a staff member of a similar stature standing in for the inmate. Because the executions are close together, Mr. Reed admitted that although the staff was conducting practices, it would not conduct twelve practice sessions for each of the eight men set to be executed.

The district court did not clearly err in finding that ADC officials were unsure of their roles and authority in the executions and they were not fully aware of all of the protocols. For example, less than a week before the first execution, Mr. Griffin was unaware when he would mix the execution drugs or that a pulse ox monitor would be used on the appellees. As of March 7, 2017, Mr. Reed had not seen the execution policy.

The district court also was not clearly erroneous in concluding that Arkansas does not have a contingency plan if something goes wrong during an execution. The testimony supports the district court's finding that the staff is not aware of a plan for if or when lifesaving techniques will be used or how they will be implemented if complications arise. At most, Director Kelley said if complications arose, she would close the curtain and call the Governor. Mr. Griffin said they had never rehearsed seeking medical treatment and was not aware whether medical staff would ever be called to assist. The ADC does not possess any drugs to reverse the effects of any of the three execution drugs, despite the fact that antidotes are available. Perhaps most concerning, Arkansas' midazolam protocol is silent on what happens if the appellees remain conscious after the two 500 mg injections of midazolam. Mr. Griffin testified that he is aware of no plans to reverse the effects of midazolam if an appellee remains conscious after the injections. Such contingency planning, including how to stop the execution and whether to provide life-saving measures, was similarly missing from Oklahoma's execution protocol prior to Lockett's execution, and Oklahoma recommended establishing protocols and training to address these possibilities. The record supports the district court's finding that if complications arise during any of appellees' executions, the ADC does not have a plan regarding whether to cancel or postpone any following executions.

1. Substantial Risk of Serious Harm

Based on these detailed factual findings, the district court did not clearly err in finding that appellees have demonstrated a significant possibility that they will succeed in showing that Arkansas' plan for executing them creates a "substantial risk of serious harm." Glossip, 135 S.Ct. at 2737 ***505** (quoting Baze, 553 U.S. at 50, 128 S.Ct. 1520). The district court relied on "numerous aspects of the protocol that ... create opportunities for error." Baze, 553 U.S. at 53, 128 S.Ct. 1520. The court also examined whether Arkansas was following its procedures in this case. Case law recognizes that opportunities for error and failure to follow established procedures "[s]ubject [ ] individuals to a risk of future harm—not simply actually inflicting pain—[and] can qualify as cruel

and unusual punishment." Baze, 553 U.S. at 49, 128 S.Ct. 1520. Thus, it was not clearly erroneous for the district court to conclude that Arkansas' method of execution entails an "objectively intolerable risk of harm" where it relies on a drug—midazolam—that may not on its own produce sedation or relieve pain, intends to conduct four double executions within eleven days, has not performed an execution since 2005, and relies on an execution protocol and policies that do not contain adequate safeguards against complications that have occurred in other recent midazolam executions. Glossip, 135 S.Ct. at 2737; cf. id. at 2742 (finding no clear error in district court conclusion that "safeguards help to minimize any risk that might occur in the even that midazolam does not operate as intended").

The compounding risk for error identified by the district court distinguishes this claim from Glossip. The Glossip Court was not faced with a record of four back-to-back executions over eleven days, where the ADC had only 49 days to prepare. No state has attempted a similar schedule since capital punishment resumed in the United States in 1977. Cf. Baze, 553 U.S. at 53, 128 S.Ct. 1520 ("[I]t is difficult to regard a practice as 'objectively intolerable' when it is in fact widely tolerated."). The Glossip Court did not address the risk of harm when officials with limited execution experience intend to carry out eight executions with precise detail and timing at an unprecedented speed, using for the first time a drug with the potential to fail to induce sedation or to take away the severe pain caused by remaining two drugs. Cf. id. at 54, 128 S.Ct. 1520 (finding inadequate experience of employees irrelevant where trial court concluded the task was "[n]ot difficult at all" (alteration in original)); id. at 46, 128 S.Ct. 1520 (noting that the state executed another prisoner using the same lethal injections protocol without any reported problems). Nor was there any evidence in Glossip that the staff conducting the executions would be under a inordinate amount of stress beyond that inherent in any execution, would not have had time to conduct the usual practices and procedures they undertake before and after an execution, or would be acting without a contingency plan in case of complications during any one of the eight executions. Cf. id. at 55, 128 S.Ct. 1520 (finding IV line issues did not create a substantial risk of harm because the written protocol required IV team members to "participate in at least 10 practice sessions per year"); see Arthur v. Thomas, 674 F.3d 1257, 1263 (11th Cir. 2012) ("Significant deviations from a protocol that protects inmates from cruel and unusual punishment can violate the Eighth Amendment."). With the addition of these aggravating facts, this case presents a stronger case for concluding that appellees face a substantial risk of harm than that presented in Glossip or Baze.

2. Available Alternatives

Appellees also presented the court with evidence that there are alternatives to the condensed execution schedule and execution protocol. These alternatives satisfy the appellees' "burden of establishing that any risk of harm was substantial when compared to a known and available alternative method of execution." ***506** Glossip, 135 S.Ct. at 2738. Most obviously, Arkansas could reschedule the executions to allow more time between each one and to avoid scheduling multiple executions on a single day. This "known and available" alternative would permit more time for ADC officials to familiarize themselves with the execution protocol, to conduct a sufficient number of practice sessions for each appellee with a person of similar stature, to conduct debriefings after every execution, and to develop contingency plans in case midazolam does not have its desired effect. Spreading out the executions "effectively address[es]" the substantial risks of harm identified by the district court as to the expedited schedule and the execution protocol. Baze, 553 U.S. at 52, 128 S.Ct. 1520. The state does not seriously contest the appellees' contention that this alternative is "feasible" and "readily implemented." Id. The state's only response is that modifying the schedule past April 30 will "make it impossible for Arkansas to perform lawful executions because Arkansas' supply of midazolam ... expires into two weeks." Such an assertion is belied by the district court's well-supported findings, as discussed above, that there are several alternative methods the state could use to execute appellees. Where, as here, "a State refuses to adopt such an alternative in the face of these documented advantages, without a legitimate penological justification for adhering to its current method of execution, then a State's refusal to change its method can be viewed as 'cruel and unusual' under the Eighth Amendment." Baze, 553 U.S. at 52, 128 S.Ct. 1520.

In Baze, the petitioners proposed a one-drug protocol that no state had adopted, no evidence showed it was equally effective, and another state had rejected it. In contrast, here, the "comparative efficacy" of the elongated execution schedule is "well established." Id. at 57, 128

S.Ct. 1520. No other state has adopted a comparably compressed schedule put forth by the state in the last 50 years. Two states, in fact, have implemented recommendations that prevent multiple executions per day, or even multiple executions per week or per month. Moreover, the elongated schedule has the benefit of allowing additional time to develop contingency plans, conduct practice sessions, engage in debriefs, and educate all staff involved in the executions.

III. Evolving Standards of Decency

The state's expedited execution schedule is troubling on a more fundamental level. As the Baze court noted, "throughout our history" "[o]ur society has [ ] steadily moved to more humane methods of carrying out capital punishment." 553 U.S. at 62, 128 S.Ct. 1520. The state's plan to execute eight men over an eleven day period, however, represents a step backward.

"By protecting even those convicted of heinous crimes, the Eighth Amendment reaffirms the duty of the government to respect the dignity of all persons." Roper v. Simmons, 543 U.S. 551, 560, 125 S.Ct. 1183, 161 L.Ed.2d 1 (2005). As explained by the Supreme Court:

> The Eighth Amendment is not fastened to the obsolete but may acquire meaning as public opinion becomes enlightened by a humane justice. To enforce the Constitution's protection of human dignity, this Court looks to the evolving standards of decency that mark the progress of a maturing society. The Eighth Amendment's protection of dignity reflects the Nation we have been, the Nation we are, and the Nation we aspire to be. This is to affirm that the Nation's constant, unyielding purpose must be to transmit the Constitution so that its precepts and guarantees retain their meaning and force.

***507** Hall v. Florida, —— U.S. ——, 134 S.Ct. 1986, 1992, 188 L.Ed.2d 1007 (2014) (internal citations and quotations omitted). In determining whether the evolving standards of decency permit a practice, the court "should be informed by objective factors to the maximum possible extent," Atkins v. Virginia, 536 U.S. 304, 312, 122 S.Ct. 2242, 153 L.Ed.2d 335 (2002) (internal quotation omitted), including "legislative enactments and state practice with respect to executions," Roper, 543 U.S. at 563, 125 S.Ct. 1183. But, "objective evidence, though of great importance, [does] not 'wholly determine' the controversy, 'for the Constitution contemplates that in the end our own judgment will be brought to bear on the question of the acceptability of the death penalty under the Eighth Amendment.' " Atkins, 536 U.S. at 312, 122 S.Ct. 2242 (quoting Coker v. Georgia, 433 U.S. 584, 597, 97 S.Ct. 2861, 53 L.Ed.2d 982 (1977)).

In the first part of the twentieth century, multiple executions per day and several per week were common. For example, in 1957, Georgia executed seven men over a fifteen day period in March, with two men executed on the fifteenth and three men on the nineteenth. Since at least 1977, there have been no similar clusters of executions conducted by any state. The last time eight executions were attempted within a month was in 1997. No state has conducted a double execution in a single day since 2000. See Kennedy, 554 U.S. at 433, 128 S.Ct. 2641 (relying on "[s]tatistics about the number of executions" to confirm whether a practice "is regarded as unacceptable in our society"). Moreover, the Supreme Court of Missouri has issued a rule limiting executions to one per month. Mo. Sup. Ct. R. 30.30(f). Likewise, Oklahoma's investigation following Lockett's execution recommended a maximum of one execution every seven days. From this objective evidence, under the "currently prevail[ing]" standards, compressed execution schedules may violate the Eighth Amendment. Atkins, 536 U.S. at 311, 122 S.Ct. 2242. To permit the state to execute two men per night on four nights over an eleven day period "risks [the law's] sudden descent into brutality, transgressing the constitutional commitment to decency and restraint." Kennedy v. Louisiana, 554 U.S. 407, 420, 128 S.Ct. 2641, 171 L.Ed.2d 525 (2008), opinion modified on denial of reh'g, 554 U.S. 945, 129 S.Ct. 1, 171 L.Ed.2d 932 (2008).

Our "own understanding and interpretation of the Eighth Amendment's text, history, meaning, and purpose" reinforces the constitutional violation revealed by the objective evidence. Id. at 421, 128 S.Ct. 2641. "The basic concept underlying the Eighth Amendment is nothing less than the dignity of man." Atkins, 536 U.S. at 311, 122 S.Ct. 2242 (quotation omitted). Successive execution

denies all involved the dignity to which he is entitled. Grouped together to face execution, the eight appellees are no longer treated as individuals in the criminal justice system. The dignity of prison administrators and the staff involved in the execution is also at stake. They are made to repeatedly suffer the stresses of the execution environment without the time for debriefing or reflection. With back-to-back executions set barely more than an hour apart, the family members of the victims, particularly those who wish to witness the execution, are denied the time to grieve and find closure in the viewing room. Finally, inflicting the penalty of death en masse risks eroding the public's trust in the judicial process and the fairness of the execution process. See Hall, 134 S.Ct. at 1993 (limiting the reach of the death penalty in part "to protect the integrity of the trial process").

The inmates, the state, and the public all have an interest in ensuring that these ***508** sentences are not imposed in violation of the United States Constitution. The district court did not err in granting a preliminary injunction to achieve that goal.

All Citations

854 F.3d 488

Footnotes

1 Chief Judge Smith did not participate in the consideration or decision of this matter.

2 The appellees also presented evidence of the state's ability to utilize a firing squad. In so doing, the appellees provided evidence that execution by firing squad may result in a faster death than execution by lethal injection, and that ADC employees receive some training in marksmanship.

2016 WL 11258099 (W.D.Mo.) (Expert Report and Affidavit)
United States District Court, W.D. Missouri.

Russell BUCKLEW, Plaintiff,
v.
George A. LOMBARDI, David A. Dormire And Terry Russell, Defendants.

No. 4:14-CV-8000-BP.
November 8, 2016.

Rule 26(a)(2) Expert Report Declaration of Joseph F. Antognini, M.D., M.B.A.

Case Type: Civil Rights & Constitutional Law >> Section 1983
Case Type: Civil Rights & Constitutional Law >> Prisoners Rights
Jurisdiction: W.D.Mo.
Name of Expert: Joseph F. Antognini, M.D.
Area of Expertise: Health Care-Physicians & Health Professionals >>Anesthesiologist

Representing: Defendant

JOSEPH F. ANTOGNINI, acting in accordance with 28 U.S.C. § 1746, Rule 26(a)(2)(B), Fed. R. Civ. P., and Rules 702 and 703, Fed. R. Evid., does hereby declare and say:

1. My name is Joseph F. Antognini. I am a medical doctor, board-certified in anesthesiology. I received a B.A. degree from the University of California, Berkeley in Economics in 1980. I received my M.D. degree from the University of Southern California in 1984. I also received an M.B.A. from California State University, Sacramento in 2010. I was previously the Director of Peri-operative Services at the University of California, Davis Health System and a Professor of Anesthesiology and Pain Medicine and Professor of Neurobiology, Physiology and Behavior at the University of California, Davis. I am licensed to practice medicine in the State of California. I have over 30 years of experience practicing anesthesiology since 1984 when I began my residency at the University of California, Davis Health System. I am the author or co-author of over 200 publications. My area of research has been focused on anesthetic mechanisms, specifically related to where anesthetics produce unconsciousness, amnesia and immobility. A true and correct copy of my curriculum vitae is attached hereto as Exhibit A.

2. I have reviewed, and am familiar with, the allegations made in the amended complaints, the reports and/or declarations of Plaintiffs' experts, and additional information in the documents described below including medical records dated from May 1997 to September 2016 (see also #7 below).

Scope of Engagement

3. I have been asked to render expert opinions in the fields of general medicine and anesthesiology, especially regarding the use, actions and efficacy of pentobarbital, in relation to Missouri's lethal injection protocol, and the effectiveness of the procedures therein. I have also been asked to render opinions regarding the efficacy of pentobarbital in the case of Russell Bucklew, a condemned prisoner who has a congenital cavernous hemangioma, and whether that hemangioma would affect the efficacy of pentobarbital or otherwise inflict a substantial risk of severe pain as the result of Missouri's lethal injection procedure. This report contains a complete statement of my opinions, and the basis and reasons therefor,

including the facts or data I have considered in forming them. The opinions that I do provide are within my field of anesthesiology and such fields as are necessarily related to anesthesiology, including general medicine, and fall within the scope of my expertise. All opinions expressed herein are stated to a reasonable degree of medical and scientific certainty unless otherwise noted.

4. I have reviewed Rules 702 and 703 of the Federal Rules of Evidence and Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure. I am generally familiar with their provisions and requirements, and of what is expected of a person providing opinions subject to these rules. Within my understanding of the meaning of Rule 702, I am, by reason of my knowledge and skill, which are a function of my experience, training and education, an expert in the fields of anesthesiology and general medicine. This declaration constitutes my expert report pursuant to Rule 26(a)(2), of the Federal Rules of Civil Procedure. *5.* I have been deposed and/or given expert testimony twice in the last four years: 1) January 2016, California Department of Public Health vs. Garden Grove Hospital. I gave testimony at an administrative hearing on behalf of Garden Grove Hospital regarding the actions of midazolam given to an elderly patient (Prime Healthcare Services-Garden Grove, LLC DBA Garden Grove Hospital and Medical Center, Appeal Nos. LNC 15-0615-941-VB and LNC 15-0415-774-VB); 2) I have submitted a report in *Richard Jordan, et al., v. Marshall L. Fisher, et al.,* (Civil Action No. 3:15-cv-00295) a case related to the use of midazolam for lethal injection.

Compensation

6. My fee schedule for this matter is as follows: a. Preliminary Case Review and Oral Opinion: $400/hour; b. Case Review, Consultation, Research, Reports, Pretrial Preparation, and Miscellaneous Services: $400 per hour; c. Deposition Appearance: $2000; e. Courtroom Appearance: $4,000 per day or partial day; f. Travel time at $2000 per travel day (excludes day or days of trial or hearing).

Materials Reviewed

7. I have reviewed the pleadings in this case to gain a general familiarity with the matters at issue and the contentions of the parties. I have conferred with attorneys for Defendants. Among the documents I have reviewed in connection with this case are: Missouri's lethal injection protocol, as amended in October 2013; the Declarations (initial and supplemental) by Dr. Joel Zivot and filed in this case; the Declaration of Dr. Larry Sasich filed in this case; the Declaration of Dr. Gregory Jamroz filed in this case; and the Supplemental Declaration of Dr. Joel Zivot filed in this case; medical records of Russell Bucklew dated May 23, 1997 to September 2, 2016; and various published papers in the "References Cited" section. A complete list of documents I reviewed in preparation of this report is included in "Materials Reviewed" attached hereto as Exhibit B.

8. I am advised that discovery is not complete in this case and that more documents and information may become available to me at a later date. Should additional documents or information be provided to me for review and analysis, I reserve the right to take those additional materials into account, and to modify and/or supplement my opinions accordingly. I may also be present at hearings and/or trial. I may take into account any testimony or other evidence to the extent related to my opinions; I may modify and/or supplement my opinions accordingly. In performing my analysis, I have relied on my professional training, education and experience. The opinions presented in this report are my opinions and mine alone. I have reviewed and considered other documents and information, and identified those materials (Exhibit B). These documents and other information that I reviewed and considered are of a type reasonably relied upon by experts in the field of anesthesiology in forming opinions or inferences on questions in this area. I have looked upon all of these as valuable sources of information that I am obliged to consider.

Background

9. Inmate Russell Bucklew suffers from a congenital cavernous hemangioma that involves his face, upper neck, nasopharynx and oral cavity. His hemangioma has progressively caused bleeding and difficulty breathing, especially when laying supine. Medical consultants, including an otolaryngologist, have concluded that the hemangioma is inoperable, to the extent that surgery would carry a high risk of severe intraoperative and postoperative bleeding, with a concomitant risk to his life. The expert witnesses for the plaintiff give several reasons why lethal injection would not work effectively in the inmate, including 1) the drugs would not be distributed normally; 2) the abnormal drug distribution would be the result of the cavernous hemangioma "stealing" blood from normal tissues, especially the brain; 3) the inmate would suffocate and choke as the result of inadequate action of the drugs. All these reasons and conclusions are not based on sound interpretation of the known relevant anatomic, physiological and pharmacological factors pertinent to this inmate and situation, as outlined below.

10. Several facts are relevant to this case. On October 11, 2000, the inmate had an angiogram to delineate the blood flow to his hemangioma. The radiologist's conclusion was "....no true fistula was seen in this angio a very slow flow type of lesion is very likely". Importantly, the inmate's hemangioma was large and symptomatic during this period when he was being evaluated. This finding indicates that the inmate's hemangioma does not have high blood flow, and thus would not alter drug distribution. Furthermore, cavernous hemangiomas, while they can grow progressively larger, do not change their blood flow characteristics, i.e., the hemangiomas maintain relatively low blood flow. (Note: I do not believe a high flow lesion, even if present, would significantly affect drug distribution, as discussed in section 14).

11. Between December 2000 and November 2003 the inmate underwent at least eight (8) surgical procedures requiring general anesthesia. Of note, on December 6, 2000, Bucklew had a tracheostomy and sclerotherapy for his hemangioma. He had been symptomatic for many months prior to this procedure, including bleeding episodes. His medical record clearly documents that his hemangioma was large and involved his soft palate and hard palate. During this procedure on Dec 6, 2000 he was supine, received a tracheosotomy with local anesthesia (i.e., he was awake for this portion of the procedure), and then he received general anesthetic drugs intravenously. The record indicates that he reacted normally to the drugs, i.e., he was unconscious. He received general anesthesia uneventfully over the next three years for additional sclerotherapy treatments, thoracotomies (chest surgery) and dental extractions. The dental extractions were performed on November 3, 2003, and prior to this surgery the record indicates that his hemangioma was large. These various facts show that the inmate reacted normally to anesthetic drugs during periods when his hemangioma was large, indicating that the hemangioma did not alter his response to general anesthetic drugs.

Physiological, Anatomical and Pharmacological Considerations

12. Drugs injected intravenously would enter the venous system and travel to the right side of the heart, flow through the lungs, back to the left side of the heart, and then out through the arterial system. Some of that blood would travel to the head and neck, including the brain. Both Dr. Zivot and Dr. Jamroz, in my opinion, misapply basic anatomic and physiological principles. For example, Dr. Zivot writes (#13 and #19 of his 5-8-14 declaration) that the hemangioma would "....steal blood flow from normal adjacent tissues, thereby depriving those tissues of necessary oxygen" and the hemangioma "...creates alternative low-resistance pathways to injected drugs". Dr. Jamroz writes (#21 of his declaration) that the "...presence of the vascular malformations compromises the supply of blood to the brain".

13. It is my opinion that Drs. Zivot and Jamroz conflate the anatomical and physiological characteristics of various abnormal vascular growths, including arteriovenous malformations (AVMs) and cavernous hemangiomas. Arteriovenous malformations have a direct connection between the small feeding arteries and the draining veins, so the AVM acts as a low resistance, high flow system. Cavernous hemangiomas (as is present in the inmate), however, have large intervening "caverns" between the arteries and veins, and these caverns act like pools, which limit blood flow. Studies have reported blood flow through AVMs and cavernous hemangiomas, and there is clear documentation that blood flow in the cavernous hemangioma, unlike blood flow in an AVM, is low compared to surrounding tissue (*De Reuck et al., 1994; Little et al., 1990 Xiao et al., 2014*). For this reason, it is my opinion that overall blood flow to this

inmate's cavernous hemangioma is relatively low compared to the blood flow to his brain. Furthermore, as noted above, the inmate had an angiogram demonstrating the hemangioma was low-flow. Nevertheless, even if there was a "steal" phenomenon, it is my opinion that it would not materially alter the distribution and action of drugs affecting the brain (see #14, next).

14. The argument by Drs. Zivot and Jamroz goes something like this: the cavernous hemangioma takes blood flow away from the brain or parts of the brain, and thereby alters the drug distribution. Taking their argument to its necessary conclusion, in order that the drug not get to the brain requires that the hemangioma takes all the blood away from the brain. But this clearly cannot happen without obvious effect. If the hemangioma "steals" more and more blood, it would deprive the brain (or parts of the brain) of blood, which eventually would cause death of those brain areas so deprived. Clearly, this is not happening, as the inmate has not suffered a stroke. He has recently been observed to speak normally and walk without difficulty. Furthermore, following a large pentobarbital dose, brain areas that might have low blood flow would still receive blood with high concentrations of the drug, and thereby depress those brain areas. Finally, if these brain areas have died because of low, or no blood flow, drug action there is immaterial. Thus, the "steal" argument by Drs. Zivot and Jamroz is specious and fundamentally flawed because 1) cavernous hemangiomas do not have high blood flow; 2) this inmate has a low-flow hemangioma documented by angiogram; 3) a "steal" phenomenon would not significantly alter the drug distribution; 4) brain areas with low blood flow would still receive blood with high drug concentrations. And, as noted above, the inmate has indeed reacted normally to anesthetic drugs-as expected.

15. Dr. Zivot states that ".... Mr. Bucklew's airway is severely compromised, which raises a very substantial risk that during an execution, Mr. Bucklew may gasp and struggle to breathe" (Declaration 10-13-15, #12). Anesthetic drugs normally cause some degree of upper airway narrowing. Dr. Zivot rests his opinion on a scenario whereby the inmate would be in a light level of sedation and would then have airway collapse. For the reasons noted above, the inmate would achieve rapid unconsciousness and would not experience any feelings of suffocation and choking.

16. Inmate Bucklew apparently has breathing difficulty when laying supine and it is not clear from the records what position he favors when sleeping. In some medical notes, he has been observed to sleep on his side while at other times he has been seen to sleep supine. If he were to undergo a medical procedure that required general anesthesia, and laying supine caused him difficulty, then the normal practice would be to induce anesthesia with him in the semi-recumbent or sitting position.

17. Dr. Zivot states that, based on his examination, Bucklew's airway is "....friable, meaning it is weak and could readily tear and rupture. If you touch it, it bleeds" (#9, 10-13-15 declaration). Dr. Zivot uses this observation as evidence that Bucklew could suffer "feelings of suffocation and extreme or excruciating pain" (#10, 10-13-15 declaration). Yet, curiously, further in his declaration, Dr. Zivot recommends that Bucklew undergo a clinical examination that would "...include bronchoscopy and the use of a Glidescope" (#18, 10-13-15 declaration). These procedures, especially using a Glidescope, would require airway manipulations that are counter to Dr. Zivot's concerns regarding Bucklew's airway. Brochoscopy involves placing a small plastic tube with a camera into either the nose or mouth and advancing the tube through the upper airway and into the trachea (windpipe), for the purpose of visualizing the airway anatomy. This procedure almost always requires administration of local anesthesia in the nose/mouth and oropharynx, as well as the windpipe. Patients commonly gag and cough during bronchoscopies (*Kajekar et al., 2014)*. Furthermore, blood pressure can increase substantially in some patients undergoing bronchoscopy (*Davies et al., 1997)*. The Glidescope is a trade name for a brand of videolaryngoscope, a device which is used to visualize the mouth and oropharynx during airway manipulation. As with bronchoscopy, topical local anesthesia is required in an awake patient, and there is risk of gagging and coughing with the use of a Glidescope, or other videolaryngoscopes. It is difficult to reconcile Dr. Zivot's concern about the risk of bleeding as the result of the execution protocol with the real risk of gagging, coughing, increased blood pressure and bleeding from the bronchoscopy and videolaryngoscopic examinations he proposes to do (*Rosenstock et al., 2012; Kajecar et al., 2014)*. Finally, to emphasize the inherent contradiction in his argument, Dr. Zivot states "...the placement of any device in the pharynx will cause instant bleeding" (#15, 12-4-15 declaration).

18. Dr. Zivot, in his declaration dated 12-4-2015 (#21), states the use of"... standard airway equipment creates an extreme risk during any execution by lethal injection, as the use of such equipment would cause immediate bleeding and lead to coughing, choking and feelings of suffocation". Because resuscitation (including airway manipulation) is not intended to be used during the execution process, this argument is not germane.

19. Dr. Zivot also claims that the inmate might suffer from serotonin syndrome if he were injected with methylene blue. Missouri does not intend to use methylene blue. Nevertheless, the serotonin syndrome manifests with varying signs and symptoms, including agitation, confusion, increased heart rate, increased temperature, however, importantly, these manifestations occur over the course of hours and days (*Volpi-Abadie J, et al. 2013),* and not the few minutes between injection of pentobarbital and death.

20. Dr. Zivot claims that central nervous system depressants that Bucklew takes, including clonazepam and tramadol, would enhance the effects of pentobarbital. This enhancement would be inconsequential compared to the overwhelming (and intended) effect of the pentobarbital doses used during the lethal injection protocol. Furthermore, Dr. Zivot raises the issue of pentobarbital having antalgesic properties (Note: hyperalgesia is the preferred term). This effect has only been demonstrated at low doses of barbiturates (i.e., doses that cause sedation but not unconsciousness), although the human evidence is equivocal, with some reports showing no such effect in humans (*Anker-Møller, et al. 1991; Wilder-Smith, et al., 1995).* Nonetheless, the pentobarbital dose used for lethal injection would cause rapid unconsciousness and precludes any potential hyperalgesic effects of pentobarbital.

21. Dr. Sasich, in his declaration dated May 8, 2014, raises two main issues related to Missouri's use of its lethal injection protocol for Bucklew: 1) the use of methylene blue would cause an increase in blood pressure; 2) the use of compounded pentobarbital poses increased risks, including increased risk of bleeding. With regard to methylene blue, Missouri does not intend to use methylene blue. Even so, the blood pressure increase Dr. Sasich quotes is small and within the range of blood pressure increases that occur during everyday activities, such as defecation, awakening from sleep, and mild exercise (*Imai et al., 2015 Tsimakouridze et al., 2015; Wielemborek-Musial et al., 2016).*

22. While Dr. Sasich uses recent episodes of compounded drugs and fungal meningitis to bolster his claims, he provides no direct evidence that compounded pentobarbital would put the prisoner at increased risk. At most, he invokes the specter of various contaminants and impurities, a risk that also applies to drugs produced using good manufacturing practices. Indeed, contamination (chemical, particulate, bacterial and fungal) is a problem that plagues manufacture and administration of medications in various healthcare settings (*Tran et al., 2006).* The FDA has archived recalls of products, including drugs that have been found to have contaminants (see FDA Archives website in Ref Cited). Furthermore, impurities cannot be eliminated and the United States Pharmacopeia has set lower limits on elemental contamination and particulate matter-and these lower limits are not zero (see USP, 2nd Suppl. website in Ref Cited).

23. In this inmate the use of lethal gas does not hold any advantage compared to lethal injection with respect to pain and suffering. Both methods would result in minimal pain and suffering. Specifically, the intravenous injection of a large dose of pentobarbital would result in rapid unconsciousness. The inmate claims, through counsel, that execution by a gas would be preferable because "...the lethal agent enters the body through the lungs..." and it "....bypasses Mr. Bucklew's circulatory system..." (Doc 53, 4 th amended complaint, at #29). This assertion is incorrect. The use of various gases (hydrogen cyanide, nitrogen, for example) work by the gas entering the lungs, and then being transported by the circulatory system. Whether the effect is the presence of an active poison (hydrogen cyanide) or the displacement of oxygen by an otherwise inert gas (nitrogen) the circulatory system is needed.

24. The inmate's medical records are replete with episodes documented over many years describing his pain, bleeding and choking sensations. He would likely continue to have these symptoms up to the point of death (either natural death or by execution from pentobarbital).

25. Numerous eyewitness observations of nineteen (19) executions in Missouri (from 11-20-13 to 5-11-16) indicate that pentobarbital has its intended effect: a rapid onset of unconsciousness followed by death. It is my opinion, to a reasonable degree of medical and scientific certainty, that Bucklew would react to pentobarbital nearly identical to the reactions of the inmates described in the eyewitness accounts, that is, Bucklew would have the rapid onset of unconsciousness followed by death.

Conclusion

26. It is my opinion, to a reasonable degree of medical and scientific certainty, that 1) Bucklew has reacted normally to anesthetic drugs numerous times during periods when his hemangioma was large and symptomatic; 2) the hemangioma in this inmate would not significantly alter his response to intravenous drugs, including barbiturates at usual clinical doses as well as at massive doses; 3) injection of massive doses of barbiturates in this inmate would not inflict mild, moderate or severe pain; 4) the use of lethal gas would not significantly lessen any suffering or be less painful than lethal injection in this inmate; 5) any pain and suffering that he risks during an execution using pentobarbital is not of greater quality or magnitude than the risk of pain and suffering that he currently experiences, and the risk would end with rapid unconsciousness from the injection of pentobarbital.

27. Should additional information become available I reserve the opportunity to amend my statements herein.

End of Document

2017 WL 9471457 (W.D.Mo.) (Expert Deposition)
United States District Court, W.D. Missouri.

Russell BUCKLEW, Plaintiff,
v.
George A. LOMBARDI, David Dormire, and Troy Steele, Defendants.

No. 14-08000-CV-W-BP.
February 27, 2017.

(Deposition of Joseph F. Antognini, M.D., M.B.A.)

Case Type: Civil Rights & Constitutional Law >> Section 1983
Case Type: Civil Rights & Constitutional Law >> Prisoners Rights
Jurisdiction: W.D.Mo.
Name of Expert: Joseph F. Antognini, M.D.
Area of Expertise: Health Care-Physicians & Health Professionals >>Anesthesiologist

Representing: Defendant

Appearances:

For Plaintiff: Sidley Austin, LLP, By: Lawrence P. Fogel, Esq., Suzanne Bpindise Notton, Esq., One South Dearborn, Chicago, Illinois 60603, 312-853-6892, lawrence.fogel@sidley.com.

For Defendants: Attorney General's Office, By: Michael J. Spillane, Esq., P.O. Box 899, Jefferson City, Missouri 65102, 573-751-1307, mike.spillane @ago.mo.gov.

Deposition of DR. JOSEPH F. ANTOGNINI, taken on behalf of Plaintiff, at 555 West 5th Street, Suite 4000, Los Angeles, California, beginning at 9:04 A.M. and ending at 3:27 P.M. on Monday, February 27, 2017, before Amanda J. Kallas, Certified Shorthand Reporter No. 13901.

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EXHIBITS

TABLE

Monday, February 27, 2017; Los Angeles, California 9:04 A.M.

DR. JOSEPH F. ANTOGNINI, the witness, having been administered an oath in accordance with CCP Section 2094, testified as follows:

EXAMINATION

BY MR. FOGEL:

Q Good morning.

A Good morning.

Q Dr. Antognini, my name's Larry Fogel, I think you met my colleague, Suzy Norton; we work for the law firm, Sidley Austin, and represent the plaintiff, Rusty Bucklew, in this matter.

You okay if I call you Dr. Antognini --

A That's fine.

Q -- throughout the course of the deposition today?

A That's fine, yes.

Q Excellent. And let's do a little housekeeping matter right off the top, here: You've submitted two reports in this matter; is that right?

A Yes. That's correct.

MR. FOGEL: Go ahead and mark this first report.

(Whereupon Exhibit I was marked for identification by the court reporter and is attached hereto.)

MR, FOGEL: And I'll show you both documents.

(Whereupon Exhibit 2 was marked for identification by the court reporter and is attached hereto.)

BY MR. FOGEL:

Q Have you had a chance to look at both documents, Doctor?

A I did. Yeah, they appear to be the documents I submitted, the two reports that I submitted.

Q All right. And the first one, I believe it's marked Exhibit 1.

A Correct.

Q That is your initial declaration for November 2016 that you submitted --

A That's--

Q -- in connection with this case?

A That's correct.

Q And does it appear to be a true and correct copy of your report including the exhibits thereto?

A It does appear to be, yes. And not having read through the whole thing --

Q Sure.

A -- but it appears to be.

Q Absolutely. And you also submitted a supplemental report, and you submitted that in February of 2016. Is what's been marked as Exhibit 2 appear to be a true and correct copy of that report?

A Yes.

THE REPORTER: And if you could just wait until he's done.

THE WITNESS: Oh, I'm sorry.

THE REPORTER: It's all right.

MR, FOGEL: That's actually a good reminder.

THE WITNESS: Yeah.

MR. FOGEL: So we'll just go over a few basic ground rules.

BY MR. FOGEL:

Q Have you sat for a deposition before, Doctor?

A Yes,

Q So I assume you're generally familiar with the rules, but as the court reporter just reminded us, I ask that you wait until I finish asking my question before you respond --

A Sure.

Q -- and I'll, of course, extend to you the same courtesy when you're answering the question. Inevitably, I will probably ask a question that doesn't make much sense, so please feel free to ask me to repeat it, if it's at all confusing to you --

A Inevitably, I'll probably give you an answer that -- no, hopefully I'll be very clear, but...

Q So at least we're in agreement on that.

And then also feel free to take a break, if you'd like, at any point today. I'd just ask that you ask or complete a question that's pending --

A Sure,

Q -- before you leave to take a break.

A Sure.

Q Before we get going, any other questions you might have?

A No. I do tend to -- as my wife is so apt to point out, I do tend to interrupt people mid-sentence, so I will try to refrain from doing that.

Q I appreciate that. And that's why we have the court reporter here, to help keep us in line.

A Yeah.

Q So going back to your reports, can you describe your process in preparing them?

A I looked at the material that I was provided to me, and I -- off the top of my head, I cannot remember all the material that was provided to me by the attorney general's office, but it included -- may I refer to my document here to see?

Q Sure.

A Yeah, I cannot remember exactly what was provided to me, they were some of the declarations by Dr. Zivot, and then the medical records for Russel Bucklew, and then some letters from some other physicians, including Franz Wippold, and then Larry Sasich, and Dr. Gregory Jamroz. And then a lot of the Court documents that are numbered.

I don't remember specifically what they refer to, I'd have to look at them again. And then there were some judgments from various courts including the Eighth Circuit Court and the Supreme Court and so forth, and then the Missouri -- the injection protocol, the witness statements for 19 executions in Missouri.

So I took all those into consideration and reviewed those in preparation of my report --

Q And just to be clear for the record--

A And -- excuse me.

Q Go ahead.

A I apologize, I --

Q Go ahead.

A And -- and -- and also, of course, during my research, I referred to some articles that I cited in my report.

Q Thank you.

And just to be clear for the record, when you were listing those various sources that you consulted, you were reviewing an exhibit to your November 2016 report --

A Correct.

Q -- as Exhibit B, your materials reviewed; is that -- does that sound correct?

A Yes.

Q Okay. You also reviewed some additional materials that you notated in connection with your supplemental report; is that right?

A That's correct. And do you want me to...

Q If you flip to the last page of your report, at the header it says, “Exhibit A, materials reviewed”?

A Yes.

Q Is that the right page?

A Correct.

Q And just to make sure I'm clear on this: Are the materials that you reviewed in connection with your supplemental report the items that are listed --

A Yes.

Q -- on this page?

There's no other list of materials that you reviewed?

A No. No. That refers to what was below, which was the reference as cited, and then the studies that I cited there -- or papers and then the package insert, and then my interview and examination of the -- of Bucklew, and then the medical records of-- through February 3rd of 2017, which includes the most recent imaging studies that were performed.

Q The MRI report for--

A Correct.

Q --for 2016?

A Correct.

(Whereupon the reporter requested clarification.)

MR. FOGEL: 2016.

BY MR. FOGEL:

Q And we'll go into more detail on those materials later on. So you consulted these materials and what else did you to -- in preparing your reports?

A Well, I thought about the process by which a -- as I understand the lethal injection protocol is implemented. To make a determination whether the -- this particular inmate, based on the information that I've been provided in terms of his medical findings, whether this inmate would suffer pain, choking sensations, et cetera, as described by Dr. Zivot.

And I applied my understanding of the materials that I reviewed in my scientific and medical background to his condition to make my assessment. Which, as you know, I do not believe that his medical condition is -- would materially affect the -- the action of the drug, or that it would cause him to have any additional -- or any suffering or pain, excruciating pain, as described by Dr. Zivot.

I'm not sure if that answers your question, and you kind of asked the question in a very general way, but for-

Q Yeah, it was intentionally general --

A Yeah.

Q -- in order to allow you sufficient space to describe everything that you did.

A Okay.

Q And prior statement, when you were talking about any suffering or pain, you were referring to one of the opinions you rendered in this case; is that right?

A That's correct.

Q Okay. And we'll go into a little bit more detail, but I want to make sure I understood what you said. Is it your opinion that Mr. Bucklew will suffer no pain and suffering?

A No. Can you elaborate about -- you mean, no pain and suffering during the lethal injection? Or during the execution process?

Q I just want to make sure I fully captured what you said.

MR. FOGEL: Do you mind going back to when the doctor was testifying about pain and suffering, and repeat what he said?

(Whereupon the record was read.)

BY MR. FOGEL:

Q So that last part is what my question was referring to: So your opinion is that he would not suffer any additional pain and suffering?

A That is correct. I mean, obviously, I think any -- I think we all have an understanding, hopefully, that most modes of death do involve pain and suffering in some way. And my understanding of the lethal injection process is, that you have to start an intervenous line, that can be painful. Usually, not too painful, we do it all the time, patients having surgeries, but beyond that, the actual process, of where the drug is injected and so forth, would not cause any pain or suffering to somebody.

So there's always going to be a minimal amount of pain with a lethal injection process as I understand it, because you have to start an intravenous line, but beyond that, I don't see that this inmate would suffer any more than that.

Q Okay. Who did you work with in connection with the preparation of your reports?

A Mr. Spillane.

Q Anybody else?

A No.

Q Do you have any assistants that you work with?

A No.

Q No graduate assistants?

A No.

Q When were you first contacted regarding this matter?

A I'm going to say it was August -- I -- I can tell you the specific date, because I believe I have the letter somewhere, but I got a letter, by Fedex, from Mr. Spillane. I think it was dated August 27th or somewhere around there, I'm not sure exactly when it was, but it might have been before that, a little bit before that. It was some time in August -- or mid-to-late August --

Q Was that --

A -- of 2016.

Q Was that your first involvement in this case?

A Yes.

Q Had you -- have you worked with the Missouri State Attorney General's office before?

A No.

Q Have you worked with Mr. Spillane before?

A No.

Q What did Mr. Spillane ask you to do?

A He asked me to provide my expert opinion about this particular inmate and whether his -- well, may I -- just pause for a moment. I cannot specifically -- I mean, I'm going to give you my general understanding of what he asked me to do, but there may be some written documentation, where he has some specific questions that] could refer to, but I don't -- what would you --

Q To make it easier, and not make this a memory test: How about I direct you to paragraph 3 of Exhibit 1, which is your November 2016 report?

A Okay.

Q And you see paragraph 3 --

A Yes.

Q -- inner scope of engagement?

A Yes.

Q Does that help?

A Oh, thank you, yeah.

So I was asked to render my expert opinion, specifically, in general medicine and anesthesiology in regards to the actions and the efficacy of Pentobarbital, especially related to Missouri's lethal injection protocol. And also, the efficacy of Pentobarbital in this particular inmate, Bucklew, who has this cavernous hemangioma.

(Whereupon the reporter requested clarification.)

THE WITNESS: Has a cavernous hemangioma.

BY MR. FOGEL:

Q Doctor --

A Yes.

Q -- let me ask you, does paragraph 3, Scope of Engagement, accurately summarize everything that you were asked to do in this matter?

A Yeah. I think it does. I mean, there might be -- again, not -- not making this a memory test, I believe that captures everything, I mean, there might be something I missed that I provided opinion in, but I think that captures pretty much everything.

Q What is anesthesiology?

A That's a field of medicine that describes -- I should -- that is involved with the administration of anesthetic to patients who are having surgeries or painful procedures. So we're physicians who specialize and go to residency for that, and render patients unconscious and, in a sense, during surgical procedures. That's part of what we do, but some people are also involved in critical care medicine, pain medicine, sort of, some of the branches off of anesthesiology.

Q Is Pentobarbital a type of anesthetic?

A Yes.

Q Have you worked with Pentobarbital before?

A Yes.

Q What is your experience with Pentobarbital?

A I've used it in settings where patients would require Pentobarbital for induced coma, or to induce -- to decrease activity in the brain.

Q So could you help me out here, because I'm not a doctor --

A Yeah.

Q -- and no prior education in the area --

A Sure.

Q -- of anesthetics, how does Pentobarbital induce whatever you were just --

A Yes.

Q -- describing?

A Okay. Well, the -- the short answer is, we don't know. We don't know how anesthetics work, how they truly work. We know the Pentobarbital, like other anesthetics, work with what's called a GABA receptor -- G-A-B-A -- G-A-B-A, GABA receptor.

The GABA receptor is something that we all have. And when the Gaba receptor's active, it allows chloride ions to enter into the cell, and causes the cell to become what Ave call hyperpolarized, and makes it less likely to fire. And when it's a neuron, like a neuron in the brain, then it's less likely to fire, and that produces the anesthetic effect, it produces unconsciousness, and the other things, immobility and so forth.

But we don't truly know how the work -- we know how they work at a receptor and cellular level, but how they end up resulting in a system -- what we call a system effect. That is, how they produce the actual unconsciousness, we really don't know. I mean, nobody knows for sure, that's the simple answer. We have a lot of pieces of the puzzle, but we don't know for sure for any of the anesthetics.

Q Do all anesthetics render a patient unconscious?

A Local anesthetics, obviously, by definition of anesthetics that leaves the term, local anesthetics, that's something we use for when you get a dental procedure done, that numbs up the nerve, so that does not cause unconsciousness in a dose as it's administered, but an anesthetic, when you use the term, anesthetic in the sense of sort of general anesthesia, then yes, they all produce unconsciousness. Because that is the -- that is one of the three essential endpoints of-- of anesthesia, which is unconsciousness.

Q What are the other two endpoints?

A Amnesia, and then immobility. So patients don't want to remember their surgery, patients don't want to be awake during the surgery, and physicians, specifically surgeons, do not want a moving patient during surgery. So the three special endpoints, as I described them -- now some people would also argue that analgesia is an important endpoint. But analgesia is, in my mind, and I may be a minority in this, but, in my mind, analgesia is not a required endpoint of anesthesia.

Q What is analgesia?

A So analgesia basically means something that -- that -- or an analgesic, for example, would be a drug or something that -- that lessens pain. So, for example, if you were out playing soccer or whatever and you hurt yourself, you might take Ibuprofen or you might take Tylenol, or maybe, if you'd had surgery on your -- dental surgery, you might take Tylenol with Codeine, those medications decrease pain, they provide some -- they have analgesic properties, they provide that.

But in order to be, again, this sort of gets into the semantics side more than anything else, in order for you to, in my mind, classify a drug as analgesic, the patient has to be awake. The patient has to say, “Oh, yes. I took this drug. My pain is less.” But anesthetics, by definition, if given a sufficient dose, makes someone unconscious, so they're not awake to be able to perceive pain. So analgesia is not really important in that setting, from that particular aspect.

Now, some people-- oh, I should say, so when you're having surgery and the surgeon makes an incision, your heart rate will go up, your blood pressure will go up. Even though you're unconscious and you may not move and you're not going to remember, but you're going to have these, you know, physiological responses to that. Now, you are a relatively young man --

Q Thank you.

A -- and you look in very good health.

Q Thank you.

A And if I were to anesthetize you, and your heart rate and blood pressure were to go up, it's probably not that critical to me or to you that I treat that. I probably would give you something for that, but I -- it wouldn't be necessary during the surgery, but most people would anyway.

If your grandmother was having surgery, let's say she's in her 80s, if her heart rate and blood pressure goes up, I'd be more concerned about that because that might be more harmful to her, so I'm more concerned about providing analgesia -- or analgesic-type of drug during surgery for her. But it's not -- it's a long answer to your question, but it's, in my mind, analgesia is not a critical component or a necessary component of an anesthetic.

Q So let me ask a few follow-up questions based on what you just explained.

A Sure.

Q Which is very helpful, thank you for that.

Is the pain irrelevant when someone is unconscious?

A Is pain irrelevant?

Q Irrelevant when someone is unconscious.

A I want to make sure that we have an understanding of the terms: So pain is the conscious awareness of a noxious stimulus.

Q Excuse me, you said of a noxious?

A Noxious stimulus.

Q What's --

A Noxious. So something that causes tissue damage. So if I took a sharp instrument and poked you in the hand with it, that would be noxious, it would be painful to you.

Q But what about choking? Is choking, would you consider that painful?

A Choking, I wouldn't consider it painful, I mean, it certainly is distressing.

Q Well, let's get away from the word “pain.”

A Yeah.

Q Self- -- is it a type of suffering?

A Yes. Absolutely, yes. Choking would be a suffering, you know, you would have what I would describe as suffering sensation from that.

Q And is choking, or that type of suffering, irrelevant if someone is unconscious?

A In my opinion, yes. They're not going to be conscious and -- and aware of that sensation. If they're unconscious from a -- from a drug and choking or the lack of breathing, in my opinion, they would not be •- they're not aware, so they can't have the suffering component that we think about.

Suffering is a word or term describing sort of the emotional component of all (his; right? So -- so suffering is an emotional part, and you can't have emotions when you're unconscious. I mean, you don't...

Q Doctor, you're -- your practice is as an anesthesiologist for some time; is that right?

A Yes. That's correct.

Q And you've administered an anesthetic for a patient who was unconscious during a procedure?

A Yes.

Q If that patient started choking during the procedure, would you say that it was irrelevant, it didn't matter, because they were unaware of the choking?

A Well, that is not -- it's not -- make sure we understand each other in terms of the question and the answer.

So if somebody was choking during surgery, and I'll use that term because that's the term you're using, but someone who has an airway obstruction during the surgery, that's an emergency; right? One of the things that we have to do as an anesthesiologist, of course, is to maintain breathing during surgery, and that requires an unobstructed airway. And that's a medical emergency. I'm not worried that the patient is suffering, but I am worried that the patient may die because they have an obstructed airway. Those are two different things.

Q I appreciate that. And certainly, we want to be very concerned of whether the patient lives or dies, but why are you not concerned whether the patient is suffering or not?

A Because suffering is not -- again, it's a -- it's a term describing someone's emotional -- what's the word I want to use? -- basically emotional response to that particular situation. And it requires someone to be awake. So let's, just to -- maybe, so I can clarify my answer to this.

Q Well, I -- sorry, do you mind if I just have a quick question on this?

A Yeah.

Q But if you want to finish your answer, go ahead.

A Well, let me just finish this to clarify this: So, getting back to you having surgery, if your blood pressure increases and your heart rate increases, I'm not concerned that you're suffering in the sense that if -- if you -- if we were doing surgery on you, with you awake, we would all agree, I think, you'd be -- you'd have suffering. Because you're awake and you have a surgical incision and so forth; you're experiencing pain. I'm not concerned about that -- that part of it, when you're unconscious, because you're unconscious. You don't -- you don't have that emotional reaction that you would have when you're awake.

Now, you could have -- certainly, you could have the physiological responses to that stimulation. That is, your blood pressure would go up, your heart rate would go up, and I would be concerned -- potentially concerned about that. But I'm not concerned about the emotional part of it, because you're not having those emotional reactions.

Now, I will be honest with you, there is some indication in the field now, that there may be some imprinting on the brain, so to speak, where people might -- even during a normal anesthetic, there might be some -- oh, how should *I* say this? -- that there might be some lasting effect of -- of the surgery, and potentially that -- I'll just leave it at that: That there might be some lasting effect.

Q Are you referring to anesthetic awareness? Or is that something different?

A That's something different in a sense that that is something that, you know, where, in general, there's a lighter level of anesthetic and so people are awake during their surgery, that's basically where there's insufficient anesthetic. And I'm talking more about even deeper levels of anesthesia. But we've been doing this for over 150 years and people come out of surgery just fine, so I think if anything is going on in terms of anything else, you know, aside from the physiological responses, it's -- it's going to be minimal.

And -- and -- and it happens every day, you know, people having surgery and anesthetic every day, so I don't think that there's anything going on there in terms of any long-lasting effects of what you're getting at as a potentially suffering. I just don't think suffering has occurred in the sense that you're -- we think about suffering.

Q Well, let's make sure we're talking about suffering in the same way, because I've heard you use the term "emotional response." What do you mean when you say emotional response?

A So I'll give you an example of -- of this in the literature. So there is a part of your brain called the amygdala, which is near the hippocampus. The hippocampus is important to memory formation. The amygdala is important for the emotional component of memory.

So as an example, I remember where I ate dinner last night, and there's nothing particularly emotional about that. But if I had been mugged after dinner, it'd be a tot of emotions attached to that, you know, the threat and so forth, you would go through a lot of emotions, so there would be an emotional component to that. And that emotional component is -- is determined, in some regard, in some -- some degree, with the amygdala, so there's two separate -- at least two separate parts of our brain -- there's more than that, but when I'm talking about the hippocampus and the amygdala -- the amygdala's more about the emotional aspect and the hippocampus more is about the factual parts.

So if my amygdala had been destroyed somehow before last night and I had been mugged, I would be able to provide to you the details of the mugging, but it wouldn't trigger any particular emotional response in me. So there is a emotional response, that -- that sort of gut terrible feeling that we get when something bad happens to us. And then there's just sort of the factual part; I remember what I had for dinner last night, it wasn't particularly --

Q So --

A -- you know, emotional.

Q Can -- can I interrupt you, because I don't -- I think I follow your analogy, and what you're explaining here, but I want to get to the more specific point: Is it your opinion that if someone cannot experience an emotional response, that they are not experiencing suffering?

A Yes. I think that -- that summarizes, for the most part, what I'm saying, yeah. Suffering is a -- a -- I mean, to me, suffering and pain are in the same category; you have to be awake to experience it.

Q So during the procedure, if somebody starts choking, which I think we discussed earlier would be a type of suffering, because they cannot experience an emotional response while they're unconscious, you would not consider that suffering?

A That's correct. So if I could elaborate, though, on that, you might be able to determine some physiological responses to the choking, you know, maybe their heart rate would change and so forth. Just like you could do that with pain -- I mean, sorry, with a noxious stimulus during surgery, but you're not forming -- having the same type of formation of emotional -- the emotional response or the emotional aspect of all that when you're unconscious.

Q Why -- why are you focused on the emotional response?

A I'm not, You're -- you're -- you're asking a question about suffering, and I'm trying to put it in words that you can understand, that suffering is a -- a term that I believe is used, maybe in this context is used incorrectly, because you seem to think that suffering is something that can happen when you're unconscious, and I'm saying that it can't.

Because suffering is a -- the --the -- the -- suffering has an emotional part to it, and you don't have that emotional part, and also, you have to be awake for it, to suffer. I mean, how could you -- I mean, maybe I should ask you, can you explain to me how you -- how you would have suffering in somebody who is unconscious? I don't -- I don't see how that can happen based on my understanding of how -- how all this works.

Q Well, fortunately the way today works, I'm the one who asks the questions --

A I know.

Q -- and you're the one who gives the answers.

A I understand that.

Q You're the expert here. And I'm not opining or offering any of my own opinions --

A Sure.

Q -- we're here for your opinions and --

A Got you. I know, I know. I think I've answered as best as I can.

Q And I appreciate that.

Now, we -- you talked about an individual's weight, their blood pressure, does that affect the quantity of the anesthetic or the chemical that you administer?

A If it's a drug like Pentobarbital, then the weight does -- it does matter.

Q Why does the weight matter?

A Well, I mean, if you're giving -- usually, we dose a drug on a per-kilogram basis, per-weight basis. So you take a 3-kilogram baby, and you give an intravenous drug, you would give a lot less to a baby than you would 100-kilogram man, because 3 kilograms versus 100 kilograms. So for an injectable drug, you would give a small amount. So...

Q And does the amount you administer affect how quickly or how long it takes for someone to succumb to the effects of the anesthetic?

A Yes.

Q Meaning how long it takes for them to become unconscious?

A Yes.

Q So what other characteristics, besides someone's weight, would you take into consideration when determining the quantity of the anesthetic to administer?

A Again, we're talking about an injectable drug like Pentobarbital?

Q Sure.

A So besides the weight, you would be concerned about several factors: Actually, one would be their age, one would be other medications that they're receiving, one would be their other conditions, medical conditions.

Q Well, I'll let you complete your list and then we can go back.

A Those are the three that come to the top of my head. I'm probably missing some others, but those are some of the important ones I think.

Q Why is it important to take into consideration the medications that the individual may be taking?

A Well, because there -- you can have drug interactions with --

(Whereupon the reporter requested clarification.)

THE WITNESS: You can have drug interactions.

BY MR. FOGEL:

Q C-A-N.

A Yes. C-A-N.

In -- in a clinical setting, some of the drugs that we give can interact or maybe either in a positive way or a negative way. So if somebody's on a -- an opiate of some sort, they could be tolerant of that. Or if they're acutely intoxicated from something, then that has to be taken into consideration. So there are a variety of different drug interactions that can occur.

Q And what is the import of the drug interaction? Could it prolong the effect of the anesthetic? Could it diminish the effect of the anesthetic? What are the potential consequences of the drug interaction?

A Could prolong it, could shorten it, potentially.

Q It depends on the type of medication, how frequently --

A Yes.

Q -- the individual's been taking it, and those are all things that the person applying the anesthetic would need to take into consideration?

A Yes. That's correct.

Q You also mentioned medical conditions?

A (Inaudible response.)

Q Why is that important?

A Well, if somebody has a serious medical condition, such as they're -- have renal disease, that can affect how much drug you give, usually, you're going to give less of it. Especially if they've just had hemodialysis, that's just one example, if somebody has heart problems, congestive heart failure, that could affect the -- how much drug that you give. So those are just examples of some of the considerations that you'd take into -- you want to think about.

Q And I believe, as you mentioned, it could affect how long it takes before the drug takes effect?

A Some of these -- yes -- conditions could do that.

Q So it's unique to the individual?

A Yes.

Q Would you have used -- when you -- let me make sure I have this right first: I -- I believe you said you have used Pentobarbital --

A Yes.

Q -- in a clinical setting in the past?

A Yes.

Q What quantity of Pentobarbital have you used in those settings?

A I do not remember, and this is a long time ago, I have not used it very -- I haven't used it at all, probably, in the last 15 to 20 years. So it was a long time ago, when Pentobarbital was more in vogue in terms (producing a coma. I don't think it's used as much anymore these days. So the doses were probably in the range of several milligrams per kilogram, as my recollection, and usually was given as an infusion after that. So clearly a lot less than the dose that is used in lethal injection. I don't think anybody -- well.

Q No. No. Go ahead.

A I was just going to say, I don't think anybody has an experience with that dose, except for the people that use it for lethal injection. It's not used clinically, of course, in that dose.

Q When you used Pentobarbital, I believe you said, to 20 years ago approximately --

A Yeah.

Q -- had you used it several times in the period -- period that you used it?

A I would say probably not more man two or three times, is my recollection, so very limited use.

Q Is Pentobarbital generally infrequently used as an anesthetic today?

A It is. I know you're thinking frequent is -- right, I think it would have to be rare, if, at all. I don't think anybody's using it or I don't think anybody should be using it as an anesthetic in humans.

Q How --

A Because we have such -- much better drugs now.

Q How did you familiarize yourself with Pentobarbital and its effects as an anesthetic in order to render an opinion in this case?

A So Pentobarbital --

Q Well, let me ask a -- a first question: Did you think it was necessary to familiarize yourself with Pentobarbital in preparation for your reports in this case?

A Yes. In some of these --some of the --the issues that came up, absolutely. And --

Q And so how did you go about doing that?

A I looked at the -- I compared, primarily, the effects of Thiopental to Pentobarbital, because Thiopental's a drug that many people in my age and background have used. Because when I was first learning anesthesiology and training, and then after that, we used Thiopental for induction. This is before Propofol came out, so I used Thiopental many, many times. And Pentobarbital is very similar to Thiopental. It's not obviously the exact same thing, they have some structural differences, but I was mostly concerned about the onset of action of Pentobarbital relative to Thiopental. In terms of determining my report.

And then looked at basically the -- yeah, I was primarily concerned with the onset, and then also blood levels of the Pentobarbital relative to its clinical effects. In terms of coma, and lethal amounts, and things like that. So that was sort of the -- the -- the main area that I focused on. In terms of trying to -- to look at what are the effects of Pentobarbital.

And I felt that was important because, obviously, from my report and the reports that we have -- reports that we have from Dr. Zivot, there is a disagreement about the onset of action and how deeply someone achieves coma or go into coma after the injection. And I -- it's my opinion that based on kinetics of the drug, and the way the drug happens, is unconscious will happen within 20 to seconds and I think that the data that's published out there supports that.

Q What sources, specifically, did you rely upon to conclude that Pentobarbital would render somebody unconsciousness in 20 to 30 seconds?

In the quant- -- and I assume your opinion is limited to the quantities that are administered pursuant to the Missouri execution protocol.

A That is correct. Although -- and I'll elaborate on this, I think even a much lower dose of Pentobarbital will achieve coma, but they use 5,000 milligrams. So I relied on two --

Q When you say “coma,” are you meaning unconscious? Are you using *those* terms interchangeably?

(Whereupon the reporter requested clarification.)

BY MR. FOGEL:

Q Are you using those terms interchangeably?

A I probably shouldn't use them interchangeably. I think for the purposes of our discussion here, we could do that, but coma and unconscious are not the same thing. So basically, if you think of a -- of -- of a VIN diagram, so a VIN diagram, this would be unconsciousness and coma would be a part of that, so you can be unconscious, but not necessarily in a coma. So if I were to be more precise, I should not use those terms interchangeably. So maybe I -- in the future, I will not do that.

Q Sure, So let's focus on your specific opinion in this case, then.

It's your opinion that the quantity of Pentobarbital administered pursuant to Missouri's execution protocol would render the subject unconscious in to 30 seconds; is that right?

A That is correct. That's my assessment

Q And my question is, what sources did you rely upon in forming that conclusion?

A I looked at the package insert for Pentobarbital, and then I also relied on a paper that was published by Ehrnebo -- spelled E-H-R-N-E-B-0 -- that I referenced in my supplemental report that looks at the pharmacokinetics and distribution of Pentobarbital in humans.

Q Did --

A So the way I did it --

Q Sony, did you rely upon any other information or sources?

A For this particular report that I have submitted, those are the two that I -- I looked at. Now, as I've mentioned to Mr. Spillane, subsequent to writing this report, I did find another study, which I think runs credence to my opinion, but it's not contained in the report, here. And I can provide that report to you or -- or...

Q Are you relying -- relying upon that report in forming your conclusion that it would last -- excuse me, that unconscious would set in within 20 to 30 seconds?

A I would say I -- probably, the answer is yes, in the sense -- I mean, I feel more confident in my answer -- I was very confident in my answer before I saw that report, I'm even more confident now in my answer.

Q Then, yes, we'd -- we'd like to be provided with at least the name and title --

A Yes. I can give it to you now --

Q --of that report.

A -- if you want?

Or do you want to wait?

Q You can give it to us during the break.

A Okay.

Q So those three sources are the only source- -- are the sources --

A Those --

Q -- in the entire universe that you relied upon to conclude that 20 to 30 seconds is what --

A I'm sorry, not --

Q -- it would take for unconsciousness?

A -- not everything. And then, of course, I looked at the witness executions -- I'm sorry, the -- yeah, the execution witnesses, the 19 reports that were provided to me, where people that talked about -- you know, who had observed prior executions, and said that, you know, the inmates seem to be unconscious very quickly and so forth, so that, I also relied upon.

And then, I -- I relied upon my -- again, my understanding of how these barbiturates work -- Thiopental, Pentobarbital -- especially when you think about the massive doses that are given to form my opinion.

Q Have you ever participated in any sort of setting, whether it be a clinical or academic setting, where you've administered Pentobarbital in this quantity to some subject?

A No.

Q So you've never observed the effects of Pentobarbital on somebody when it was administered in this quantity?

A No.

Q Did any of the treatises or sources that you previously mentioned specifically state that Pentobarbital would render the subject unconscious in 20 to 30 seconds?

A Let's see here. The third report that I described to you, that -- that I will provide to you, has a paragraph in the discussion -- so the -- the third report that I mentioned is a dog study, but in the discussion section, they talk about the effects of Pentobarbital in man, where they're looking at the electroencephalogram, and my recollection is that they said within I think it was 15 to 30 seconds, I can't remember the exact number of seconds, that they observed the clinical -- the changes in the EEG in man.

Now, obviously, in the dose that was used in that study had to be a very small dose relative to what's used in -- in Missouri, because you wouldn't be given any lethal dose of Pentobarbital to man to study the effects. But again, that sort of added more, I think weight to my argument, that this drug is going to act very quickly, in the 20 to 30 seconds, and make somebody unconscious. I hope that answers your question.

Q I-

A Sometimes my answer's so long, I forget what the question was about

Q To make sure I'm clear: That report did not state that it takes 20 to 30 seconds in order for a patient to be rendered unconscious?

A It did not. It stated that the changes in the EEG occurred -- started to occur within I think 20 to seconds or whatever that -- I think it might have been to 30 seconds. So the drug --

Q This -- this was the study regarding dogs; is that right?

A Well, yes. But in the discussion section of the paper, they sort of threw in this paragraph, where they said almost, "By the way, we also have given this Pentobarbital to humans," comparing it to Thiopental. And the onset of action of the Thiopental and the Pentobarbital on the EEG was about -- it was the same. There was a small delay with the Pentobarbital, in terms of the full effect, so basically, after a minute or -- minute, they had the full effect for -- for Pentobarbital. They don't really describe what that full effect is. And they don't say what -- what the dose was either. But to me, when they talk about the effect on the EEG began the electroencephalogram, is what the EEG is, when Thiopental and Pentobarbital had the same onset, again, it -- it makes me believe that, in this -- with this dose of Pentobarbital, you're going to have an onset of 20 to 30 seconds; it's going to be like Thiopental.

I think -- I want to make sure we're clear about some of the kinetic issues, here. When you're comparing Thiopental to Pentobarbital if I may...

Q Well, let me stop you because I don't want to go too far down. Because we haven't had a chance to review that report.

A Sure. That's fine.

Q So it might be a little premature to probe that. You did not render an opinion -- the opinion I'm referring to, that Mr. Bucklew would be unconscious, as well as any subject would be unconscious, within 20 to 30 seconds after the administration of this quantity of Pentobarbital. Did you render that opinion in your opening report?

A I did not. I said -- I used the term rapid onset of unconsciousness followed by death is the term that I used. I did not say instantaneous.

Q I understand. And we're not here to do that. I'm talking specifically about your opinion --

A Yeah.

Q -- that it would render him unconsciousness in 20 to 30 seconds.

A That was in my second report, as I remember. Where I got more specific about the timing.

Q And let's -- so -- so let's turn to your second report.

A Sure.

Q And that's Exhibit 2 before you,

A Yeah.

Q And if you could turn to paragraph 5, which is on page 3.

A Uh-huh. Yes, I have it here.

Q And it's a paragraph that begins, "the intravenous administration of 5 grams of Pentobarbital --

A Yes.

Q -- would result in rapid unconscious." And then the next sentence starts, (reading):

"I clarify that opinion, that the rapid onset of unconscious would occur within 20 to 30 seconds after the administration of the large dose of Pentobarbital. To reiterate and expand on my earlier statements" And then you --

A Uh-huh.

Q -- go on to expand further.

Why did you think it was necessary to expand upon your earlier statements, to specify that unconsciousness would take effect in 20 to 30 seconds?

A Well, it was primarily because Dr. Zivot took issue with my use of the term "rapid onset of unconscious followed by death." And he basically said, "Well, there's a period between the -- when the drug is administered and when death occurs," and that's the period during which the inmate will, in his opinion, have such sensations of choking, gasping, and so forth. And suffering.

So he seemed to indicate that there -- there would be this period, during which the inmate is lingering and languishing in this sort of semiconscious zone, and, again, experiencing these sensations. And this was my way of basically refuting that argument, by providing more detail about what I think is occurring. In terms of the onset of unconscious and then what would be occurring after that.

I mean, I think we all surely must agree that 5,000 milligrams or 5 grams of Pentobarbital is a lethal dose. It's been demonstrated in other lethal injections. There's no doubt -- or should be no doubt in anyone's mind that it causes death.

Q Without --

A So --

Q Without any equivocation, it causes death? 100 percent?

A Pro- -- with -- with -- unless there's issues with administration, which we all also agree, that there has to be a proper functioning IV and all that, you know, executions have, to my knowledge, and the information that I was provided, it caused death within around 8 to 9, minutes, so --

Q Are --

A Are --

Q -- you done?

A No, I'm not.

Q Okay, Go ahead.

A So we have to sort of figure out, okay; well, how -- how does a drug kill somebody? What are the -- what is the physiological and pharmacological ways in which that drug would kill somebody at that dose? And that's why I laid out this -- and this is not a complete sort of diagram or -- or -- or way of looking at it, but this is sort of my understanding of how this drug probably is killing somebody, is producing rapid, deep unconscious, respiratory depression, followed by loss of -- or -- or complete absence of respiration, decreased oxygen levels, slowing of the heart rate, and then the heart stopping. And then during all of this, we also have cardiovascular collapse because the blood pressure is plummeting.

So that is the mechanism by which the physiological steps, so to speak, by which this drug causes death. And I just wanted to sort of lay it out for people to understand what I think is occurring with this. That's why I went into that detail.

Q Are you relying on any information that someone from the attorney general's office told you regarding the length of time until unconscious sets in?

A No. No, I have not been provided. I mean, I have the witness statements.

Q But no other information was provided to you to support -- from the State -- to support your opinion, that Mr. Bucklew or someone else would be rendered unconscious in 20 to 30 seconds?

A No. Uh-uh. Not to my knowledge, no. I -- I -- I -- it was my -- it's my opinion, and was then and is now, based on the -- the action of that drug, especially when -- when comparing it to Thiopental, Remember, I've never given 5,000 milligrams of Pentobarbital to anyone. And neither has your expert witness, I presume. Or anyone else in --

Q So you have no personal experience to draw upon, in order to support your conclusion that Mr. Bucklew would be unconscious in 20 to 30 seconds?

A I do not have any personal experience with the use of that drug at that dose, no. Which is why I make the comparison between Thiopental and Pentobarbital. I know how Thiopental -- quickly Thiopental works.

Q Is Thiopental -- say the word one more time, please.

A Thiopental.

Q Thiopental.

It's another type of anesthetic?

A Barbiturate.

Q Barbiturate.

A In fact, the only difference between Thiopental and Pentobarbital is one atom.

Q Is it used on humans?

A Thiopental?

Q Uh-huh.

A Yes. It's not used very often anymore, and it's probably not used -- it's not used in the United States anymore, but it's probably used in other parts of the world. And it was used very commonly for a long time.

Q The Thiopental, that was the chemical that was referenced in the study concerning its effect on dogs; is that right?

A That was one of the drugs that was used. There's actually multiple barbiturates that were used.

Q But that's the study that you referenced?

A Yeah.

Q Could it be longer than 20 to 30 seconds?

A At this -- at -- at the dose of 5,000 milligrams, I don't think so, no.

Q So you can say, with 100 percent certainty, that anybody who was administered that quantity of Pentobarbital would be rendered unconscious in 20 to seconds?

A One of the things I learned in medical school is never say always and never say never. So I -- 100 percent certainty, more like 99.99 percent certainty. I mean, I cannot -- there may be some very peculiar thing occurring that would prevent someone from being unconscious within to 30 seconds, I can't think of what that might be, 1 mean, of course we've already talked about making sure the administration is appropriate, they have a well-functioning IV, that certainly would have affected things. If you had a very slow circulation time, very slow circulation time -- and that term, I use, is somebody who has a very low blood flow in their body because their heart's not working properly, let's say, or their -- their fluid levels is very, very low, so their -- there's not much blood circulating. We call that slow circulation time -- that can affect the onset of these drugs. But Mr. Bucklew --

Q What -- what about somebody's weight? We--we talked earlier about somebody's weight --

A Yeah.

Q -- their medications, their medical condition, those are all things that could affect the onsets of the drug as well; correct?

A Yes. But you have to make sure we're understanding something, here, which is that some of these effects we're discussing may be clinically relevant in the sense of the -- a clinical dose, but not with the dose of 5,000 milligrams. Even those conditions are not going to materially affect, save, perhaps the issue of a slow -- slow circulation time. That potentially could affect the onset of Pentobarbital even in 5,000 milligrams.

Q The other two reports that you said you relied upon, could you remind me which ones those are in your report?

A It was a study by Ehrnebo -- Ehrnebo -- Ehrnebo, I'm not sure how it's pronounced, but it's --

Q The pharmacokinetics study?

A And distribution properties of Pentobarbital in humans following oral and intravenous administration. And that was published in the Journal of Pharmaceutical Sciences, I think. I just have it as pharm sciences.

Q I see where you're referring to.

And what was the other one?

A It's the package insert.

Q The package insert.

A Of Pentobarbital, yes.

Q Does the package insert specify how long it takes to render someone unconscious?

A It just says immediate. As I recall. May I -- if I may refer to it, I think that's the term that is -- the word that is used. I have it here, if you want to -- unless you have it. I have it here (indicating.) Although, you're probably going to enter it as an exhibit, so this copy's going to be mine.

Q Here we go.

A Maybe I cannot -- I'm not sure --

MR. FOGEL: Let's -- let's go ahead and just put this in as an exhibit.

(Whereupon Exhibit 3 was marked for identification by the court reporter and is attached hereto.)

THE WITNESS: So I -- may I continue?

BY MR. FOGEL:

Q Well, just make sure you -- you've just been handed an exhibit that's been marked --

A Yes.

Q -- or a document that's been marked as Exhibit 3. Is this, from your review, a true and correct copy of the package insert that you were just referring to?

A Yes. It looks like it is, yes. Yup.

Q Okay, Just wanted to establish that. Go ahead,

A Yup. So I said earlier, just a moment ago, immediate, I --

Q Uh-huh,

A That's my recollection. But there's lot of stuff here, and I'm not sure that's exactly what it says, so I don't want to commit myself to that word until I've found it and then -- see if I can.

Q Well, you did not point to this in your report. I understand that you reference this report, but you did not point to this specifically for that assertion that --

A No, I did not,

Q -- would be rendered in the --

A I don't think so. I mean, I thought I had something like that, but I didn't -- I used this primarily because of the table they have there, in which they describe the barbiturate levels relative to the different C-N-S depression.

Q So we can put that to the side --

A Yeah. Okay.

Q -- for now.

And then the pharmacokinetics report that you reference, did that specifically state that an individual be rendered unconscious in 20 to 30 seconds?

A No, it did not.

Q And then the other source you relied upon were the witness statements?

A Correct.

Q And is it your recollection that those witness statements asserted that the individual was rendered unconscious in 20 to 30 seconds?

A They did not specify -- in some cases, they specified within half a minute to a minute. In other cases, they specified longer. Sometimes they didn't specify at all, just that they were quickly rendered -- you know, they seem to be unconscious or whatever term that they used. Obviously, the witness statements, they're not medical professionals, they may not know what they're looking for, so you can't take it -- you have to take that with a grain of salt, which I admit to. But the witness statements are consistent with my impression or my opinion that the drug is going to act within 20 to seconds to -- that that's the dose to make somebody unconscious.

Q So I want to make sure we're very precise, here: I believe you said it would act within 20 to 30 seconds to make somebody unconscious. Is the individual unconscious at the end of the 30-second period? Or are you saying that the drug starts to take effect in 20 to 30 seconds, but they might not be unconscious?

A Well, let's see, how do I want to answer that. I'd say that the -- they are unconscious after -- 20 to seconds after the drug has been administered. Does that answer your question?

Q And in part.

You're -- are you defining administered from the moment the Pentobarbital starts to enter into the individual's circulatory system, via the IV line?

A Yes. It starts -- it may and -- you know, I -- one thing -- one piece of information that I do not have, and I -- and that's how -- how fast the drug's injected, that is not something that's -- either it's not known or it's not provided to me. I don't know how quickly it's injected, but I -- I -- my guess would be that it's probably injected -- we're talking about 100 CCs, 100 MLs of the drug --

Q Are you --

A -- is my understanding, so it takes some time to inject it,

Q Do you understand that there are two syringes of CCs?

A Yes. And I believe they use -- they use both of them. They're both hooked up, one syringe has 2- -- 2.5 grams, the other syringe has 2.5 grams. That's my recollection.

Q Is it your understanding that they're injected simultaneously?

A No. They're -- I believe they're injected one after the other.

Q Do you know how long it takes to inject the respective 100 CCs?

A I have not provided -- been provided with that information, so I don't know.

Q And when you say -- as I just parroted you, the -- how quickly the -- it -- it's injected, what -- what do you mean when you say that?

A Well, usually, when you talk about an injection rate, you say 1 -- 1 CC or I ML per minute -- I mean, for a second. So every second, a milliliter of a solution goes in. So if you have to inject 100 milliliters, it could take 100 seconds to inject. I don't know whether these are both hooked up to the IV line or they have to take one off and put the other one on, I don't know how that part works.

Q So if there's one syringe of 100 milliliters, and that could take 100 seconds to be fully injected, and then another syringe of 100 milliliters, which would take another 100 seconds, that's approximately three minutes if-- and that's assuming it's I millimeter per second before the Pentobarbital's fully in the individual's system; is that right?

A I believe you might have that a little bit off. I believe that there are two syringes --

Q You're right.

A -- of 50-

Q Of 50 milliliters.

A -- each. So it would be 50 and then another 50.

Q Okay.

A So if it was one MLs -- one ML per second, then it would take 100 seconds for all the drug to get in. Which would be almost-- close to two minutes. Now, if we could certainly talk about while based on my analysis of that study, what blood level do you achieve after just 100 CCs of the drug? I believe that you achieve the sufficient drug level to make somebody unconscious. So, again, that's why I'm thinking about, it's not going to take very long for that first part of the Pentobarbital to get in, to make somebody unconscious. You don't need 5 grams of Pentobarbital to make somebody unconscious; you only need probably -- make to use volumes, part of it.

You don't need 100 MLs of that Pentobarbital to make somebody unconscious; you probably only need 10 MLs to make somebody unconscious.

Q Do you -- do you -- you don't know how quickly the Pentobarbital is injected into the individual, do you?

A No.

Q Was that information provided to you?

A No.

Q If it takes -- could -- would that affect your opinion in terms of how long it would take for the individual to be rendered unconscious?

A At the extreme, yes. I mean, if somebody was injecting that at 1 ML per hour, then that would affect the onset. I mean, that's sort of the -- that's sort of an extreme example, almost an absurd example of that. You know, absolutely, the speed of injection could affect it. But based on my understanding of how quickly these inmates die after the beginning of the process, again, it sounds like, based on the witness statements and so forth, that death occurs within 8 to 10 -- to 10 minutes, after the injection is started or the execution process starts.

I mean, it has to -- the -- the injection can't -- you know, it has to be probably one or two minutes at most, I would imagine. I don't know for sure, but that's just sort of my -- my -- my -- my guess. I -- but I have to guess, I think anybody does, because that information has not been provided to me, at least.

Q So you can't say for certain -- you don't know for sure how long it could take for the individual to be rendered unconscious?

A I still feel very confident in how long it takes. Because I don't think that the injection -- the -- the -- the length of the time of the injection, how long it takes, it would only be materially important if it was a very, very slow injection. So, again, we're talking about ML, maybe, 30 -- per 30 seconds or whatever, I -- you know, I -- I would have to do the numbers, I guess, to -- to -- to see what it would be, but...

Q If a witness -- you relied, at least, in part, on the witness statements; is that right?

A Yes.

Q If a witness had reported that it took several minutes for the drug to take effect, would that change your opinion at all in terms of how long it takes for someone to be rendered unconscious?

A No. Because -- and -- and, again, I'm looking at this -- I'm -- I'm interpreting these witness statements, which I know they're not medical people, and I'm interpreting, maybe with my own bias, with my own lens, I'm interpreting some of these comments as ones in which they may be seeing something that they believe is the signs of a conscious individual, which, in fact, it's probably not.

So as an example, gasping, the best example that I could think of would be -- and many of us have probably experienced this -- when you have an animal that you've had to put to sleep. And you give them the euthanasia drug, and sometimes the animal goes to sleep and then maybe a minute later, they have an agonal breath, they go, huhuhuhuh (phonetic.)

Q Have you spoken to any of the witnesses?

A No.

Q So the entire universe of information you're relying upon is contained within the four comers of the witness statements?

A Yes. I have not spoken to any witnesses about this, no. Absolutely not.

Q Right. And are these statements or observations made by -- you mentioned, they're not medical personnel?

A I'm assuming they are. I mean, based on the -- the -- the titles that they're -- that they were provided to me of these individuals, you know, some of them are journalists, some of them are -- they -- they're called like staff witness I think, things like that. So it's possible some of them -- maybe I've been wrong about my assumption, but it's possible that some of them have had medical background, I don't know.

(Whereupon Exhibit 4 was marked for identification by the court reporter and is attached hereto.)

THE WITNESS: So -- but I -- my assumption is that none of them did, maybe I'm wrong about that.

MR. FOGEL: So I'm handing the court reporter a document and asking if she can mark this as Exhibit 4.

BY MR. FOGEL:

Q Doctor, take a moment just to familiarize yourself with the document.

A Yes. Uh-huh.

Q Does this appear to be a true and accurate copy of the witness statements that you reviewed?

A Yes.

Q And were these documents that were provided to you by the State Attorney General's office?

A Yes, they were.

Q And is it your understanding that these are documents that were prepared by the State Attorney General's Office?

A Yes.

Q Did you take that into consideration at all when rendering your opinion?

A Well, of course. You -- obviously, you look at that and say, “Well, these were interviews performed by an investigator for the -- for the Attorney General's Office, and, you know, I -- I -- I have to take them at face-value, I mean, is there a potential bias in how they were collected? I have no idea to know that, one way or the other.

Q Well, do you see many of the names -- look at the first page, for example, you see “state witness” next to many of the names?

A Yes. Uh-huh.

Q What is your understanding of state witness?

A My guess is that, if I understand it correctly, that these were witnesses that if-- the State has asked to be present for the execution, and, of course, some of these are labeled as being members of the press.

Q How -- how did you form that understanding?

A Well, I'd say, for example, the first page, Jessica Machetta, state witness, then it says “press” next to it.

Q So aside from reading that, do you have any other independent knowledge? Or were you otherwise provided with further information to form that understanding?

A No.

Q You see later on, there's some names that have the title “staff witness” next to that name?

A Yes. Uh-huh.

Q Do you -- do you have an understanding what staff witness refers to?

A My guess is that, it is somebody who works for the Department of Corrections, but I don't know if that -- could be somebody who works for the Attorney General's Office or somebody that's a member of the staff of some state agency for Missouri, is what I -- my best guess would be that it's from the Department of Corrections.

Q Did you ask the Attorney General's Office to provide any information or further clarification of who these individuals were?

A I don't think so. I -- I don't think I would have asked. If-- if-- if anything, I would have asked the question, “Do any of these people have a medical background?” And I don't think I asked that question. I don't think I asked that question of anybody. Except asking myself.

Q Would that be important to forming your opinion, whether or not any of these individuals have a medical background?

A Yes. If some of them had a medical background and knew what they were looking for, then I would probably -- that would be more -- would lead -- give it more credence, what they're observing and saying.

Q What if it was determined that most or none of them had a medical background?

A Then, again, I would say that their -- some of -- some of which they're observing -- some of the things they observed may not be accurate, one way or the other. I mean, some of them describe the onset of the drug as being within 15 seconds or so, or whatever, and sometimes, you know, longer period of time. So, again, I -- you have to look at this and say, “It's not -- I -- I don't want to hang my hat on just the witness statements,” but I did rely upon them.

Q So if somebody said it took 15 seconds from their naked-eye observation for the drug to take effect, that might not be accurate?

A That's correct. That might not be accurate. Nor maybe, if someone said it was two minutes. Maybe it took only 30 seconds, but they thought it was two minutes, so it could go either way in my opinion.

Q Are you aware that some witnesses have opined that it took over five minutes for the drug to take effect?

A I believe that in some of-- in some of these -- somewhere in here, I do believe someone said it took five min- -- it was a long time, I mean, I don't know whether it was five minutes or not, and you'd have to point that out to me if it was -- if-- but I do remember seeing something in here, that it did take that long, you know...

Q Did that affect your opinion at all?

A Not particularly, no. Because I -- again, I asked myself the question -- based on my understanding of how the -- how this drug works, and in terms of its kinetics and -- and its effects on the brain, is it possible that it could take five minutes for the drug to take effect?

Again, the only possibility that comes to mind -- or possibilities that come to mind would be if the IV's not working properly. Or if there's a slow circulation time, which would occur in somebody who has, again, you know, really bad congestive heart failure, let's say, where their heart's not functioning properly. Those are the main reasons why I think that you would have -- have that effect.

But, again, you sort of look at what -- well -- well, when this individual said it took five minutes for the drug to take effect. What is the endpoint that they're looking for? So -- so for example, you might be -- again, from a non- -- nonmedical perspective, you might say that the inmate appeared to be unconscious after to 30 seconds, but at five -- at minute five, he took a breath, that's -- and then there was no breath after that, so it took five minutes to have its full effect.

Well, that's maybe a different definition than somebody else, who just basically says, “Well, they appeared to be unconscious within 20 to 30 seconds, and -- and the rest of it was just these agonal breaths.” So I'm not sure what endpoints each of these individuals are using.

And that's part of the -- the confusion, let's say, or the lack of clarity around some of these statements. So I certainly do concede that the witness statements do not provide crystal clear guidance to us about how quickly the drug acts. But it does lend support to my contention, that it acts pretty quickly within 20 to seconds.

Q What -- what I don't understand is, why you're willing to discount some witness's observations, that it might take several minutes, but you seem to be putting credence in witness statements who say it happened in a matter of seconds.

MR. SPILLANE: I'm going to object to the form of the question. If there's a witness in here that said it took five minutes, I haven't found them; I've found less than five minutes. I was wondering if you could point to one and ask the doctor to explain it.

MR. FOGEL: Well, that's a different question from the question that I asked. Because I said minutes and the doctor acknowledged that there are statements in here that say minutes. And I ham happy to point the doctor to a statement, but first, I would like him to answer my question:

BY MR. FOGEL:

Q Why, based on his recollection that there are statements in here that do discuss minutes, why he is willing to discount those statements, yet attach credence and significance to those that say seconds?

A Well, there are probably over 150 individual statements in here, from 19 executions. I'm not, you know, I'm not sure how many there are in total, but there -- there probably -- it's probably more than 150; it might be 200. And if you look at some of these statements about the minute part, you know, it says -- so to get to the issue about the five minutes, there is a -- on page 6 of 56, Patrick Martin.

Q Uh-huh.

A (Reading):

“Martin said it was hard to tell, but appeared to take more than five minutes, but less than ten minutes for the drug to take -- to fully take effect.”

So let's take a look at all these statements, here. And -- and one of my faults is, I'm a very quantitative person, one of my strengths is, I'm a very quantitative person; you could take it either way, but let's look at this particular execution, here. There are probably -- let's count them: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, (inaudible) -- there are 29 statements here -- well, there's not 29, because some of these people couldn't be reached.

Priddy, first one, “Seemed to happen quickly.”

Powell --

Then the next person basically said wasn't -- didn't -- didn't return his answers.

Powell said, “He took two deep breaths, and that was it.”

Hufford said, “It was over very quickly.”

Jones said, “Appeared to take a deep breath, and that was it.”

Taylor, “Less than two minutes.”

Martin, “More than five, but less than ten.”

The next person, “Less than two.”

Next person, “Less than one.”

A lot of these say less than one; one says less than five. So, you know, I have over 20 witness statements, a small minority said five to ten, five or so. But most of them said less than one, so I have to ask myself, “Is that one person that said it was five to ten --

BY MR. FOGEL:

Q Well, I don't think that's a fair characterization, Doctor, I mean, because we -- you just read a few that said minutes, there are a few -- several more you did not get to that said three to four minutes, there's one that took less than five minutes. I don't want to do number counting with you right now, but my question is, you do acknowledge that there are other witnesses who said it took minutes as opposed to seconds.

A That is true.

Q Yeah.

A There are -- there are witnesses -- and they have statements saying that it took three, four -- five minutes to take...

Q And my question for you is, does that affect your opinion in terms of how long it might take to render somebody unconscious?

A No, it does not. If the vast majority of the witnesses said that the inmate -- you know, not just in this execution, but in other executions, you know, took five/ten minutes, you know, that they -- they -- and they specifically said, "The inmate was still breathing, the inmate was still moving, it took five minutes," then I'd say, "Wow. Maybe this drug is not acting as quickly as I think it is."

But the overwhelming -- in my mind, the overwhelming evidence here is, that the drug -- these witness statements support my contention that the drug acts very quickly, within 20 to 30 seconds. So...

And that's just the ones -- by the way, the one execution where you can pull out those -- I believe, there may be one or two others, I don't know, that you could pull out those kind of numbers, but most of these will say in these executions, it's one, less than one minute. Maybe less than two minutes.

Q Well, let me ask you a question, because you're -- now you're talking about that specific execution. It could vary by execution?

A Yes. I would say --

Q Why -- why could it vary by execution?

A There may be issues with how fast they can inject the drug. So I don't know what those -- what those specific issues are in these cases. Obviously, I wasn't present and that information has not been provided to me, if that information is even known. But for whatever reason, maybe they didn't inject the drug as quickly as they wanted to. Or maybe some of these inmates did have -- I don't know their medical history, you know, how much they weigh, but, you know, some of those issues could have an impact in the time that it takes, as we previously discussed, for the drug to act.

Q And therefore, render the individual unconscious?

A Correct.

Q It's possible that it could affect it?

A Yes.

Q You can put the witness statements aside for the moment. Have you ever witnessed an execution in the State of Missouri?

A No.

Q Have you ever witnessed an execution period?

A No.

Q Going back to your scope of engagement, which is on paragraph -- excuse me, in your November 2016 report, at paragraph 3.

A Yes. Yes. Uh-huh.

Q You said, (Reading):

“I've been asked to render expert opinions in the fields of general medicine and anesthesiology. Especially regarding the use, actions, and efficacy of Pentobarbital.”

And then the next sentence -- that sentence continues on --

A Right, the --

Q The next sentence that I will focus on, it starts, (Reading continued):

“I have also been asked to render opinions regarding the efficacy of Pentobarbital in the case of Rusty Bucklew.” What do you mean by efficacy?

A Efficacy is used in its, you know, defined term, which is basically the -- the ability of the drug to produce the intended effect essentially.

Q The intended effect, here, being...

A Death.

Q Death.

A Yeah.

Q Do you understand plaintiff to be challenging whether or not he would die from the administration of Pentobarbital in this quantity?

A Could you ask that again.

Q Sure. Do you understand plaintiff to be asserting or to be challenging whether or not he would die from the administration of Pentobarbital in the quantity set forth in Missouri's execution protocol?

A I don't think -- I mean, I -- that's news me. I think he was challenging the efficacy of the drug in terms of its ability to -- well, let me -- let me rephrase that.

My understanding, he's sort of challenging the issue around this method would cause undue suffering, pain, et cetera. I did not think that he was challenging the fact that -- that it would cause -- it would not cause death.

Q Right. It's a question of whether he would die in violation of--

A Right.

Q -- his 8th Amendment rights?

A Correct. I mean, I don't think he's saying, somehow, that the drug, as it would be administered, would not cause his death. I don't think -- I don't think I read that anywhere.

Q Do you know what cavernous hemangioma is?

A Yes.

Q What is cavernous hemangioma?

A It's a condition -- usually, it's congenital, but it's a condition where you have an abnormal growth of blood vessels that produce what's essentially on -- if you were to look at the tissue under a microscope, there are these pools of blood or caverns of blood that are part of that hemangioma. And that's where that term cavernous comes from. So basically, the hemangioma has this blood that will enter it slowly and pool there in these caverns, and then that causes the growth of the hemangioma, as, you know, if it's congenital as the child gets older, this -- this can sometimes grow larger. And so its definition -- or its term is based on, primarily, its finding under microscopy.

Q And how did you form that understanding of cavernous hemangioma?

A I reviewed some of the literature. I -- I had a general understanding of that term before this case, but had certainly gained more specific knowledge about the pathology, so to speak, of -- of -- after reviewing some of the medical literature on it.

Q And did you form that general understanding prior to this case in connection with your treatment of patients? Or otherwise?

A No, not -- I don't know, off the top of my head, if I've ever had a patient with a cavernous hemangioma that I've had to anesthetize, I don't know. I mean, and I don't -- my -- my recollection, I don't recall actually learning that about a cavernous hemangioma during medical school, but my recollection, at the time, when I saw this is, I -- when I saw this, I said, “Oh, yes. Okay. I know what that is.” And in a very general sense.

Q But you've never treated a patient who had cavernous hemangioma?

A I --

Q Or -- sorry, go ahead.

A I don't think so. If I did, I do not recall.

Q The paragraph we were just looking at --

A Yes.

Q -- the sentence continues (reading):

“Rusty Bucklew, a condemned prisoner who has a congenital cavernous hemangioma, and whether that hemangioma would affect the efficacy of Pentobarbital or otherwise inflict the substantial risk of severe pain as a result of Missouri's lethal injection procedure.”

Do you see where I was reading?

A Yes. Uh-huh.

Q What -- what do you mean by whether that hemangioma would affect the efficacy of Pentobarbital?

A One of the claims that your expert witness made -- well, actually, not just Dr. Zivot, but I think it was -- was always Dr. Wippold and Jamroz, I believe was the other one, they made claim that the hemangioma would cause a abnormal distribution of the Pentobarbital, and thereby affect -- affect its efficacy, you know, how the drug acts.

And so that's why that statement is in there, so that I can, you know, I wanted to render opinion as to what the effect of the cavernous hemangioma would have on the distribution of Pentobarbital.

Q Sure. And the sentence continues, (reading):

“Or otherwise inflict a substantial risk of severe pain as a result of Missouri's lethal injection procedure.”

A Uh-huh.

Q Do you think that there is some risk, due to Mr. Bucklew's condition, that he would suffer severe pain as a result of-- let me strike that.

Do you think that there is some risk that Mr. Bucklew would suffer some pain as a result of Missouri's lethal injection procedure?

A As I said earlier, inserting an intravenous line can be painful. Beyond that, if -- if the IV was not functioning properly, and the IV infiltrated, then there would be some pain associated with that. When drugs infiltrate, then that could be painful. So especially with something like Pentobarbital.

Q Well, let's pause on that.

Why would it be painful?

A Well, some of the drugs that we use have a the -- the PH, which is the acid level basically --

Q Uh-huh.

A -- can either be high or low. And because of that, when it gets into the tissue, it can be painful. It's been described with many drugs, especially drugs we use in anesthesiology, such as Thiopental is a classic example. And I've never said otherwise, about you have to have a properly functioning IV for these -- for any drug, really, that you give. Whether it's in this protocol or whether it's for a clinical reason, to work properly. So there is that risk.

Q And what could happen if you don't have a properly functioning IV?

A Well, the drug won't work as quickly as we want it to. Whether it's in a clinical setting or -- I'm not putting myself in that weed when it's --

Q Sure.

A -- used in the lethal injection process, but from a clinical perspective, the -- the drug will not work fast. In fact, it may not work at all. Because it's -- it's very slow -- once it gets out, in the tissue, it's going to be very, very slowly absorbed, and it won't have its intended effect.

Q And what are some of the factors that affect whether you have a properly functioning IV line?

A Primarily, it's going to be the patency and size of the vein that you put the intravenous -- the catheter in. That would be the -- not the -- that's the main reason from a -- from a -- sort of a clinical perspective.

Q What does patency mean?

A Whether it's open or not.

Q Yeah.

A Yeah, so...

Q And -- and that varies by person?

A That is correct.

Q Did you make any observations -- well, you previously did examine Rusty Bucklew, didn't you?

A I did.

Q Did you make any observations regarding IV access points?

A I did.

Q And what were your observations?

A So his IV access is -- is what I would consider to be limited. So his left hand in particular, and arm, there are very few -- there are just a few small veins that I could find. There are some more on his right arm. Sufficient that I -- that I believe I, with my expertise -- or somebody with the expertise of starting an intravenous line would be about to get an intravenous line in his right hand, but the veins are small.

Q And what happens when the veins are small? What does that mean?

A Well, that gets to the issue of, if you inject -- you have to watch how quickly you inject a drug. And you could cause infiltration in the -- the vein could -- you could -- we call blow the IV. Basically, where the -- you rupture the vein, so now you're going to get to that drug going out into the tissue instead of into the vein, so...

Q And that could be particularly problematic when you have a drug with a PH level like Pentobarbital?

A Correct.

Q Okay. And what happens when a drug like Pentobarbital gets into the tissue?

A Well, it can be painful.

Q Uh-huh.

A And it can destroy the tissue. You can actually get ischemic and gangrenous tissue, where the tissue dies. Almost like a chemical burn in a sense, so...

Q Right. When somebody has a small IV line -- sorry. Does quantity of the chemical that you're injecting affect the success of the IV line?

A It's more the speed than the quantity. I mean, it's -- it's -- yeah, it's more the speed. I mean, if you injected -- you could inject a lot if you did it slowly.

Q Right.

A It's really more about the speed of the injection than the actual quantity.

Q And why does the speed matter?

A Well, because the -- the vein -- let's see, so imagine that you're -- if you had -- I'll use an example, if you had a mouthful of water and you're trying to spit it out through a straw. If you spit it out through a large straw, a large diameter straw, you're going to be able to get a lot more water out of that straw, in a certain amount of time, than if it were a small diameter straw. And a straw -- I know we're thinking about a typical straw that is made of plastic and can stand high pressure, but if that straw was made of a very thin material, if you really applied a lot of pressure to that, it would blow. And that's essentially what's happening when you're injecting too quickly.

Q So correct me if I don't have this right, but the smaller the IV or the smaller the vein, the slower you want to inject the chemical.

Is that fair to say?

A That would be an accurate assessment, yeah. Because you'd have to be -- if you're concerned about blowing the vein, you'd have to be worried about the speed of injection, yes.

Now, I will -- if I can elaborate on that.

Q Go ahead. Go ahead. If you have something further to say in response to my question.

A I mean, certainly in the clinical setting, we may have to start IVs in places that we normally wouldn't want to start IVs because of that. So we might start a central line. I mean, and that's certainly happened in my practice many times, and I'm sure Dr. Zivot -- and any anesthesiologist is going to say the same thing, where you have to -- you have to put in a central line when you have very poor IV access.

Q What is a central line?

A So that's a term that we use for the central circulation. So usually, it's going to be a catheter that we put into a neck vein, it could be in a subclavian vein, or it could be in the femoral vein. I mean, you -- you -- you're able to access -- those veins are very big.

Q Uh-huh.

A And you can put catheters in that. So in a clinical setting, if we were worried about injecting drugs or other substances, then we would put in a central line. Generally speaking -- yeah, that's -- that's the way that we would manage that many times.

Q That's in a clinical setting. Do you know how that would be handled in the execution setting?

A I have been told that, I believe, that -- that they have inserted central lines in some of the inmates -- I don't know whether that's been in Missouri or not, I'm really -- I'm not positive about that. So --

Q You've -- you've been told it could be done?

A I -- that there have been central lines that have been placed in some inmates.

Q You -- you just don't know if that's -- who -- who told you that?

A I'm not sure if that's something that I've read in the newspapers, I'm not sure. Yeah.

And then maybe -- maybe, it was something that Mr. Spillane and I discussed. I'm not -- I'm not even sure -- maybe it was in the -- I'm not sure if the Missouri protocol has it in there, I forget. Maybe we can refer to that, I don't know.

Q Would it be helpful to look at the --

A Sure.

Q -- open protocol?

(Whereupon Exhibit 5 was marked for identification by the court reporter and is attached hereto.)

THE WITNESS: Oh, yeah. It does say, in C, it says, (reading):

“Medical personnel may insert the primary IV line as a peripheral line or as a central venous line.”

And then it lists femoral, jugular, subclavian. So that refers to the femoral, which is in the groin area; and the jugular, which is in the neck area; and the subclavian, which is below the clavicle or the collarbone.

BY MR. FOGEL:

Q Right. And do you see the end of that sentence it says, “Provided, they have appropriate training, education, and experience for that procedure”?

A Yes.

Q Does inserting an IV line in -- as a central venous line, require additional training or expertise?

A Yes.

Q Why is that?

A Additional -- well, for example, a nurse may have a lot of experience in inserting a peripheral IV, but there are very, very few nurses that probably have experience in inserting a central line. The only -- there might be some nurse practitioners that have that experience -- in the clinical setting, there might be -- certainly CRNAs or nurse anesthetists would have that experience. But usually you have to have additional experience, and that's going to be somebody who has, you know, maybe a physician that has experience.

Q All right. So do you know if the medical personnel, that are present as part of the execution team, have that training and experience?

A I believe that there is a anesthesiologist involved in the Missouri process.

Q Right. But this condition, here, when it says, "provided, they have appropriate training, education, and experience for that procedure," are you assuming that somebody present would have that expertise?

A They would have to have that expertise in order to safely place that -- those -- those types of lines, yes.

Q Right. And you're assuming that somebody with that expertise would be present --

A Yes.

Q -- in order to do this?

A That's my assumption.

Q Okay. And what would be all the alternatives if you could not insert it through a central venous line?

A If you did not have adequate -- what you considered an adequate peripheral IV, and you did not have central access --

Q And sorry, what is a peripheral IV?

A So that would be like a IV --

Q Through the hand?

A -- in the hand, or in the arm. This is considered basically the periphery (indicating), it could be in the foot.

Q Uh-huh.

A We often have placed IVs in the feet in a clinical setting. But a central line, so it's usually considered to be peripheral -- peripheral versus central. Central line would be something where the catheter's actually in what we call the central circulation. Usually we're talking about a large vein such as a jugular or the subclavian or the femoral, and pretty much everything else is -- is -- is peripheral.

Q Sorry, I -- I think you were answering a question before I interrupted you.

A I -- I -- I think I --

Q Do you want me to repeat the question?

A Sure.

(Whereupon the record was read.)

THE WITNESS: You wouldn't be able to administer the drug. I mean, you do not have -- you do not have a properly functioning peripheral line, you do not have a properly functioning central line, you cannot inject the drug because there's no vein to inject it in. I mean, I've never said otherwise. You have to have a properly functioning IV somewhere to be able to safely administer any intravenous drug. Just to make that clear.

BY MR. FOGEL:

Q Now, in your report, your supplemental report, Doctor, you state there had were small superficial veins in his hands?

A Yes.

Q And that -- and that is referring to what you said earlier, that he has small veins --

A Yes.

Q -- in his hands, which would make it difficult to administer an IV through the hands; is that correct?

A I don't think difficult would be the right word. I mean, it made it more challenging.

Q More challenging. Sure.

A Yeah.

Q And --

A And by way of an example -- I know you can't put this in the report, but look at my veins (indicating.) Right? People look at that and they just salivate of over those veins; they're huge,

Q But Rusty does not have those types of veins?

A No, he does not.

Q He's not as lucky as you to have those veins?

A Right.

Q So --

A Just --just as an aside, and I'm sorry I got to throw this in there: Anesthesiologists, when we're out in the world, we look at veins and we look at the airway of everybody. So I guess it's just what we do, so...

Q You -- you also stated in your report that there are limited sites for IV access in upper extremities --

A Yes.

Q --is that right? And when you say “upper extremities,” what are you referring to?

A The arms. I didn't examine his feet.

Q Okay. When we talk about peripheral IV access --

A Uh-huh.

Q -- are you generally talking -- is that what you're referring to when you say the upper extremities in the hands, that's --

A Yes, that's the --

Q -- the peripheral IV access.

A -- that's the peripheral IV access that I'm talking about, yes.

Q So you did not examine whether -- where the potential of a central venous line --

A No, I did not. (Whereupon the reporter requested clarification.)

BY MR. FOGEL:

Q Is that -- is that accurate?

A I did not. I did not examine him.

Q What -- what type of-- in the clinical setting, what equipment, if any, would you use to identify the central venous line?

A Well, if you are using a -- if you're going to insert a catheter in the jugular vein, the standard of care now is to use an ultrasound machine, where you identify the -- the jugular vein. If you are inserting a femoral line, you don't need any -- I mean, people can use an ultrasound machine, but it's not necessary. It's not -- you wouldn't have to use that.

And likewise, with a subclavian vein, you wouldn't have to use an ultrasound machine. I think people do do that, but it's not absolutely necessary. But I think for the purposes of the jugular vein, you'd want to use a ultrasound machine, but for the others, I wouldn't say it's absolutely necessary.

Q Do you know if an ultrasound machine -- are there any other pieces of equipment that you would use in order to identify an central venous line?

A No. I mean, ultrasound would be the -- the one that I would use.

Q Do you know if an ultrasound machine is available in the execution setting?

A I do not know.

Q For somebody with veins as poor as Rusty's as you've described them, is there anything to increase the likelihood of the vein to blow once the fluid begins flowing through it? Through the needle.

A Yes. There is -- with poor IV access or limited IV access, small veins, then the risk of an infiltration is higher. I can't give you any numbers, I'm not even sure those people have ever studied that, quite frankly. But just based on my clinical experience and I think, based on general teaching and clinical experience of others, yes, there's an increased risk of a vein blowing when provided with limited IV access. Which he did have

Q Right.

MR. FOGEL: Why don't we take a -- a break.

(Whereupon there was a break in the proceedings.)

MR. FOGEL: We're ready to resume?

BY MR. FOGEL:

Q Doctor, I want to pick up on something we were discussing shortly before we took a break. And that was the -- accessing the central venous line.

Now, do any of the veins that you discussed have arteries -- well, first of all, what is the difference between a vein and an artery?

A An artery is the term that we use that describes blood that takes a tube, essentially, that takes blood away from the heart. And usually, that's to the systemic circulation. So for example, the left ventricle will have the aorta coming out of it and that will have branches, and those are arteries. Like the carotid artery and so forth.

And then veins we describe as structures that bring blood to the heart. And that's sort of the -- that's the basic structure. And usually, for the most part, arteries have oxygenated blood in it, and veins have deo- -- what we call deoxygenated blood it in.

But there are the two main exceptions to that is, that when the blood comes back from the lungs back into the heart, those are called pulmonary veins because they are veins that are bringing blood back into the heart but actually it's oxygenated blood. And likewise, the pulmonary artery takes blood from the heart to the lungs, it's called an artery, but it's got deoxygenated blood.

But in terms of the systemic circulation, which is the typical term we use to describe blood flow through the -- through the body. Arteries carry blood from the heart to the various organs and then veins bring that blood back from the periphery or from those organs back into the heart.

Q Can you use an artery instead of a vein--

A For?

Q -- for purposes of an IV line?

A You cannot.

Q Why -- why not?

A Well, let me just clarify that. You can use an artery -- in fact, that -- people do use arteries for an- -- what's called angiography, where they are -- they are looking at the structure of an artery, and -- and the -- the blood flow through that artery, so they will inject a contrast through that artery. But for the purposes of giving a drug for, you know, having a systemic effect, you would not use an artery. In fact, you would want to avoid using an artery.

Q Okay.

A Because these drugs can damage arteries. You know, many drugs can damage arteries.

Q Do any of these veins that you would use, as you described as a central line, do any of them have neighboring arteries?

A Yes, they do. And I guess, for purposes of -- of making a complete statement about the artery, there is one exception to the -- the -- what I said about arteries. The pulmonary artery, sometimes will have a catheter, it's called, interestingly enough, a pulmonary artery catheter. And it goes through the heart, into the pulmonary artery. And you can't inject drugs into that, because that's -- in that sense, it's like a vein.

Q Yeah.

A But it's -- anyway, back to your question: Do these structures, where the -- the central line being placed in a femoral artery, you know, the --

Q And the jugular?

A -- jugular and stuff like that.

Q Yes.

A Yes. There are arteries very close to the veins.

Q So the important-- based on what you described and why you would use the vein as opposed to an artery -- to be very careful that you don't insert the IV into the artery, and not into the vein?

A Correct.

Q So what do doctors use in a clinical setting to make sure they don't put it into the artery instead of the vein?

A Well, we already brought up the issue or the technology of an ultrasound machine.

Q Right.

A And that's one way of more accurately diagnosing where your catheter is. The other things that you do, I mean, there are a variety of different techniques. So for example, I mean, I'm going to go into some detail because I think maybe that's what you want, but...

Q Well, do you need an ultrasound in order to --

A No.

Q -- access --

A You don't need an ultrasound to --

Q -- the central venous line to make sure you do not --

A You do not --

Q -- put the IV into the artery?

A You do not need an ultrasound to -- we used to do that all the time, for many years.

Q What is preferred practice today?

A For the placement of the central line in the jugular vein, it's going to be the ultrasound. I'm not so sure that it's preferred practice or a standard of care for the other veins. It may be in some settings and some institutions, where they say you should do that, but...

Q If you were to insert an IV into the central line, would your practice be to use an ultrasound?

A I think you want to rephrase that question. You said to put my IV in a central line, you mean in a--

Q Central vein,

A -- central vein.

I would use it for a jugular -- I'm not sure that I would need to use it for the femoral vein or the subclavian. The subclavian vein is a little bit more difficult for the ultrasound to be useful, I think, but I think people can use it.

But it's really primarily for the jugular vein because the concern there, is that, when you puncture the artery, the carotid artery, that's the blood flow to the brain, there's risk of stroke and things like that. There's obviously risks involved in terms of puncturing the other arteries, but not nearly cat- -- potentially catastrophic as with the somehow puncturing or having a problem with the carotid artery,

Q Are you familiar with a cutdown procedure?

A Yes.

Q What is it?

A So a cutdown procedure is where you actually have to make an incision into the skin to gain access to a -- the structure that you're trying you -- and usually, it's going to be a vein that you're trying to cannulate. So we use the term percutaneous -- you got that?

THE REPORTER: (Inaudible response.)

THE WITNESS: Okay.

Percutaneous means through the skin, basically. And that's essentially where you use a needle to gain access, like a intravenous line. A cutdown is where you would actually use a scalpel to make an incision in the skin and then you do a dissection to actually -- to find the vein.

BY MR. FOGEL:

Q What -- when would a doctor use -- or some medical professional, use the cutdown procedure?

A If they had difficulty gaining access to the venous system, but the usual methods of, you know, they can't access it peripherally, they can't get a central venous line placed. Most cutdowns are usually done on -- I shouldn't say most -- most cutdowns, in my experience, in the -- in the clinical practice that I was in, most cutdowns were done on the saphenous vein, which is a vein in the ankle. It's usually patients in the -- who's been in trauma. So they come into the emergency room and the;' get a cutdown on the saphenous vein, and they -- or they find the saphenous vein and they insert a large bore of tubing or a catheter into that vein.

Q When -- have you ever used the cutdown procedure on somebody before?

A I have.

Q What position was the individual lying in when you applied the cutdown procedure?

A Supine.

Q Which means?

A Flat.

Q Lying flat?

A Lying flat, yes.

Q And why were they lying flat?

A Because they are -- were trauma patients, and they have injuries, and they were -- they had -- they'd be lying flat -- all -- all trauma patients -- I shouldn't say all, like I said earlier, never say never, never say always, but vast majority of the trauma patients are going to be lying flat, so that's why. And that's the best position to be able to get access to the ankle and to do the -- to do the other things that need to be done in a trauma patient.

Q Would you agree that for somebody where it is difficult to locate a IV site through the skin, that it's more likely that they need to have a cutdown procedure?

A Yes. More likely, I mean, that wouldn't be the next step, the next step would be the central line. But failing that, and a cutdown would be needed, I mean, for the most part. I mean, those are sort of the ways in which you could access the venous circulation.

Q Do you have any understanding of whether the cutdown procedure was used under Missouri's execution protocol?

A Say that again.

Q Sorry. Do you have any understanding of whether the cutdown procedure is an option under the Missouri execution protocol?

A I -- I don't know if it's in there or not. I don't remember seeing that.

Q Do you know if it's used at all?

A In --

Q The Missouri -- in Missouri executions?

A I don't know.

Q Or is it an option?

A I don't know.

Q You mentioned the -- was it the saphenous vein?

A Yes.

Q Do I have that right?

A Yes.

Q And it run -- starts in the ankle.

Does it run all the way up, into the groin?

A Yes, It's -- well, it's not called the saphenous vein, once it gets up to that level. But yes, that's the way the pathway goes up, into the femoral vein.

Q So it's different from the femoral vein?

A Yes. So you could think of the femoral -- so there's several veins -- there are a lot of veins, let's say -- let's take the leg, there are a lot of veins in the -- in your leg. Some of them have names, because they're commonly -- you know, they have a common location. The others don't. So they all sort of come together -- not all of them -- but many will come together -- not all of them, but many of them will come together to form the femoral vein? So...

Q And where do you access the femoral vein?

A In the groin.

Q In the groin.

And you mentioned that as an option if you were to do a central venous line; correct?

A Yes.

Q If you were to access the femoral vein, would you need to cover it with a sheet, if you were trying to shield someone -- if there was somebody observing --

A Yes.

Q -- the person who was having the IV inserted, would you recommend them covering it with a sheet because the groin would be otherwise exposed?

A Kind of depends on the clinical setting. So for example -- so normally, what we could do the -- for the femoral vein, you would use a -- a central line kit, basically, and most of these -- you know, some of these kits could be used for almost any central line location, whether it's a saph- -- I mean, a subclavian or a jugular or a femoral.

And you prep the area, you disinfect it, basically, and then you take a -- a large sheet that's sterile, and it has a hole in it, and that's where you put -- that's where you're going to be doing your work. So it's -- you do cover a large part of the, you know, the lower-torso part, there, including the genitalia. But the actual area where you're working is going to have a hole in that sheet, that you're going to -- that's where you're going to be doing your work.

Q Uh-huh.

A I don't know if that's what you were --

Q Well, I suppose it's -- it might be a little bit of an unfair question, because you don't know if the cutdown procedure is allowed or used under Missouri execution protocol; is that right?

A I don't know that.

Q And you don't know -- and therefore, you wouldn't know how it is employed?

A Yeah. Well, you're talking about central line placement. I thought. A femoral line.

Q Well, I was talking about femoral line, but also the cutdown procedure.

Would you use the cutdown procedure on the femoral line?

A I don't know whether people do that. I've never done that. I've never done a cutdown on a femoral vein because in my experience, the femoral vein is -- is easily accessed. Well, I shouldn't -- you know, it's -- it's easily accessed. I mean everybody, for the most part, I mean, I should, again, never say never and never say always, but almost everybody has a femoral vein. And the anatomic location is very consistent from one person to the next.

Q Uh-huh.

A So you wouldn't need to do a cutdown in somebody for a femoral vein in the groin. I mean, I don't -- I suppose it has happened somewhere, but I've never seen it and I've never done it.

Q Right.

A For the purposes of gaining access.

Q Have you ever had a conversation with any of the execution medical team on --

A Never.

Q -- (he access of the femoral vein?

A Nope. I've never spoken to anybody for, you know, execution team, not at all. No contact whatsoever.

Q I think you used the word “challenging” when talking about accessing Rusty's IV line. What -- what are the consequences, for somebody like Rusty, if the medical team is having challenges accessing an IV line?

A So I will answer that in sort of the setting of what has happened in my clinical experience.

Q Uh-huh.

A You may end up having several attempts, more than several attempts. I've probably seen patients that have had more than, probably, ten attempts to try to get IV access. And sometimes, depending on how the patient's tolerating, you might end up saying, “You know what, we're going to go over to try a central line, you know, we're not going to do -- do this anymore.”

So that's -- that's where, if there was a challenge, you know, I say challenge, if there was a problem, then, after so many attempts -- and I don't know what that number would be, it's going to vary from individual to individual. But they would --

Q But for somebody with Rusty's veins, as you've described them, you've acknowledged it could be challenging to access the IV lines. Is that something that you would -- is it likely to induce stress on somebody like Rusty?

A It would induce stress on almost anybody. Because you're sticking them with sharp needles, yeah.

Q Would it increase the likelihood of heavy breathing?

A It -- yes, it could increase the likelihood of that, because, you know, it's stressful, you're going to be breathing more rapidly potentially.

Q Could it increase the likelihood that Rusty's hemangiomas would start bleeding?

A I'm not so sure about that. I don't know, I'm not sure that I -- I know that the -- Dr. Zivot and others, and, you know, the other experts have said -- talked about changes in the blood pressure, I'm not sure that the, you know, increase in blood pressure would cause -- make it more likely to rupture, I'm not so sure that that's well documented based on the pathology, essentially, of -- of these types of hemangiomas. I -- I don't think I buy that, that an increase in blood pressure is more likely to do that.

Q To cause the hemangioma to start bleeding?

A Correct. I don't think it's going to be more likely, yeah.

Q What causes Rusty's hemangiomas to bleed in your opinion?

A Well, the histology in the -- my, you know, or the basic structure of these hemangiomas is that No. 1, for him, they're superficial. Part of it's superficial, I mean, obviously some of it's gone up, on the inside of his neck, but in -- in -- into

his -- into his head. But part of it is actually, you can see it in -- in his mouth. And you can see that -- and you can always see, of course, some of it on his nose and on his face. And that tissue, if you were to -- in terms of Zivot -- Dr. Zivot uses his friable.

(Whereupon the reporter requested clarification.)

THE WITNESS: Friable.

I don't know if that's the best term to use, but I do agree that that hemangioma, and that, if you were to traumatize it in some way, that it would be more likely to bleed compared to, if I provided the same type of, quote, “trauma” to you.

And when I use the term, I'm -- for example, I'm thinking about if I had to intubate him, put a tube into him, you know, let's say the -- the inmate needed to have surgery, then there's -- you would normally put a tube into the windpipe to breathe for them. And use a -- what I call when I talk to patients, a metal tongue blade basically, it's called a laryngoscope, and when you insert that into the mouth, even a normal individual, could you, you, or you, or any of us, when we do that, sometimes you get bleeding. Rusty or Mr. Bucklew's going to have increased risk for that because of his tissue. If you were -- if you were to manipulate his airway in that way.

BY MR. FOGEL:

Q Through the insertion of the tube?

A Correct.

Q Right. So what -- under what other conditions would cause -- because Mr. -- as you know, and I think you observed Mr. Bucklew has some periodic experience of bleeding from his hemangiomas.

A Yes.

Q Obviously, without the insertion of a tube. To your understanding, what causes those hemangiomas to bleed in those circumstances?

A Well, there're probably parts of that hemangioma that are -- again, we have used the term “friable,” that are very, very, very thin, and just the normal, you know, maybe when he's eating something and just the act of swallowing can irritate or scrape, basically, the back of -- the back of his throat or the pallet, and cause the bleeding. He reported to me that he gets -- when he wakes up in the morning, he sometimes has blood on his -- on his sheets. So maybe there's some type of spontaneous bleeding, I don't know. Maybe -- I don't know what -- why that is happening, but he does report that.

Q Any other understanding of why or how his hemangiomas would start bleeding?

A If his airway -- if he is -- so for example, if he's snoring, on, you know, there's no doubt, of course, that, you know, the hemangioma involves his airway, he's more -- he's going to be more prone to snoring, having some sort of the tongue fall back into the back of his throat. Maybe somehow that vibration causes him to have some bleeding potentially. That could be another cause of it.

Q So we're -- we're -- you're talking about some of your observations from your examination of Rusty; is that right?

A Some of these, yes.

Q And -- and you did, in fact, Rust- -- examine Rusty --

A Yes, I did.

Q -- in person. And you documented that in your supplemental report; is that right?

A Correct.

Q So let's take a look at that.

And I'm specifically looking at paragraph 3 of your supplemental report.

A Uh-huh.

Q And it continues on -- it starts on page 2 and continues on to page 3, ending with No. 4, limited sites for IV access in upper extremities?

A Yes.

Q Do you see that?

A Yes.

Q And so does that -- is that the entirety of your observations from your examination of Mr. Bucklew?

A I think so. I mean, I -- doctors never write everything down that they observe. I mean, I'll be honest with you.

Q I -- that's fine. I just want to make sure I'm looking at --

A Right.

Q --at everything that's relevant.

A Yeah. I'll -- but that's -- I put as much down there as I thought. I mean, you know, if -- there may be some other things that I saw that I didn't put down there, but that's the vast majority of what I observed.

Q Great. Just want to make sure that we're looking at-

A Yeah. Okay.

Q -- all the information.

Why -- why did you examine Mr. Bucklew?

A Well, two -- I guess, two basic reasons: One was credibility; right? I mean, if -- if -- how can I make a medical or make an assessment of this guy if I haven't examined him, and Dr. Zivot pointed that out. And then No. 2, I do want to have a sort of independent -- be -- be -- being able to make an independent judgment of what he looks like and what the airway -- what his hemangioma looks like.

So I felt that was likewise important, so... that was the -- that was the main reason why I wanted to do that.

Q So like Dr. Zivot, you found that Rusty has a hemangioma on the right side of his face; is that right?

A Correct.

Q And -- and he has multiple hemangiomas, but you specifically focused on the one on the right side of his face; is that right?

A Well, I think that the hemangiomas, I don't know that they're anatomically completely separate, I don't know that for sure. I'm sort of thinking to call it -- call it an all -- so there's an -- obviously a hemangioma that the -- hemangioma's involving his -- the outside of his -- the exterior, external part of his right face, but of course, it's also internal.

Q Uh-huh.

A And so this hemangioma seems to be all in- -- interconnected, so you can call it one hemangioma or several. But...

Q Understood.

But you also agree with Dr. Zivot, that this hemangioma or hemangiomas, plural, affect Rusty's airway?

A Yes.

Q And how does it affect his airway?

A So he had a -- or he has a hemangioma -- the hemangioma involves his pallet --

Q Uh-huh.

A -- his uvula, his -- basically, his cheek, both in the mucosal side or the internal -- oral side, and the external. And it extends -- seems to extend down, into his tonsil region a little bit.

Q And the pallet, is that -- what does that mean? The roof of the mouth?

A Yeah, the roof of the mouth.

Q Right.

A So we talked about the hard pallet and the soft pallet. So the hard pallet is where it's hard and the soft pallet is further back where the uvula is, you know, that thing that hangs there, and is attached to the soft pallet.

Q So how -- I mean, now that you've described kind of the presence of the hemangioma, how does that affect his airway?

A Well, it causes him to have some of the symptoms that he describes, he, being Rusty Bucklew, some of the symptoms that he describes of, you know, sometimes he feels like he can't, you know, he's choking a little bit, or he has the bleeding problem, he has to -- he says that sometimes he has to sleep on his side or be in a particular position. And then, those are the primary things that he described to me. And --

Q Go ahead,

A No. No.

Q Do you have any more?

A No. No.

Q Do you know what a Mallampati is?

A Yes.

Q What is a Mallampati?

A It's a scoring system that's used in our specialty to describe a airway for the purposes of how easy it will be to intubate somebody, to manage their airway. And Mallampati is actually the name of the person who described it. It's usually, going to be a score of one to four. One, being an airway that's primarily going to be high- -- higher likelihood that it's going to be an easy airway, and a four, being a higher likelihood that it's going to be a difficult airway. But it's not absolute. For example, you can have somebody --

THE REPORTER: Can you slow down a bit.

THE WITNESS: -- with a Mallampati score of 1, who has a difficult airway. And then you can somebody who has a 4, that has an easier airway. But in general, it's going to be easier for a I and a -- a more difficult airway for a 4.

BY MR. FOGEL:

Q Does Rusty have a Mallampati 4?

A Yes.

Q And so that means that Rusty has the most difficult airway to manage?

A Higher risk for that.

Q Higher risk.

A Yeah. Higher risk is probably the way that I would say that.

Q Have you ever anesthestized somebody with a Mallampati 4 airway?

A I have.

Q How many times?

A A lot. I, you know, it's not uncommon in the population, especially, with people that are obese. Obesity increases your risk for -- because you get a lot of redunentation in the back of the -- you know, the mouth and you get, you know, a thick neck and that kind of thing, so...

Q When you, quote, “manage the airway,” what are you doing as a doctor?

A So, in -- in our specialty, you -- you have to obviously breathe for the patient. You give these drugs that stop breathing, and you have to breathe for the patient. And most of the time, you're going to do that using some type of air -- airway device. So might -- might be a mask, you know, we put a mask on you, and when -- when you're anesthetized, we can hold that mask on your face and we have a infuser machine with a circuit and with a bag, and we can actually manually inflate your lungs through that mechanism.

Q So the purpose of that is -- I'm sorry.

A If I could continue...

Q Yeah, go ahead.

A So sometimes, we put in another airway device, several airway -- there's an oral airway device that we use to help lift the tongue up, off the back of the throat and back of the mouth. We use something called an L-M-A to put in the back of the throat and then we use an endotracheal tube to go back into the back of the mouth and back, into the windpipe.

So we use all these different tools to be able to breathe for the patient, and that's called managing the airway, basically, and we use those types of techniques to make sure that we can breathe -- breathe for the patient.

Q Because they, otherwise, would not be breathing or would have difficulty breathing?

A Correct.

Q And somebody who has a Mallampati 4, is at the highest risk of having difficulty breathing?

A During that induction process of anesthetic, where you're starting to take over their breathing, yes. In a clinical setting, where the patient's going to be, hopefully, alive at the end of the procedure.

Q Do you consider Rusty's airway irrelevant in the context of your opinions in this matter?

A Yes, I do. I think that it's not -- I mean, I -- irrelevant, I mean, I do -- I do understand the concept that is being proposed here around bleeding in the airway. I don't think that's important in a sense that -- could -- could he, the inmate, bleed before, you know, during the process when he is getting the IV placed and all that? Well, he's already bleeding now. We know that. So could he bleed at that point? Yes. Is it going to be more than what he bleeds now? I -- I have no idea.

But, actually bleeding during -- after the injection of the drug, and, you know, these choking, you know, again, choking sensations, he'll be unconscious, so his airway's irrelevant in that sense. Because we're not interested in -- I'm sorry -- the State of Missouri is not interested in -- if I may use that term, I'm sort of putting maybe words in their mouth -- but they're not interested in -- in this airway issue because the intended outcome is death; it's not to keep someone alive. So airway management is really not that important at all. That's sort of my perspective on that.

Q So you -- airway management is, I understand you would say that State of Missouri doesn't think it's relevant because he's going to die, but is airway management not relevant only after he's rendered unconsciousness? Is that your opinion?

A Repeat the question.

(Whereupon the record was read.)

THE WITNESS: I'm hesitating here, I'm thinking why -- why would it be relevant before he is unconscious? I -- I -- I have thought about scenarios. Would -- would there be something that would stop -- stop the execution? Well, I suppose. I mean, not to -- not to put too silly of a point out there, but I'm reminded of what happened last night at the Oscars, where the wrong envelope was presented to Warren Beatty? You know, what if the governor said, "Go ahead and -- and in this execution. And oops, I made a mistake and I meant stop," and they've already started, I mean, I'm not -- I suppose you could think of scenarios like that, where you -- or the, you know, Missouri has to, now, resuscitate an inmate, you know, of course, in that -- in that particular case, Rusty Bucklew, with his airway and all that, is going to be more of an issue.

But beyond that, I'm grasping at, you know, reasons why the airway would be an issue beforehand. I mean, it just -- I -- I -- my opinion about what -- what the case is being made, here, about Dr. Zivot is, that he -- and -- and others, perhaps, are applying clinical or they're taking a clinical perspective on this execution when I don't think that applies.

BY MR. FOGEL:

Q Aren't you drawing upon your clinical knowledge and expertise in order to render an opinion here?

A Well, I'm not -- I --I -- I'm not -- maybe I didn't make that clear.

He is -- he is basically saying -- if I understand what he's written, he's basically saying, you know, this inmate has a -- an abnormal airway, and therefore, he's at higher risk for problems during this execution. Well, I agree with him, that Bucklew has an abnormal airway, but it doesn't affect the intended outcome. It doesn't impact the intended outcome.

If I were anesthetizing Bucklew for a clinical procedure, absolutely, I'd be concerned at his airway, both, before and after he was unconscious. But not for the lethal injection, so...

Q Let me make sure I'm following here: Because it doesn't affect the intended outcome, meaning, that he dies?

A Correct.

Q Correct. Do you not understand -- do you understand that Dr. Zivot was not addressing whether or not he would die, but whether he would die in violation of the 8th Amendment, meaning intolerably suffering during during a procedure?

A Well, that's, I think, what he was -- he was certainly trying to get at in some of his -- in his reports. But I think my interpretation of he was saying in some of his reports, might -- again, my interpretation is that he's misapplying -- he's sort of conflating, you know, the clinical picture of someone who's going to be, you know, the intention is that they be alive at the end of the procedure with what occurs in an execution. So...

Q Sure. But maybe we just need go back to the questions that we were talking about earlier, at the beginning of the deposition.,

Do you think Rusty would suffer any pain and suffering as a result of his blocked airway during the course of the execution?

A The answer to that is, I don't think he will suffer or have any pain. Aside from, again, starting the IV, and, you know, could he have a massive bleeding prior to that? I suppose that's possible.

Q So you don't know if Rusty might -- his hemangiomas might start bleeding during the procedure?

A They probably -- my guess is that they -- you know, I don't know, we don't know. You won't know that until, you know, if- if this -- this if the execution occurs, but...

Q Could Rusty choke on his blood?

A Well, he would -- so he could have bleeding after he's unconscious or before he's unconscious, and he could aspirate that blood. You know, I mean, that's entirely possible because that, you know, his -- his hemangioma, we don't know what the -- the course of that will be exactly. But, you know, that is a possibility, but that -- but it may never happen either. I mean, it's possible that it would never happen. While he was awake, he would have a massive bleeding that would cause him to choke on his blood, so...

Q Do you think Rusty's at an increased risk of bleeding from his hemangiomas as a result of execution procedure?

A I'm trying to think of a scenario whereby the -- he -- he would be at increased risk.

So could an increase in blood pressure cause that? In my opinion, unless it was a massive increase in his blood pressure, I don't think that it would, you know, affect it. I mean, his blood pressure was 144 over 100 when I examined him and I think it was very similar to, if not identical, to when Dr. Zivot examined him. You know I -- is it a increased risk, I -- I think that was your question, yes, it is increased, but I think a small relative increase in his risk during the execution protocol. Because, you know, he's going to be stressed, like anybody would be, if you're, you know, you have impending death. But I think that risk is -- is pretty small.

Q Do you think it's relevant whether Rusty suffers any pain and suffering, notwithstanding the fact that he was going to die at the conclusion -- that he would die at the conclusion of the execution process?

A Do I think it's --

Could you repeat that question, please.

(Whereupon the record was read.)

MR. SPILLANE: I'm going to object to the form of the question. Because the doctor probably needs to know relevant to what.

BY MR. FOGEL:

Q Well, it's a very -- I mean, we can start with that baseline question: Do you think it's relevant whether he suffers any pain and suffering?

A I think it is, from a -- and I'm going to get off into a legal/constitutional area that maybe I don't have the expertise to, but I -- any method of execution, for the most part, is going to involve some type of pain and suffering. So, you know, is it -- is it relevant? I think it's only relevant if-- if you think that it's going to -- it's going to be more than what would be legally permissible, I guess.

So I don't want to say it's not relevant at all. But in -- you know, in this particular case -- and that's, of course, why we're here -- I don't see the -- the type of suffering, as you say, that we're talking about here, I don't see that as being any more or any less than what, you know, the suffering that he already has. I mean, he already has symptoms; right? He already talks about, he -- he -- he has these gasping, choking, bleeding episodes. So -- and none of us can do anything about that.

I don't see that that's going to be -- marked the increase as a result of this execution process. So I'm not sure that answers your question, but -- so I don't want to say it's in- -- you know, the suffering is irrelevant, but it's just -- you know, I -- I --

Q Well, you -- you used the term “legally permissible,” do you have an understanding, an independent understanding of what is a legally permissible amount of pain and suffering?

A I mean, I have sort of a-- I guess, a layperson's understanding of it.

Q Right And did you apply that in the context of your opinion here? Did you render an opinion on what would be a legally permissible amount of pain and suffering?

A No, I don't think so. I don't think I did that, I mean, I just looked at the amount of pain and suffering that I think that somebody would have in general with -- with -- with this protocol. Which, again, I mentioned, you know, you're starting an intravenous line, so that is painful or can be painful.

Within the setting of this particular individual, I just don't think that there is a -- would be a marked increase in his pain and suffering, you know, preceding the injection of the drug. But does that -- I -- I don't know what the -- again, I have sort of a vague understanding of what would be sort of permissible, but 1 don't know -- I mean, it is a -- I guess a judgment call, in regards to, you know, what's permissible and what's not. But I didn't apply that in this particular case, I just sort of looked at the, you know, facts of the case, you know, my medical and scientific background, determine how the drug's going to work, and would the drug work in -- in the -- its intended way.

Q So let's focus more specifically on the actual opinion that you rendered.

A Okay.

Q And if you go to paragraph 26 of your November 2016 report, so this will be Exhibit 1.

A Uh-huh. Okay.

Q And the paragraph starts, (reading):

“It is my opinion, to a reasonable degree of medical and scientific certainty” And then you list --

A Yes.

Q -- five different --

And first, as a threshold matter, are all the opinions that you're rendering captured here, in paragraph 26?

A I wouldn't say all of them. I'm sure I have other opinions in this -- in my other report.

Q In your supplemental report?

A Yeah. But I probably -- I probably have opinions that are in here that I didn't put in my conclusion, I think these are the main ones that I put in there.

Q Okay. And No. 3 is, (reading continued):

"Injection of massive doses of barbiturates in this inmate would not inflict mild, moderate, or severe pain." Did I read that right?

A Yes, I read that.

Q And let me ask you, what are the basis of this conclusion?

A For No. 3?

Q Uh-huh.

A Well, the injection process of actually injecting the drug, if done the way it should be done, which is with a well-functioning IV, that is not a painful process, to actually inject the drug into a well-functioning IV.

Q So you're assuming that there's a well-functioning IV?

A That's correct.

Q Does the fact that Rusty has a challenging or it could be challenging to access Rusty's IVs, render it more or less likely that the IV would be well-functioning?

MR. SPILLANE: I'm going to object to the form of the question. I think he said it would be challenging to access his IVs, I think he means challenging to access his veins.

MR. FOGEL: Thank you for correcting me.

BY MR. FOGEL:

Q With that clarification, please go ahead.

A Repeat the question now that we've -- or maybe you just want to repeat it then.

Q Sure. Because based on your prior -- on your observations of Rusty, you concluded that it would be challenging to access his veins, does it make it more or less likely that you would have a well-functioning IV line?

A It would be less likely that you would have success of get having a well-functioning IV line.

Q Does that at all affect your opinion at No. 3?

A No.

Q Why not?

A Because my understanding of the protocol is, that the drugs would not be injected unless there was a well-functioning IV, either a peripheral or a central line. So maybe some clarification would -- was -- should have been added to that, but my assumption there, based on what I read in the protocol, is that you have a well-functioning IV. And having a well-functioning IV, either a peripheral one or a central one, the actual injection of the -- of the drug would not inflict mild, moderate, or severe pain has I had written there.

Q Right. You're assuming, though, that there is a well-functioning IV line?

A I am assuming that, yup.

Q Now, at No. 5, you also say, (reading):

"Any pain and suffering that he risks during an execution using Pentobarbital is not a greater quality or magnitude than a risk of pain and suffering that he currently experiences and the risk would end up a rapid unconsciousness from the injection of Pentobarbital."

A Yes.

Q What were the bases for that opinion?

A Well, he is suffering or, you know, he's having these symptoms as it is. He's having episodes of bleeding, he -- he has episodes where he can't -- he -- he has -- I can't remember the exact term that he uses, but airway closure and he gasps, things like that. Choking sensations. And that, you know, those are going to -- those will continue, you know, up to his death, probably. Whether it's by natural causes or by execution, I mean, this is a -- that's nature of the hemangioma, I mean, his symptoms are not going to get any better. So he carries that risk all the way up to his death, whether it's natural or by execution.

And basically, the only way that he will -- that suffering and pain and, you know, symptoms that he has will stop, will be when he, you know, during times when he's asleep; right? He's not going to experience those because, by -- by definition he's asleep. Or when he's -- achieves or when he's given the Pentobarbital or, you know, if he was -- had to have surgery for something else and he was given, you know, those -- those episodes, where he'd be unconscious, where he wouldn't have those symptoms. That's essentially what I'm writing there -- or what I've written there.

Q Okay. Any other basis you relied upon in order to form that opinion?

A Not that I can recall.

Q And here, at paragraph 26, you also mentioned that you rendered some other opinions that would be set forth in your supplemental report?

A Uh-huh.

Q Is that right?

Can you direct me to where I can find those opinions in your supplemental report?

A Well, opinions about what? Just all -- any of my opinions?

Q What -- what are the opinions? You said you had rendered some additional opinions in your supplemental report.

A Well, I think all of the paragraph that I've wrote in any supplemental report are opinions. I guess, I'm not sure what, specifically, you're --

Q Are there any conclusions --

A Oh.

Q -- similar to how you phrased it --

A Oh, I see.

Q -- in your opening report?

A Well, as we've discussed, I gave my opinion and assessment of his -- my physical examination, my -- my history and physical examination, which are shown on pages and 3.

Q Uh-huh.

A My opinion assessment of his airway -- or my assessment of his airway doesn't alter my opinion regarding the actions of the -- of the Pentobarbital, which is that you've got rapid unconsciousness and respiratory rest.

I gave an opinion about my -- what I wrote regarding the Pentobarbital action in the prior supplement, and then I clarified -- or in the prior opinion, and I clarified that in terms of action, adding the timeframe, along with the physiological responses to the Pentobarbital. And then even if there was bleeding in his airway after the Pentobarbital, that the -- the inmate would be unconscious and deeply unconscious, and unable to sense that bleeding.

And then I go on to talk about the --

Q So you're essentially just flipping through your report right now?

A I am. THE REPORTER: Hang on. One at a time.

BY MR. FOGEL:

Q So you're flipping through your report?

A Yes.

Q All I was asking was, for you to identify if there's another section in your supplemental report --

A I see.

Q -- that sets forth your conclusions similar to what you have done in your opening report.

A All right, I -- I -- I'm sorry, I just don't know how to answer your question. I mean, I'd have to go word through word --

Q No. No, that's fine.

A Yeah.

Q You said you had rendered some additional opinions here --

A Oh, I'm sorry.

Q -- in your supplemental report, so I was just asking you to point out what you had meant or what you were referring to.

A Oh, I see.

Q And what you were saying.

A Yeah. I -- I talk about, for example, I clarified some issues around the action of the drug, how quickly I think it would work. You know, the physiological effects, why death occurs from the Pentobarbital. I -- obviously, I refute some of the things that Dr. Zivot states, so --

Q Sure.

A -- I'm not sure I actually --

Q Okay. Sure.

A I'm not sure I actually changed my conclusion --

Q I think we're on the same page.

A Yeah.

Q Okay. I think we're on the same page.

And I think that's probably a good point to -- you want to break for lunch at this point?

MR. SPILLANE: Okay.

THE WITNESS: Sure.

(At 11:55 p.m., the deposition adjourned for lunch.)

(At 12:34 p.m., the deposition of Joseph F. Antognini was reconvened.)

BY MR. FOGEL:

Q Dr. Antognini, right before our break, we were talking about the opinions you've offered in this case.

A Uh-huh.

Q Aside from the opinions that are set forth in your two reports, do you intend to offer an opinion on anything else?

A I guess, if I was asked. I'm intending to write another report. If I mean, do you mean in the context of offering something right now, more opinions? Or in...

Q At -- at any point, between when you last submitted your supplemental report --

A Uh-huh.

Q -- going forward to this moment, do you intend to offer any other opinions?

A There are some details that I think probably are worth explaining, relative to some of the drug-level issues that I talked about and I think are worthwhile understanding, that I don't think have been completely fully elucidated -- or not elucidated, but fully described.

Q Right.

A So yes, I guess there are opinions and things that I want to say that I haven't said yet.

Q During the course of today's deposition?

A During the course of today's deposition.

Q But you're -- you do not in!end to issue another formal opinion, be it, in a report?

A I don't have that intention --

Q Yeah.

A -- but sometimes, I don't know what I'm going to be asked to do.

Q That's fine. Just asking about your present intention.

A Yeah. Okay.

Q Are you offering any opinions on the feasibility of lethal gas as an alternative method of execution?

A Do 1? Or have I? Or sorry, what was the question?

Q Have you or are you --

A Or have I.

Q -- offering any opinions on the feasibility of gas as an alternative of lethal injection?

A On my initial report, first one that is on -- the one dated November 8th, I did offer an opinion, that's summary 23 of that report where I -- so obviously, we're, not sure, aware of the some of the ethical issues around recommending one method of execution over another, I guess that's an ethical issue for -- for me, not so much for anyone else. But I did talk about the use of lethal gas and basically, I don't offer an opinion about one being better than the other, because I just think that -- that my understanding of the use of a lethal gas, and obviously, there are many kinds of gases that can be lethal, that that would not affect the risk of an innate, in particular, this inmate, suffering one way or the other, you know, suffering more.

Q Right. Are you aware that the state has taken the position that lethal gas is not that viable alternative to lethal injection?

A I am aware that -- again, I'm sorry, I'm going to have to get into some legal terms that I've -- I've heard and I think I have an understanding of them, but basically, that it has to be readily available -- a readily available alternative, so what -- whether you say that it's -- I'm sorry, I'm -- I'm going off on a tangent.

Q I don't -- I don't intend to make this complicated.

I -- are you offering any opinions on the viability of lethal gas as an alternative method of execution? I understand you've rendered opinions in terms of whether it would be more or less painful in relation to lethal injection.

My question is, are you offering any opinions in terms of its viability --

A Oh, I see.

Q -- as an option?

A No, I'm not -- I have no knowledge, really, about whether lethal gas is readily available or viable in this area or -- or not, I have no idea what --

Q That's what I thought.

A Okay. Yeah.

Q Just wanted to be clear.

A Sorry, yeah.

Q No, that's fine. Are you offering any legal opinions as to whether execution, in the manner as described, by lethal injection, would constitute a violation of Mr. Bucklew's 8th Amendment rights?

A Well, I don't really -- I can't -- I'm not in a position to offer a legal opinion, but I -- I will say that I was -- I did review some court cases, like Glossip, and they talk about -- and then Baez, they talk about the issue around; you know, substantial risk, so -- I mean, I do have that understanding, but I don't think I'm really offering an opinion, one way or the other, on that.

Q Okay. Are you aware of any errors in your reports?

A Any errors?

Q Either, in the original or the supplement?

A Am I aware of any errors in my report?

Q If you're not aware of any--

A I'm not.

Q -- right now, I'm not asking you to look.

A Yeah.

Q Just, is there anything that you want to correct?

A Maybe I should have thought about that question being asked, I wasn't -- there are probably things that I would have said differently, I guess, to make it clear, but I don't think I have any errors, so to speak, in this report that I'm --

Q Just--just giving you an opportunity--

A Yeah.

Q -- if there was something that you already identified that you wanted to correct.

A Okay. Well, I appreciate that.

Q And if the answer's “no,” it's no.

Have you been asked by counsel to undertake any additional or supplemental analyses since you've drafted these reports?

A No, I did not. I was not asked of that, but I did -- I did do it, I mean, on my own. I -- for example, I found that article that I, again, will provide to you, but I wasn't asked by Mr. Spillane or anyone else to --

Q Have you done any other -- besides identifying that article, any other supplemental work or additional work beyond your supplemental report?

A Let's see, so I looked at that -- let's see, I -- I did review -- I did look at some news articles on some, you know, art or executions that occurred in Missouri, and some of which were actually written by some of the witnesses, and that's not mentioned in my report. So that -- now that I think about that, I did look at that.

Q Uh-huh.

A So let's see, other analyses that I -- no, I don't think so. I mean, there -- my -- my approach I'll be, you know, of course, I'm going to -- I'm going to be upfront about any approach, I mean, there are certainly articles-- for example, articles that -- scientific articles, that I've looked at in my search for some information on this, that I didn't include in my report.

Q Uh-huh.

A And I don't think those articles influenced my -- my opinion, because they weren't -- they turned out not to be something that I could use or I thought was relevant to what -- to what I was looking at. So I looked at those.

Q Right.

A I mean, I don't have a list of those because I never used them, you know.

Q That's fine.

A Okay.

Q That's fine.

Did you have to make any assumptions in forming your opinions in this case?

A Yes.

Q We've talked a little bit about some of them already.

A Such as the speed of injection.

Q The speed of injection.

And what did you assume the speed of injection to be?

A My assessment -- or my assumption is probably going to be around I ML per second, that's my -- that's my assumption.

Q And that was based on --

A Just how quickly I inject drugs -- or would inject drugs in a -- in a human. In fact, quite frankly, I probably inject -- if I were to -- I inject drugs more quickly than that.

Q Okay.

A I mean, quite frankly, I do inject drugs more quickly than that, but that was sort of on the slow side, I just made an assumption that it be on the slow side,

Q We also talked about having a -- I think you called it a functional IV line?

A Yes.

Q A well-functioning IV line?

A That's --

Q You made an assumption that would be true?

A Yes, that's true. I -- I assume that an IV has to be functioning, well-functioning.

Q Any other assumptions?

A Well, on -- we assume that the individuals that do this are trained --

Q Uh-huh.

A -- and that they've, you know, they've done this before. Or -- or obviously, may be the first time for somebody, it's got to be the first time for somebody, at some point in their life. But in general, these individuals are going to be trained in the various techniques that need to be used, so make that -- I had to make that assumption.

Q For example, when we saw on the open protocol that it referenced --

A Yes.

Q -- you know, provided there are, you know, sufficient expertise or trained individuals.

A Yes. That's what I'm referring to.

Q Okay. Anything else -- well, let me --

A Well, and the drug has to be effective; right? It has to be Pentobarbital. I mean, you assume it's going to be Pentobarbital, so you have to -- I mean, those types of assumptions, you have to make.

Q Uh-huh.

A I mean, there might -- I'm probably sure there are others, I just, off the top of my head, those are the ones that come to mind.

Q Have you met the execution medical team?

A No.

Q Are you familiar with --

A I mean, I don't know -- I mean, I have not. I mean, to my knowledge. I mean, right? I was in Missouri --

Q Yeah.

A -- for -- for one reason or another, a couple times recently. Once, to examine the -- the -- the inmate, and then to -- for other business. I could have met them, but I wouldn't have known it.

Q Are you familiar with their training?

A I understand that one of them is an anesthesiologist, and I believe there's a nurse involved, and there might be a -- maybe a paramedic or something, I'm not sure. I'm not sure about the exact competition of the execution team. Except, I think one's an anesthesiologist, and one's a nurse -- and I'm not even sure they're actually involved in the -- I mean, I guess you have a question, what does “involved” mean? But I think they are a part of the team.

Q And you assume they had sufficient medical training and experience?

A Yes.

Q As we've discussed?

A Yes.

Q Okay. Are you also assuming that the execution team, including the medical staff as you described, would be familiar with Mr. Bucklew's medical condition being cavernous hemangioma?

A Yes. I -- I -- I assumed that. And my understanding, I believe Missouri does a pre-check of the inmate beforehand, so they -- they review the -- the clinical history. I -- I think. I may be wrong about that, I don't -- that's my recollection. So they certainly would know about it, but that's my assumption as well.

Q When you say “they,” you're referring to the execution team? Or the medical members of the execution team?

A I don't know who is reviewing what. But my understanding is, that there was a review of that process.

Q Right,

A But-

Q But you don't know what information is actually provided --

A No.

Q -- to the medical team?

A I do not know that, no.

Q So you're assuming that they're given a sufficient level of knowledge needed?

A Yes.

Q Let me ask you: In your personal experience, what information do you deem important regarding a patient before you administer an anesthetic?

A So we do a thorough history and physical, and we look at -- I mean, it's focussed in the sense that we do look at particular organ systems, and -- and -- and review of -- of -- of systems. So for example, I'd be interested in knowing their exercise tolerance, what medications they're on, I'd be interested in knowing what their prior experience with an anesthetic is,

During the -- the physical examination, I'd be looking at their vital signs, their weight, I'd be looking at their airway, listening to their heart and lungs. So those are the things that I would be focusing on, I mean, that's not everything, but that would be a lot of what I would be focusing on.

Q You, personally as the --

A As-

Q -- as the individual administering the anesthetic; correct?

A Correct.

Q And why would it be important for you to become familiar or knowledgeable with that information?

A Well, it impacts what type of anesthetic we use, what the risk would be to the patient. You know, managing the airway, it's just good practice to -- to -- to do that, because I -- you know, another example -- or another thing we look for is, a drug allergy; right? You might be allergic to some of the drugs that I want to use, so I have to get that information as well.

Q Are you assuming that all the information that you just described would be available to the medical execution team?

A Yes. I -- based on my understanding, I assume they -- they would -- they would have that information. Or somebody on the team would have that information.

Q Somebody present for the --

A Present, yeah,

Q -- execution?

A That's why, in my assumption. I'm not sure that it makes a big difference, though, but that's my assumption in terms of how the execution is carried out.

Q Do you know what a gurney is?

A Yes.

Q What is a gurney?

A It is a -- basically, a -- a bed with wheels -- a small bed with wheels, with a mattress on it, that a -- a patient would lay on. If they're waiting to have a procedure done, they're waiting in the preop area before surgery, things like that, yeah. And it has wheels on it so you can wheel them around.

Q What is your understanding of the use of a gurney in the context of Missouri's execution protocol?

A I don't know what they use, if they have a gurney, if they have an OR table. I've -- I've seen a picture of it from the internet, I think. I don't know whether -- I don't think it's a gurney, but I'm not -- I'm not sure. I thought it might be an OR table, but I'm not positive, or a procedural table, I don't really know, I don't recall.

Q Whatever device or sorry, not device --

A Yeah.

Q -- whatever structure, whether it be an OR table or a gurney --

A Yeah.

Q -- that an inmate would be lying on during the course of the execution, did you make any assumptions regarding whether that gurney or OR table is adjustable?

A I did assume that it could be adjusted so that someone could use it in the sitting position or semi-recumbent, semisitting position. Again, based on my understanding of and experience with gurneys, I mean, almost all gurneys are going to have the ability to sit somebody up, and all OR tables, likewise, have that. So I did assume that would be the case in -- in -- in Missouri.

Q You -- you don't know for sure?

A But I don't know for sure.

Q You don't know for sure; right?

A I don't know for sure.

Q If you found out the gurney was not adjustable, would that affect the opinions that you've rendered in this case?

A No, I don't think so. You wouldn't have to have an adjustable table. I mean, if you needed to sit somebody up, you could do it in other ways besides having a gurney that didn't sit up. You could use a lot of pillows or you -- you could use other devices like that.

For that matter, you could use a chair, quite frankly. I didn't see any reason why a chair wouldn't, you know... if you wanted to anesthetize somebody, you could do it in -- in a chair. I mean, we wouldn't do that clinically. Again, I'm not sort of rendering an opinion about what Missouri should do, but, you know, certainly, in the clinical setting, you could anesthetize people in a sitting position.

Q Is somebody in a clinical setting, when they're anesthetized in a sitting position, are they strapped into the chair?

A Well, we wouldn't use -- I -- I said chair, and you could do that, but you never would do that clinically. Except, I guess, in -- if it's in a dentist chair. I mean, that's not really a chair like I'm sitting in right now, but you could anesthetize somebody in a chair like that. And I apologize, I'm not sure I -- what was the question?

Q Do you have an understanding -- let me ask a different question: Do you have an understanding of whether the inmate is to be strapped down during the course of the execution?

A I believe -- or I assume that they are strapped down, because I've seen straps on these things, on these gurneys or tables or whatever they are, based on the pictures I've seen, and there are straps. So my guess is, that they are strapped down for the, I guess, obvious reason that, they would pull the IV out if they, I mean, almost anybody would that if they knew they were going to get a lethal injection.

Q If it was determined or if you determined that the individual was required to be in a supine position, so a flat position, would that affect your opinion that you rendered in this matter?

A If-- if the -- Bucklew was required to be in the supine position, and he does state he has worsening symptoms -- his symptoms are worse when he's lying supine, you know, than when he's awake, then if -- and he says that his symptoms are worse when he's awake, when he's lying supine, then, yeah, laying supine would be potentially a problem for him.

Now, having said that, he was able to tolerate an MRI, he was supine for more than an hour, he said. So he is able to -- to lie supine.

Q Who said that he was able to tolerate lying in a supine position for the MRI?

A He did, when I examined him. I didn't say that in my report I don't think, but there it is, he did say that. I'm not sure if I said that or not. I think it's somewhere in --

Q So we talked earlier and now we're looking, to state for the record, we're looking at Exhibit 2, your supplemental report. And this contains your summary of your examination of Mr. Bucklew, can you point to me where --

A Yes.

Q -- in your summary he told you --

A So-

Q I that he was lying --

A -- in paragraph 7, it says -- I -- I quote Dr. Zivot in his publication, and I write, (reading):

"Bucklew can, in fact, lie flat, according to the inmate, he did so for about one hour while undergoing his recent imaging studies. While he stated he was not comfortable, he was nonetheless able to be flat,"

Q So when you say "the inmate," are you referring to Mr. Bucklew there?

A Yes.

Q Well, of course, when Mr. Bucklew was undergoing the MRI, he was conscious; correct?

A Yes.

Q Is that -- did you take that into consideration when considering whether Mr. Bucklew could make certain accommodations to handle lying in a flat position?

A Yes. I mean, obviously, if he needs to adjust -- and he said that, he needs -- he needs to be able to adjust his breathing pattern, when -- I -- that's my -- kind of my term that I use, I'm not sure exact words that he used, but to adjust his breathing pattern essentially to be able to tolerate that.

Q Adjust his breathing pattern, how so?

A Well, if-- if he felt as though he was -- maybe his uvula, which, of course, is involved with a hemangioma, was getting stuck in the back of his throat, he might be able to position that in some way that he would be able to minimize that. However, with the MRI that was performed on the -- the imaging studies that he -- that are performed, obviously, of his head, his head has to be pretty motionless, you know, he has to keep still, so it didn't require much -- I mean, he couldn't be moving a lot to be able to do that, because you wouldn't be able to get a good image study.

So I just don't see -- I mean, again, if he said, "I was able to -- to lie flat, and it wasn't comfortable, but I was able to do it," then I have to imagine, if-- if this -- if he was suffering -- had incredible amount of suffering from lying flat, he would not be able to -- to do it. And they would not have been able to do the MRI study or the other imaging studies as well.

Q You did not, personally, observe Rusty lie flat during the -- during the MRI; is that right?

A No, I did not.

Q Do you have any other basis for your conclusion aside from what Rusty -- you said Rusty told you during the examination?

A Yeah. I -- I thought Dr. Zivot said the same thing, but I'd have to refer to his report to see maybe I mis- -- maybe I don't know that. You know, but I thought he said essentially the same thing.

If we have Dr. Zivot's report somewhere, I could --

Q We do.

A -- look at that.

MR. FOGEL: We're at 6.

(Whereupon Exhibit 6 was marked for identification by the court reporter and is attached hereto.)

THE WITNESS: And this would be his supplemental report.

BY MR. FOGEL:

Q Is that right?

A Right. I could be wrong about that, but I thought I might have seen --

Q That's why we gave you the report.

A Yeah. Too bad we didn't have this as a -- I know we have it as a PDF, you could search for the word, it would be a lot faster. Okay, So -- all right. Let me go back this way.

Q And doctor?

A Yes.

Q Is your recollection or what you might be looking for, that Dr. Zivot said that he -- Rusty lied flat during the MRI, is that what you're saying?

A That he lied --

Q And-

A That -- that -- my -- my recollection was that he made a statement, similar to mine, which is that, yeah, he was able to lie flat, but he wasn't comfortable. He probably didn't use those words, but my recollection may be wrong, maybe he didn't say that at all. I mean, he just -- I'm trying to find the spot where he talks about the -- the MRI was -- showed that the mass was smaller.

Okay. He reported, (reading):

“Experiencing extreme discomfort during the procedure. In order to maintain the integrity of his airway while lying flat, Mr. Bucklew was forced to consciously alter his breathing pattern and swallow repeatedly to keep his uvula from settling and completely obstructing his airway in order to avoid checking.”

Bucklew did not report to me or say extreme discomfort. So --

Q That last sentence you just said, are you reading from Dr. Zivot's report? Or are you just --

A From -- sorry. So I read from No. 7, on page 8. Where -- where Dr. Zivot asked Bucklew to describe his experience during the MRI procedure. So --

Q Do you think Mr. Bucklew would be capable of doing, as he told-- excuse me, Dr. Zivot during the execution process? Meaning, consciously alter his breathing pattern and swallow repeatedly to keep his uvula from settling and completely obstructing his airway in order to avoid choking?

A He would be able to do that when he's awake. But once he's received Pentobarbital and he's unconscious, he's -- he's not capable of doing anything. But it wouldn't be necessary for him to be able to clear his airway because he's not going to sense any type of blockage.

Q Sure.

A Yeah.

Q And I understand that's another part of your opinion, which we'll get to later, but --

A Right.

Q -- just, there is a distinction, do you agree, between when Mr. Bucklew is conscious during an MRI procedure versus the execution protocol -- under the execution protocol, when he's administered Pentobarbital? In terms of his ability to manage his airway.

A There is a difference in a sense that, obviously, an individual who's about ready to die is probably going to be stressed. But I don't know what other difference there would be, I mean, I don't know how to address that issue about him having an MRI or having, you know, lying flat for -- for an execution in terms of, you know, the difference between his ability to maintain his airway.

Q Well, you were drawing a comparison. Because we were talking about whether the gumey --

A Right.

Q Assuming it's a gurney. Whether he's lying flat and what that might mean in terms of his ability to manage his airway, and what pain and suffering he might suffer or endure. And you said, drawing upon your examination, that because he was lying on an MRI table for an hour, you thought it would not be an issue?

A That is correct. That he -- so --

Q And -- and -- sorry.

A So the question that I'm thinking in my mind or to answer your -- your question about this is that, can Bucklew lie flat for an extended period of time? And in this case, we'll make it an hour, because that's apparently how long he had to lie flat for these exams. And, yes, he could do that. Was it comfortable for him? No, it wasn't.

He described it not being comfortable, but he was able to do it. So could he do that on an execution table, would he do it on an execution table? I don't know. I mean, my guess is that -- my opinion is that he could do it if he wanted to. On the execution table, he could maintain his airways, just like he did in the MRI scanner.

Now, the question is, would he want to? I don't know. I mean, his alternative is that he's going to choke while he's awake, but that's something he's going to be doing on his own. But clearly, he's able to -- to maintain his airway lying flat, because he did so on the MRI exam.

Q Under extreme discomfort, do you dispute that he experienced it under extreme discomfort?

A I dispute the term “extreme,” that's not the way he described it to me. He, being Bucklew.

Q Do you agree that lying in that position causes stress?

A For him, lying -- lying flat, yes. That would increase his stress level, because he has to focus on his airway management basically.

Q Does it make it more difficult for him to breathe, lying in the supine position?

A Compared to a semirecumbent or sitting position, yes.

Q Okay, Do you consider an execution a medical act?

A No.

Q How is a physician's practice applicable to the execution setting?

A A physician's -- say that? A physician's --

Q Well, we've -- you -- you've referenced the clinical setting --

A Yeah.

Q -- a handful of times today. How is that different than an execution setting?

A Well, obviously, many things that are done in an execution setting are things that we've done in a clinical setting, so start an intravenous line, if we have to start -- if they have to start a -- a central line, those are things that we do clinically. Clinically injecting the drugs.

But some of those things we would do in a clinical setting, you wouldn't do, I guess, based on my understanding, in the execution setting. So you wouldn't -- you'd give a much larger dose of the drug, you wouldn't resuscitate them and so forth. You wouldn't breathe for them, that kind of thing.

Q So there are some things that happen in the clinical setting that are not applicable to the execution setting and vice versa?

A Correct.

Q Can you look at Exhibit A to your November 2016 report? It's Exhibit 1.

A Uh-huh. Yeah.

Q And is Exhibit 1 your curriculum vitae?

A It is.

Q Or your CV?

A Yes. Uh-huh.

Q Is this accurate? Are there any changes that need to be made?

A To my knowledge, it's all accurate. I am still, to my knowledge, a -- a voluntary clinical professor of anesthesiology at UC Davis. I haven't been told otherwise, I currently work part-time for the joint commission...

Q So you did not include a CV with your supplemental report?

A Yeah.

Q So this is --

A That's correct.

Q -- the true and correct version?

A Yes, that's correct. It has not changed since then, so...

Q Now, it says from September 16 -- excuse me, September 2016 through present, and I'm looking under professional positions --

A Yes.

Q -- on the first page of your CV, you're a physician's surveyor --

A Correct.

Q -- is that right?

A Yes.

Q What -- what is -- is that?

A So the joint commission -- what the joint commission does is, they survey hospitals. So they go to hospitals and they look at different processes, and there's usually a group of three to four to five people that do that, and usually it's a physician that's in -- at least one of the individuals is a physician. And they might look at certain things that would only apply to his sort of physician-involved activities, and so that's what I -- I do. I might survey parts of a hospital that a nurse would survey, but there are some specific areas where only the physicians survey. So they-hire physicians to do that.

Q And what exactly are you surveying?

A As a physician?

Q Yeah.

A So I might go in to the operating room and watch their processes of how they manage their instruments, how they -- there's something that's called a timeout, where you're supposed to take a time out and you identify the patient before the procedure, you know, the right -- is it the right patient having the right procedure, that kind of thing.

So you make observations of their practice, doing things like that. It's -- you make observation of how patients are taken care of in the intensive care unit, so you might look at some orders and say, “Well, the physician ordered such and such, did the nurses Follow those orders?” So it's really more around looking at processes, some of these clinical and operational processes --

Q Sure. You, yourself, though, are not operating --

A No, I am not.

Q -- on a patient?

A No, I am not.

Q Got it.

A No.

Q Are you operating -- or currently --

A I am not.

Q -- practicing as an anesthesiologist in any capacity?

A I have not anesthetized anybody since December of 2015, so it's been over a year. So I'm not clinically active right now.

Q Are you retired?

A From the clinical practice of anesthesiology, 1 retired. I'm not doing it. Will I return to it? Never know, but right now, I'm not doing it.

Q Why did you retire?

A Mostly personal reasons. So we have a son that moved down to Escondido area, we wanted to be closer to him, there was a time in my life where I could do that, so I just -• financially, I can do it, so I just decided to stop practicing.

Q Is there a -- do you have a medical license?

A I do.

Q Is your license currently active?

A Yes.

Q Ever been suspended?

A No.

Q Are you currently a professor of anesthesiology?

A My title is voluntary clinical -- where is my CV here. Have to pull it up. I believe that's the accurate title: Clinical Professor of Anesthesiology and Pain Medicine. And it's a voluntary clinical faculty appointment.

To my knowledge, that's still active, I haven't been told otherwise by UC Davis. When I was there the last couple of years, that was the title -- the -- I had the clinical professor part, but the volunteer part was only made once I -- I retired and became a volunteer, basically. So I think that's an accurate statement. And the reason why I may be a little bit equivocated on that is, because, you know, if you were to call UC Davis and say, “What's Dr. Antognini's title?” Sometimes the -- it might be professor of clinical anesthesiology and pain medicine, not clinical professor. And some of these series are a little bit confusing about that, so I think I have that correct.

Q Are you compensated for --

A No.

Q -- for your position at UC Davis?

A I am not.

Q Are you compensated for your work as a physician's surveyor?

A Yes.

Q Aside from that, do you receive any other -- what are your other current sources of income aside from, perhaps, passive investments?

A I have done work, obviously, for the State of Missouri. I've worked on other cases, which I described. Which, for example, the case in Ohio. And then I did some work for the State of Mississippi about a year ago. Similar -- lethal -- lethal injection issues, and then I also did some -- a -- legal work or expert witness work for the -- for a hospital in California that was being -- it wasn't being sued by a patient, but it was -- it was being basically fined by the State of California because of something that happened, and I represented -- I was the expert witness for the hospital in that -- in defending that.

Q Was that an administrative proceeding?

A Yes.

Q Before the N-L-R-B?

A No, I don't think it was that. I'm not sure, it was a State of California administrative hearing of some sort.

Q It was an administrate hearing?

A Yeah. It wasn't --

Q You said work you've done for the State of Missouri, have you have done work for the State of Missouri outside of this expert retainment?

A No, I don't -- no. No.

Q I just wanted to clarify what you said.

A No, I have not.

Q Okay. So let's talk about the work you've done in connection with the Ohio matter.

A Yeah. Uh-huh.

Q And did you serve as an expert witness --

A I did.

Q -- in that case?

A I did, yes.

Q And what opinions were you asked to -- or what opinions did you render in that case?

A Basically, the -- the -- there are a lot of opinions that I did render through the course of that work, but essentially, the -- the main opinion that I rendered was whether the dose of Midazolam that they were going to use, which is 500 milligrams, was sufficient to produce unconsciousness to the extent that the inmate would not experience or be -- be conscious of the other two drugs that are administered, which are a paralytic, and then potassium chloride. That was basically what I was asked to -- to render an opinion on.

Q And what was your opinion?

A My opinion was that the -- that dose of Midazolam was sufficient to render an inmate unconscious, to the extent that they would not be aware and -- and have the sensations of the two drugs, that is the pain associated with potassium chloride, and then also, the paralytic drug.

Q You said the pain that's associated with potassium chloride?

A Yes.

Q That chemical can cause pain in an individual when it's administered via an IV line?

A That's correct.

Q And so your opinion was, because the patient is unconscious at that point, they would not experience any pain?

A Yes. The inmate. The inmate would be unconscious and would not experience any pain. Which, a I said earlier, pain is a conscious awareness of a noxious stimulus.

Q How long, in that context, would it take to render the patient unconscious from the administration of Midazolam?

A Midazolam?

Q Midazolam,

A M-I-D-A-Z-O-L-A-M.

Q How long did it take to render the patient unconscious after the administration of Midazolam?

A We did not -- I do not recall if I made any opinion about how long that took, quite frankly. I -- I'm not sure I rendered an opinion on that. I'd have to review my testimony and all that.

Q You just rendered an opinion of whether or not they would be unconscious?

A I did. I could have said also, how quickly it would happen, but I don't -- I'm not sure that I actually asked -- made a statement in regards to how long it -- it would take. I'd have to review my testimony and my -- my report there.

Q Is Midazolam a barbiturate?

A No, it is not,

Q Are there any similar characteristics between Midazolam and Pentobarbital?

A They both work with the GABA receptor; although, their actions at the GABA receptor, they work at different sites of the GABA receptor, based on my understanding. So even though they both work at the GABA receptor, doesn't mean they both function in the same way. In fact, they do have -- they are dissimilar in terms of the effects that they do produce, because of that. What was -- there's more -- I'm going to answer more, but I want to make sure that I've got the question. What was the question?

Q I was asking if there were any similarities between the two drugs. And I think you probably have gotten to that question.

A So yeah, there -- so there's that similarity. I -- as I said earlier, I believe they can both produce unconsciousness. Now, can you get deeper levels with Pentobarbital than you can with Midazolam? The answer is, yes. But I -- my opinion is that the level that you achieve with Midazolam is sufficient for what its intended use in that setting.

Q So explain that to me. Deeper levels, are you referring to deeper levels of unconsciousness?

A Yes.

Q So-

A And it's --

Q Are there various levels of unconsciousness?

A Yes.

Q What does that mean? Or tell me about these various levels.

A So you could think of consciousness as being on a spectrum. So we're all awake right here; although, I can see some of you may be nodding off a little bit. But I'm not a charismatic and energetic kind of person, but anyway, that's why I'm an anesthesiologist; I put people to sleep.

But there's a spectrum. So we're all awake. And then you have basically on the other end of the spectrum, deep coma, where someone could be brain dead, basically, So there's different levels of consciousness across the spectrum. So what do I mean by that? So for example, someone may be fallen asleep, and you may say, “Larry, wake up.” And you don't wake up, but then I nudge you and you wake up. As you get into deeper sleep, even a nudge may not wake you up, I have to really shake you; right?

With drug-induced unconsciousness, there's a spectrum and you get into levels where even shaking and noxious stimulation, you don't get any response. So you can assign consciousness according to that scale, and most people would define unconsciousness as occurring when they fail to be aroused from a non-noxious stimulus.

Now, that's arbitrary, which I think came out in the -- I'm not -- I think that's, you know, some people might say it's, you know, you have to -- if-- if they arouse with a noxious stimulus, that would be sort of the line between conscious and unconscious, so there's some arbitrariness in that. But it's a spectrum, so when people throw this term around, of unconsciousness, it's not an all or none thing. It's not like you're conscious and you're unconscious, it's really a spectrum. And I think that's where a lot of the issues come up about how we apply these issues -- this type of knowledge to this setting of lethal injection.

Q Did you specify where, on this spectrum, Mr. Bucklew would be, when you state that he would experience rapid unconsciousness?

A I did not specify. I may have used the term coma somewhere in there, I don't remember if I did or not, but...

Q I -- after reviewing your report, I don't recall seeing the word coma?

A And you don't want me to go through it again.

Q Well, I guess the more fundamental question is, do you know where Mr. Bucklew would be on the spectrum of unconsciousness?

A He would be at the far end, basically brain dead. I mean, he wouldn't -- at that dose of-- of Pentobarbital, you would -- I -- I'm going to backtrack a little bit here, just to -- to clarify one thing:

So when you give a huge dose of Pentobarbital like this, again, based on my understanding of how it's given and all that, and I've never done it myself, but one of the, you know, bar -- barbiturates do decrease the blood pressure, so you're going to have a huge decrease in the blood pressure in somebody. That's sort of separate in a way from the unconsciousness that occurs from a drug.

If you could maintain their blood pressure at this large dose, you still have deep coma, like a brain-death type of coma, where the brain is silent, neurons are not firing, the EEG has flat lined. So Pentobarbital at this dose would -- I mean, even at a fraction of the dose would cause that type of picture. So Pentobarbital, you'd be at the far end of the spectrum. No question about it. Where there would be deeply unconscious comatose brain-dead type of picture.

Q Do you know how much Pentobarbital would need to be administered in order reach that level of unconsciousness?

A Probably my guess -- so -- so -- I'm -- again, I am -- I have never used Pentobarbital as an induction agent. To my -- my recollection, I've never used it as an induction agent. When I use that term, I mean if I were to take you and you were going to have surgery, and I'm going to induce anesthesia, I -- I would not use Pentobarbital.

The closest I've ever come is Thiopental. But Pentobarbital and Thiopental are very similar in terms of their doses for that purpose. So when I, you know, if I give 500 milligrams of Thiopental to somebody, you can achieve these -- at least transiently, you can achieve that deep level that I'm talking about. So I think with Pentobarbital, 500 milligrams, you can do that as well. But of course, they're -- they're giving 5,000 milligrams, so that's why I say a fraction of the drug would -- would get you to that endpoint.

Q Right. But you don't know when or how much or how long it would take?

A I don't know -- I don't have any firsthand knowledge, no. I have had to -- as I -- I said earlier, I've had to piece together some information that I pulled from the literature.

Q So you're -- these most recent questions have focused on, I suppose, the far-end of the spectrum, when we're talking about this deep level of unconsciousness. And it's your opinion that the individual does not experience any pain or suffering at that level of the spectrum because they cannot experience an emotional response.

Do I have that right?

A That's correct, yes.

Q And what about closer to the other end of the spectrum? Can individuals still experience pain and suffering under your definition?

A Well, it depends on where you want to put them on that spectrum. So yes, it could be, you know, if you have awake on one end of the spectrum and a coma, deep, deep coma, brain death on the other end of the spectrum, somewhere -- somewhere along that continuum, people are going to be able to experience suffering and pain.

Q Yeah, sure.

A I don't know where that is exactly, and it kind of depends on your definition.

Q So if Mr. Bucklew was not in this deep level of unconsciousness, yet was somewhere else on the spectrum, it's possible he could still --

A Yes.

Q -- be experiencing some pain and suffering?

A Yes. But as I pointed -- yes, that's true.

But as I pointed out, he's not going to be on this end of the spectrum, he's going to be on the very far end. That's my opinion.

Q Understood.

A Yeah.

Q Now, on this -- closer to the awake end of the spectrum, would a person who -- appear unconscious to someone, even though they're not, in this deep level of unconsciousness?

A They could appear to be unconscious, yes. Because unconsciousness, you know, you -- you look at consciousness -- if you're going to take a strict medical scientific approach to it, you just don't look at the person, you'd have to do other things to, you know -- you know, you might nudge them and that kind of thing and see if they wake up or not

Q Right. So just the naked-eye observer wouldn't be able to determine whether the drug had taken full effect simply from just observing?

A Right.

Q Okay.

A So just an example: If you were to close your eyes right now, I have no idea whether you've closed your eyes and you're awake, or whether you've fallen asleep. I mean, I don't know.

Q Would you say the same is true for a nonmedical person, who is observing somebody during the execution process?

A Yes.

Q Okay. Have you ever witnessed an execution ever?

A No.

Q Have you ever worked for the Missouri Department of Corrections?

A No. I mean, I don't know what this relationship --

Q Outside of this current --

A Yeah. No, I have not.

Q -- working relationship?

A No.

Q Have you ever been consulted or ever worked for any states' department of corrections?

A No.

Q Ever consulted on the drafting of an execution protocol?

A No.

Q The use of chemicals for lethal injection?

A No.

Q Feasibility of an execution method?

A No.

Q Do you have any views on capital punishment that were germane to the opinions you rendered in this matter?

A I have ambivalence about it. So my ambivalence, there's three -- I think, I'm balanced; I'm against the capital punishment and it's primarily -- so I have three basic prongs of my approach to this: Two are religious and one is a sense of fairness.

So on a religious perspective, yeah, the Old Testament, which basically -- if I may paraphrase, an eye for an eye, and a tooth for a tooth; and then you have the New Testament, where Jesus says, you know, "Be forgiving," so I -- I do struggle with that morally and as a Catholic.

And then, from a sense of fairness, I know that there probably have been individuals that have been -- that are on death row that may be innocent. So I think that's the most -- the strongest feeling I have about my feeling on capital punishment that -- I think that's the -- fundamentally, the most unfair thing that a government can do is, to take the life of an innocent person. So those are sort of my -- that's my perspective on capital punishment, but...

Q And it -- sorry, go ahead. I was going say, I don't intend to probe --

A Yeah.

Q -- the -- your personal --

A Okay.

Q -- perspectives here, but I'm just curious to the extent that they were germane to the opinions you rendered in this case.

A No, they weren't -- they weren't germane. I mean, I think that one of the main -- the main things (hat has driven me to, you know, to -- to testify in these cases is, that the -- basically that, you know, you're -- you're representing the -- the defendant, or, I guess, the plaintiff in this case, and -- and I represent the -- am an expert witness for the defendant --

Q Huh-uh.

A --which is the State of Missouri.

Q Yeah.

A So I -- out of a sense of fairness, I mean, if I were to ask the question of somebody, and I sort of played with this in my mind about, you know, do you believe that a defendant has the right to adequate counsel? And do you believe that a defendant has the right to expert witnesses? I think we'd all say yes.

Well, in this particular case, the defendant is the State of Missouri, so I feel that they need have some type of expert represent- -- representation to be able to make their case. So that's the other thing that drives me -- why I would -- I would do something like this.

Q Aside from the Ohio case and this present matter --

A Right.

Q -- you also mentioned the Mississippi case?

A Yes.

Q What opinion did you render in the Mississippi case?

A Basically, the same as I did in Ohio. It's essentially the same type of information -- or the same type of questions. You know, does Midazolam render somebody unconscious to the extent that they would not be able to perceive the effects of the other two drugs. It's been a long -- it's been over a year since I was involved with that case, so I -- you know, I can't remember exactly everything I said, but that's the gist of it.

Q And what was your opinion?

A Well, that Midazolam would produce a level of unconsciousness that would render the inmate incapable of sensing the effects of the other two drugs, sensing in -- in the sense of--

Q Experiencing pain?

A -- experiencing pain and so forth, yeah.

Q So very similar to the opinion that you rendered in the Ohio matter.

Are there any other cases that you rendered an expert opinion on, that relate to capital punishment?

A I don't -- no, it's been Mississippi, it's been Ohio, and then now Missouri, so I don't -- no.

Q Have you ever rendered an opinion where you concluded that the inmate would not ex -- would experience pain?

A In -- in those three cases -- those three? Or any?

Q Either in those three cases or in some other matter.

A Do you mean in a legal setting? Or just in general about discussions around capital punishment?

Q Let's start, first, with the legal setting,

A No. I've not been provided any opportunity -- I've never had -- you know, it's only been in those three cases about --

Q What about outside of the legal setting?

A Well, I guess, you know, there's -- we -- I've had discussions in -- in various social settings about capital punishment, but I don't remember anything specific about that, and I didn't -- so...

Q Have you ever had your opinions challenged as being inadmissible under Daubert or a related doctrine?

A I'm -- I'm not familiar with that, so I don't know whether anything I've admitted or anything that I've said has been inadmissible. Do you want to --

Q Do you know what the Daubert motion is?

A No, I don't think -- I might, but I -- I can't tell you off the top of my head.

Q Are you familiar with the concept of challenging an expert's report as inadmissible?

A Yes. Yeah.

Q Are you aware of a report -- a judge ruling that any opinion that you've submitted in a matter was inadmissible?

A My specific opinion in a case?

Q Uh-huh.

A No. I mean, I know that I -- certainly, with the Ohio case that I just testified at, there -- there was a challenge by -- well, I'm not sure -- I'm not sure challenge is the right word. But, you know, we went through the usual thing, where I was asked questions about my background, and -- and the attorney for the State of Ohio said, “I'd like to stipulate,” or whatever word that was used, I forgot what words that you guys use, but admit Dr. Antognini as an expert witness, and there was no from -- from the other side. And then I gave my testimony.

And then when I was being -- under cross-examination, they brought up the issue about my CV I'm retired, and, you know, walked through that issue about how they -- you know, obviously, they were getting at the issue of can I give expert testimony when I'm retired, which I think I can. But you'll have to decide for yourself, and the Court will have to decide that.

Q But are you telling me that no court has ever ruled --

A As far as I know.

Q -- your opinion as --

A As far as I know.

Q Okay. So going back to your materials reviewed and your November 2015 report, Exhibit B.

A Okay.

Q Let me know when you're there.

A Yes.

Q Who's -- who selected the documents for you to review?

A These were documents sent to me by Mr. Spillane.

Q Did you ask for anything beyond what's listed here as well as under your materials reviewed in your supplemental report?

A I -- I -- I don't know, I mean, I probably did ask for some things. But off the top of my head, I'm trying to think what -- what they might be. Well, for example, I mean, one thing that comes to mind, is that I was -- I was asked to -- I shouldn't say -- Dr. Zivot refers to a scan that was done in 2005 on this inmate, and I don't think that I was ever sent the results of that scan, but he apparently had access to it, and I was never about to find that -- the results of that scan.

And I asked Mr. Spillane about that and I don't think he's been able to find it either. Now, there are over 5,000 pages of medical records that were sent to me. So, again, I told you I was a numbers person, I'm thinking, "My God. There's a lot of these," so I counted -- I mean, I didn't count them, but you do it in PDF, so there's over 5,000 pages of medical records, so I guess it could be in there, but I didn't see it and he couldn't find it. So that was one thing that I -- I --

Q Anything else?

A Let's see here, so I was interested in what happens during the execution, itself, is there any medical -- not medical. Is there any information about the execution, itself, that would provide guidance to -- to me, but I was not provided that information, you know, I don't know whether they -- what they do in terms of taking records.

I mean, sometimes I think my understanding is, that they -- I don't know what happens in Missouri, But I do remember, I think, seeing from the other cases they had or someone provided me with some notes on Florida executions, and I -- I -- I'm sorry, I don't remember if it's from Ohio, from Missouri, or where it was, but that made me think, you know, is that a type of information available, and I was not provided any information. So I, you know, maybe you don't take that information, I don't know.

Q You -- you did receive and review Missouri's open protocol; correct?

A Yes.

Q Are you aware that Missouri also has a closed protocol?

A Yes. I did not know until I think you used that term this morning, about open versus closed. I know that there's more to the protocol than what I was provided, but I've not been provided the protocol -- the -- the closed protocol.

Q Did you ask to review the closed protocol?

A No, I didn't actually. I did not ask for the -- closed protocol, as far as I -- I recall. And I think primarily because I had sufficient information with the open protocol to render my -- my opinion. Although, maybe the closed protocol has some information, like the rate of injection, that would have been useful to me. But anyway, I was not provided that information.

Q So is your awareness or understanding of the execution process that Missouri limited to what is in the open protocol?

A I'm trying to think, is there anything -- any other information that I received about the process. I think so, I mean, I'm thinking, maybe, there might have been something that Dr. Zivot would have put in his report that might have -- I suspect it would be the same thing. And, you know, he -- he would have gotten to the open protocol. So I -- I guess, yes, it's limited to the open protocol. I can't think of where -- where else I would have gotten any other information about it.

Q Is your understanding of the execution process at all informed from conversations with the State Attorney General's Office?

A No. It's not, no. I mean, obviously Mr. Spillane and I have had discussions about, you know, a lot of these issues, but nothing that he said is -- has really informed me about -- it might -- doesn't make my opinions,

Q What did you confer with -- confer about with Mr. Spillane or somebody else from the Attorney General's Office that you relied on in forming your opinions?

MR. SPILLANE: I'm going to object to the form of the question, because I think he just said that I didn't tell him anything or anybody else told him anything that formed his opinions.

But you can answer.

MR. FOGEL: Perhaps, I misheard or misunderstand what the witness said, but if that's true, then you can state as much.

THE WITNESS: Well, nothing that Mr. Spillane said to me, helped me to form my -- my opinion. I mean, there's nothing that he said that I used to rely upon my opinion. To form my opinion.

BY MR. FOGEL:

Q I'm thinking, in particular, about a statement you put in your materials reviewed. And you say, (reading):

“I reviewed the pleadings in this case to gain a general familiarity with the matters at issue and a contentions of the parties. I have conferred with the attorneys for defendants.”

So just to be clear, anything that you conferred about with the attorneys for defendants, is there anything that you took into consideration when forming your opinions?

A No. No. I'm -- I'm -- no.

Q We talked a little bit earlier about the Pentobarbital package insert.

A Yes.

Q Was that provided to you by the State?

A No. No.

Q Sorry?

A No. I got that off the internet.

Q Okay, Is it your understanding that -- well, does the package insert refer to a specific type of Pentobarbital? A commercially --

A It does.

Q -- manufactured?

A This particular -- this particular package insert refers to the Akorn brand. But that was just -- that was one that I grabbed off the internet.

Q Is it your understanding that it's the same type of Pentobarbital that would be used in Missouri's execution?

MR. SPILLANE: Well, I'm going to object to that question. That's -- that's state secret of what we use, whether it's compounded or manufactured, because it could lead to the identities of the suppliers. So I'm going to direct him not to answer anything that might lead to whether we use compounded or manufactured.

(Whereupon the witness was instructed not to answer.)

THE WITNESS: I don't know what they use.

BY MR. FOGEL:

Q Okay.

A I'm -- I'm told it's Pentobarbital. I just Googled Pentobarbital package insert, and this is the -- one of the first Ones that comes up,

Q That's -- to answer my question, the purpose of the question is not to try to get at the origin of the type of Pentobarbital uses, but why Dr. Antognini used that information and how we relied upon it.

A Yeah.

MR. FOGEL: Okay.

THE WITNESS: That's basically, I guess, if you Google those two, I think that's one of the first things that comes up, so that's what I grabbed.

So -- and for the most part, I don't want to say 100 percent, but for the most part, package inserts are very similar, from one manufacturer to the other. I'm not sure how many people manufacture Pentobarbital, but for most drugs, it's going to be the same.

BY MR. FOGEL:

Q I'm looking at your supplemental report now.

A Uh-huh. Uh-huh.

Q At paragraph 6, it talks about large dose of Pentobarbital, such as the 5 grams, would cause respiratory arrest and cardiovascular collapse, leading to death. What was your basis for that understanding?

A So if you look -- if you go to that website, as I recall that's -- what I wrote there, in No. 6, is basically a summary, a synopsis, of what the effects of Pentobarbital are. So obviously, we know that people do not use that dose in a clinical setting.

So this particular website doesn't state that, you know, if you get 5 grams of Pentobarbital, this is what's going to happen. It basically states that if you use Pentobarbital, these are the risks involved, basically respiratory arrest and cardiovascular collapse. And if you don't resuscitate somebody, you know, if you give somebody sort of a -- I don't want to say a clinical dose, but if you gave them a low dose in a clinical setting, these are the things that can occur. So obviously, if you gave a large dose in an execution setting, you're going to get the same thing.

Q So that understanding that you just explained, is that based on your review of the website article --

A That --

Q -- that you got off the internet?

A That particular statement is supported by that particular reference; although, you know, I've made claims like that in other parts of my reports and they may be supported in the same way, but from different sources, you know, this is not the only source that would support that particular statement. So for example, if you look at the package insert, basically, you would read the same thing.

Q Are you aware that the open protocol contemplates the use of Pentobarbital beyond the 5 grams -- the original 5 grams that are administered?

A Yes.

Q Why do you think it contemplates the use of additional Pentobarbital?

A So my guess is that it's out of abundance of caution; although, it may seem like a paradox when you're talking about the lethal injection process, but it's basically to ensure that, if there were any issues of with the delivery of the first dose of Pentobarbital, you know, you have a protocol that says you can give another dose. But 5 grams, if, again, properly administered through a functioning IV, would be sufficient. But the -- probably -- I don't know why they put that in there, you'd have to ask them, but my guess is, because you want to have that capability.

Q In the event that an inmate did not die from the original administration of 5 grams?

A That's correct. That's my assumption, sure. Yeah.

Q What did you do today to prepare -- or what did you do to prepare for today's deposition?

A I had a nice breakfast with Mr. Spillane, and then we spent a few minutes just going over some of the points that -- the major points that would probably be brought up in the deposition. In terms of the action of the drug, and its ability to produce unconsciousness, how fast it would work. You know, basically telling him this is -- this is -- if I were asked these questions, which I suspect I will be, this is how I would reply to them.

Q Did you review any documents?

A I looked at the reports. I looked Zivot's reports, and I looked at my own reports. I looked at the -- I have a copy of the -- that pharmacokinetics paper -- the one that I cited, not the other one that I did not cite, but I mentioned this morning. I think I looked at that.

Q Aside from that one article, and I think you said it was a dog study --

A Yes.

Q -- do I have that right?

A Yes, correct.

Q And by the way, did it study humans as well? Or just dogs?

A Well, as I said, there is a paragraph -- it's a penultimate paragraph in the paper, and a discussion that they said -- they basically gave Pentobarbital to humans, looking at the EEG and the onset of the -- the change of the EEG with Thiopental and Pentobarbital is about the same time. So I think it's 15 to 30 seconds. They don't state what the dose was in that -- in that paragraph. And then they say that the -- it took Pentobarbital a little bit longer to have -- I think they used the term “full effect.” Not sure if that's what it was.

And then -- but within one or two minutes, it said that it had it -- its full effect. And that was presumably at a dose of -- I don't know what the dose was, but my guess is, it's probably going to be similar to the dose they used for Thiopental, 500 milligrams, 400/300 milligrams, it's not clear because they don't state what that dose is,

Q Well, full effect, meaning death?

A No. Full effect, I think, in terms of consciousness. Now --

Q So it took a minute -- it said it --

A If you want --

Q -- took a --

A -- I can pull it up on my computer.

(Whereupon there was unreportable crosstalk.)

BY MR. FOGEL:

Q We can look at it later.

A All right.

Q I just wanted to make sure I understood what they were studying.

A Yeah, I cannot --

Q And what they were not studying.

A I cannot remember the specific language -- you know, the words that they used, but that's my recollection of, you know, the verbiage basically.

Q Got it. Aside from that one report or study --

A Yeah.

Q -- were there any other documents that you reviewed, in preparation for your deposition, that you did not review in connection with your reports?

A Well, I told you -- I mean, there -- like I said, there are some papers that I looked at, that I said these don't really apply, and I don't remember what they are, but there's nothing -- and there may have been some papers out there that I -- I -- I reviewed that basically -- so there might have been, let's say, three papers that I reviewed and supported a particular point that I wanted to make, but I only cited one of those papers, so there might be some papers like that out there that I -- that I looked at.

But I, you know, there's nothing out there that I -- that I reviewed that supports my opinion, basically, that -- that I didn't include in here. Again, I mean, I -- again, except for the situation, where there may be three papers, as an example, and [only cited one of them.

Q Has your review of any of these materials that you looked at informally/formally caused you to change your -- or modify your opinions in any way?

A No. No.

Q In your opening report, under your materials reviewed --

A Uh-huh.

Q -- is a document 263.

A Yes.

Q Do you know what that is?

A I'd have to -- I -- I don't remember what that is. These are all -- these -- these were documents that were sent to me, and they -- they were numbered, and that's how I put them in there. Is there not a Document 263?

Q Well, there -- there is at least some confusion on our end and perhaps --

MR. SPILLANE: If we could go off for a minute.

MR. FOGEL: Yeah. Okay.

(Whereupon there was a break in the proceedings.)

BY MR. FOGEL:

Q So I want to go back to the opinions we were talking about earlier, that you've rendered regarding whether Mr. Bucklew would experience any pain.

A Yes.

Q And again, I just want to make sure we have this established as the baseline: It's not your opinion that Mr. Bucklew would not ex- -- strike that. Are you opining that Mr. Bucklew would experience no pain?

A During?

Q During the execution process.

A It is not -- I -- it is my opinion that he would not experience pain except for the insertion of the IV, which I said earlier, but that the injection of the Pentobarbital through a properly functioning IV, would not cause, in and of itself, pain to Mr. Bucklew.

Q So let's talk through the execution process, drawing, of course, upon your understanding of how it works.

And we've talked about Mr. Bucklew being in -- strapped to a gumey or an OR table, some sort of surface, Do you know how long Mr. Bucklew would be positioned in that -- let's call it a gumey for now?

A I do not know specifically. I can -- I have a guess in my mind, but I don't know specifically how long that would be.

Q Does it depend, in part, on how long it could take to find a strong -- a good IV line?

A Yes, it would.

Q And you mentioned that somebody -- I think you used the example, in your clinical practice, you've had patients where you've had to try ten different IV locations; is that right?

A Some patients have gotten that many, yes, maybe -- yeah. I mean, I -- I -- I use that number, I -- I suspect that some patients that I've -- hopefully I -- not my personal patients, but others that I've seen have had that many IV sticks, so it could be up that high.

Q And that, of course, takes time.

A Correct.

Q Each attempt.

A Correct.

Q And we've established already, that when Mr. Bucklew was lying in a supine position, it's uncomfortable for him to lie in that position; is that correct?

A It is uncomfortable for him, that is -- that is what he reports, yes.

Q Is it your understanding that when Mr. Bucklew describes it as uncomfortable, he is experiencing pain when he's lying in a supine position?

A When -- he -- he states he's got pain all the time, no matter what position he is; and he's got pain in his face. And I -- maybe I didn't say that in my report, but he has pain in his face and in that area, so he's -- he has that as a baseline. So...

Q But I'm -- I'm talking specifically when he's lying in a supine position.

A No, I don't think he describes it as being painful, he just describes it as being uncomfortable. I mean, the inability -- or having problems with -- with breathing, we've all experienced that for one reason or another, it's not really painful, but it's uncomfortable.

Q Sure. So let me substitute -- or remove pain, and say, when Mr. Bucklew was lying in a supine position for extended periods of time, it creates difficulty for him to breathe?

A Yes. He's going to have more difficulty, absolutely, than somebody else would.

Q Do you know how long it takes to strap him into the gurney? Again, assuming we're having -- using a gumey?

A Just strapping him in, I mean, if he's cooperative or if an inmate's cooperative, it shouldn't take more than -- again, it depends on how many people are doing it. But if they're -- let's say four individuals, I'm just picking four out of a hat because there are four extremities, shouldn't take more than 30 seconds, at most, to actually put those straps on. I -- I -- I think. I mean, based on what I see in terms of those straps that I've seen from the internet, so...

Q After Mr. Bucklew is strapped in, what is your understanding of what happens next?

A My understanding would be that they -- an attempt is made to start an intravenous line.

Q And that's what we were just discussing, looking for a good IV line?

A Correct.

Q Do you know if the State of Missouri uses one or two IV lines?

A I believe the protocol uses two. There's a primary and a secondary, I think is the wording that they use. I think they use two.

Q What is the purpose of using two IV lines to your understanding?

A It's basically to have a backup IV. Where if you have a problem with one IV, you can use the other IV.

Q So when there's two syringes -- I mean, we -- we recall, we've established that there are two syringes containing 50 milliliters of Pentobarbital. And then there's a third syringe of the saline solution; correct?

A That's my understanding, yes.

Q Right. Do all three of those-and not simultaneously of course, but are all three of those syringes injected into the same IV line?

A I do not know, I -- I'm -- I'd have to review the protocol. I don't remember if they state it goes into the primary line, but I think the saline would go in -- I ---- I -- I don't know for sure, but my guess is they all go in through the same line, because if you have the Pentobarbital go in, and then next syringe of Pentobarbital, and then you have the saline -- you're using the saline to clear the line, so you'd probably be doing it all through -- all through the same IV, is my guess. But I don't know specifically what it states in the protocol and what they do.

Q Well, do you have the open protocol in front of you, which we previously marked as an exhibit?

A I have had it in front of me, and there it is.

Q So looking at section C, under intravenous lines, it says the second sentence, (reading):

“Both, a primary IV line and a secondary IV line shall be inserted, unless the prisoner's physical condition makes it unduly difficult to insert more than one IV.” Do you see where I was reading?

A Yes.

Q So would you agree that that indicates that it is preferable to have two IV lines?

A Well, I think as I interpret that whole section, there, they -- they say that, if there is difficulty, then you would have a central line. And in the secondary line, is the peripheral line. If you read further down.

So I think what they're saying here is, that, you know, if there's difficulty placing the IV, and you get one IV in, a peripheral IV in, then the -- the other IV can be a central line. But the central line in that case becomes the primary IV line, because it says the secondary -- secondary IV line is the peripheral line.

So I think what they're essentially saying, here, is mat, if we have a central line, that's the one we're going to use because that's going to be the most reliable one.

Q Well, all it says is medical -- you're looking at the next sentence. (Reading):

“Medical personnel may insert the primary IV line as a peripheral line or as a central venous line.”

A Correct.

Q So one or the other. And then the secondary IV line is a peripheral line?

A Correct.

Q That's the final sentence?

A Yes.

Q So it still contemplates two IV lines?

A Yes. That's correct, yes.

Q Right.

A I'm sorry.

Q So my question is, why would you want to have two IV lines?

A If there was a -- if there was a problem with one of the intravenous lines, then you could use -- and when I say “problem,” if you started to make an injection, it could be -- let's see, hold on just a moment.

So under C2 it says, (reading):

“A sufficient quantity of saline solution shall be injected to confirm that the IV lines have been properly inserted and that the lines are not obstructed.”

So, you know, if they had -- if they were concerned about the -- the flow of fluid through that, let's say, the peripheral -- through one of the lines on the peripheral lines, then, you know, obviously, they would use the central line in that case. I guess. I mean, that's -- I -- I -- I'm not trying to provide any -- any input to anybody about how to manage this, but I'm just trying to interpret what they -- what they wrote here, but...

Q Do you think it's more or less likely than Mr. Bucklew -- strike that.

Do you think taking into consideration the state of Mr. Bucklew's -- or the access to Mr. Bucklew's veins, that it's less likely the state would be able to identify two IV lines?

A It'd be less likely, yes, to identify two peripheral IVs, Yes, I think that's true.

Q When you say “two peripheral IVs,” you mean that the state would then need to identify a peripheral IV as well as the central IV line?

A That scenario would be more likely with someone like Mr. Bucklew, compared to an individual -- an individual who had no problems with their -- with their -- with their veins. Now, when I say more likely, I -- I can't really give you number on that.

So -- but I would say in my experience, yeah, you'd be more likely to have problems getting two IVs -- peripheral IVs in someone like him than, you know, someone else.

Q Once the IV lines are inserted into Mr. Bucklew's vein or veins, depending on how many IV lines the state is able to identify, do you know where the Pentobarbital is administered from?

A In -- in -- in -- in the tubing, itself.

Q Into the tubing, itself.

A No, I don't. I mean, there's most intravenous lines have what are called ports, and sometimes -- usually, there are several ports in the line, and one's going to be close -- usually, it's close to the IV insertion site and there's going to be another one farther up. I have no idea where they inject it.

Q So do you have any idea how long it would take for the Pentobarbital to run the length of the IV line into Rusty's vein?

A So those -- the volume of that tubing is probably, even at the most distal part, you know, maybe it's -- I don't know, could be 5 MLs, I'm not -- I -- actually, I should probably know that, but I can't remember off the top of my head, it depends upon the size of the IV tubing, but it's probably going to be a relatively small amount.

So I don't know the answer to your question of how much -- how much dead space, is what we call that, in the line because I don't know where the ports are,

Q Right. So you don't know the length of the tubing?

A Yeah. I do not know that.

Q Right. And we've always talked about, you've made an assumption in terms of the speed in which the Pentobarbital is run into Mr. Bucklew's vein; is that right?

A I did. But I do believe that it's important to point out that the, you know, when you give a drug, especially when you've given a large bolus of the drug, so you have this tubing going along and it goes into the arm, so all of a sudden you start to inject the drugs and you have sort of this bolus of the drug moving along, and so the injection has started, but it actually hasn't gone into the -- into the patient or, in this case, the inmate.

So it might take five seconds, let's say, for that Pentobarbital to start actually getting into the vein. So if you were to say to me, “Precisely, when did the Pentobarbital actually enter into the inmate?” If I started the injection at 12:00-noon and zero seconds, and maybe it actually didn't enter the inmate until 12:00-noon and five seconds, because it took five seconds for me to put sufficient volume in to get it into him. So -- but we're not talking about minutes. I mean, again, I don't know how fast the infusion --

Q That's all I'm asking.

A Yeah.

Q If you know, one way or the other.

A I don't, sorry.

Q Yeah. Okay. Once the Pentobarbital starts running into Mr. Bucklew's veins, explain to me what happens.

A The drug will go through the -- the veins and -- and get into the larger veins -- let's say that he has peripheral IV -- enter the larger veins of his arm, and go in, through the subclavian vein, and then it would go into the superior vena cava and then it goes into the heart. And then it could go through the right side of the heart, through the lungs, and then back into the left side of the heart, and then it's ejected by the left side of the heart, the ventricle, and it is then distributed to the rest of the body, so it'd go to the brain and other organs. So that's basically how that drug would be --

Q Uh-huh.

A -- distributed.

Q At some point after the Pentobarbital is running through Mr, Bucklew's veins, it's your opinion that he's rendered unconscious?

A Yes. That's correct.

Q And it's your opinion that this would occur approximately 20 to 30 seconds from when?

A It would be about 20 to 30 seconds after the -- my guess would be, the first 10CCs of the drug actually entered into his venous system. So from when it actually gets injected into the -- into the vein, this's -- that's my estimate.

Q Do you have an estimate of how long it would take for Mr. Bucklew to die from the point that the Pentobarbital enters his veins?

A My -- my estimate is -- is basically around 8, 9, or 10 minutes. Because as I said to you earlier, one of the things that I did look at, were some of the press reports of-- of some of these executions, and they almost always give the time, between the injection and when the inmate is declared dead.

Q And you said approximately eight to ten minutes?

A Yeah.

Q Okay.

A I think that's what most of the reports said. And my understanding is that's public information. I mean, obviously, it is now, because it's in these news reports. So I'm assuming that that's accurate.

Q We've talked a little bit about this already: But it's your opinion that, once Mr. Bucklew becomes or an inmate becomes unconscious, that inmate no longer experiences pain and suffering; is that correct?

A That is my opinion, yes.

Q Okay. And just to make sure I have a good understanding, what is your basis for that opinion?

A So Pentobarbital is an anesthetic that is capable of producing deep unconsciousness and coma, as we discussed before. And you can actually do surgery with Pentobarbital. And with -- just like with any -- any other anesthetic, patients do not report pain and suffering during -- when they have a normal, properly administered anesthetic. They don't report pain and suffering after the operation -- that they experienced during the operation,

Obviously, they may have pain and suffering afterwards, because they have an incision, and they're painful from that. But during the operation, itself, they don't report anything like that because they're unconscious. So that is the important thing to consider about, would somebody be suffering during the effects of Pentobarbital? And I think that's the primary thing that I'm looking at.

The other thing to consider is that the Pentobarbital is being given in a very large dose, so you're going to achieve that endpoint more quickly. The third thing to remember is that, in addition to the anesthetic effect of the Pentobarbital, you're going to get essentially cardiovascular collapse. It's my -- I don't -- I don't, I mean, just based on the action of a drug and what we see with -- with Thiopental, for example you're going to get a really low blood pressure. And then as I described in my report, hypoxia, and then the heart starts to slow. So, I don't see how you could -- how anybody could -- could have suffering and pain during that process.

I mean, once you become unconscious, the rest of it is downhill, I mean, I'm not trying to make light of it, but that's basically everything's going down hill. The blood pressure's going down, the neurofunction is going down, and it's irretrievable or just irreversible, I should say.

Q What is your--

A It's irreversible. You couldn't -- I just don't think if d be possible to resuscilate somebody out of that -- out of 5 grams of Pentobarbital.

Q Understood. But isn't that a separate question from whether they're experiencing pain before they enter -- declared dead?

A Yeah. Maybe you're right, maybe I went off a little bit more information than was needed to answer the question, but I'm kind of looking at the overall process. And I think, maybe, part of that is -- is -- is -- is informed by Dr. Zivot's opinion, which I think I again, I'm sort of paraphrasing, but -- or interpreting what he's saying is that, somehow Mr. Bucklew is going to be in this sort of zone where he's semi-awake and semiconscious. And he talks about -- he, being Zivot -- that, this could be anywhere from, you know, sev- -- it could be anywhere from several minutes, because Missouri has it in their protocol that they're going to have five -- they're going to give another 5 grams in their protocol if they need to, but my question really about that is, how -- how -- well, how can you explain or support that statement? How -- how is Pentobarbital and the doses given going to keep an innate in this sort of semi-awake zone for several minutes?

It just -- if you look at the action of the drug, if you look at the kinetics of the drug, if you look at how it affects the brain and its -- and the cardiovascular system, I just don't see how you can make that statement.

I mean, this -- this drug will cause a rapid onset of unconsciousness, 20 to 30 seconds is my opinion, could it be a minute? Maybe. And then it's going to -- it's going to -- just going to be a deepening and deepening unconsciousness, to the point of coma and brain -- or electrical silence. Cardiovascular collapse.

I don't see how he, Dr. Zivot, can put together this picture, where it's going to be this prolonged period, where the inmate is going to be in this state of semiconsciousness and -- and experiencing these symptoms of pain, and suffering, and choking. I just cannot piece it together with the information that I've been provided and the information that I pulled from these articles and so forth.

Q Is there any medical equipment that could be used to determine whether or not the individual is experiencing pain?

A Not in the current clinical use. There have been attempts in the past to try to determine whether people are experience -- if anesthetized individuals are responding to a noxious stimulus in the way that would indicate to you -- to the inclination that they are -- well, they're not -- not really, they're experiencing pain, but they are -- but that the body is responding physiologically to the -- to that stimulus.

We don't have that right now, I think there is some companies working on it, but we don't currently have that. As far as I know.

Q Could Mr. Bucklew experience feelings of suffocation and choking after the administration of Pentobarbital? i A Only during the period, where he's still conscious. But after he becomes unconscious, no. I mean, i he, you know, once that injection starts, as -- as I've already said and you've asked about, it does take some time for the patient -- for the inmate to become unconscious, and I'm seeing it's 20 to 30 seconds after that first, say, dose of 500 milligrams or so, thereabouts, gets into the -- into the inmate. But after that, no, he's -- he's not going to experience any sensation of suffocation or choking. It's my opinion.

Q From the point of unconsciousness? Therefore--

A Correct. Once he becomes unconscious.

Q What if Mr. Bucklew started bleeding from his hemangioma?

A He -- he would not -- if he's unconscious, he would not experience suffering from pain from that bleeding, no.

Q Could he start bleeding from the mouth, where the hemangioma's located?

A He could. But if he was unconscious, he wouldn't -- in my opinion, he wouldn't be suffering or be feeling it.

Q How do you know that he would not be suffering or experiencing it?

A Because he's unconscious, so you don't -- as I -- as I mentioned earlier, you -- in -- in my opinion, suffering is a something that you have as a conscious experience. You don't have suffering and pain as a unconscious experience.

But I've also been very clear that you can certainly have physiological responses to various stimulation -- various stimuli of when you're unconscious. So as an example, brain-dead humans, if you do -- obviously, brain-dead humans are -- are organ donors. Am by definition, you wouldn't necessarily need to give an anesthetic because they're brain-dead. But in fact, you do need to give some anesthesias and some drugs because they have physiological responses to the noxious stimulation to the surgery, their blood pressure goes up, their heart rate goes up, that's a -- a reflex that they -- that the brain-dead humans retain.

So yes, you can have these physiological responses to these different types of stimulation, but that doesn't mean that they're suffering or have pain. I mean, obviously, example of the brain-dead, but by definition, they can't because they're brain-dead.

Q So what -- what information are you relying upon?

A For what?

Q To -- to say what you just asserted.

A I -- based on my clinical experience, because I have provided care for brain-dead humans, who are organ donors. And then also, based on my review of literature and some of the research that I have done over the years. Some of my research is related to where the anesthetics work in the body, so that was part of my -- my review of that area.

Q Are you familiar with anesthesia awareness?

A Yes.

Q What is it?

A That's a term that usually is used to describe somebody who is aware, awake, conscious during a surgical procedure, usually because of insufficient anesthesia that was provided, that -- sometimes it's because it's -- it's an error or an oversight, sometimes it's because we just can't give enough anesthetic to a person, so if it's a patient that's been in trauma and they've lost a lot of blood, then you can't, you know, you can't provide anesthesia to them -- or as much anesthesia to them. And in my own practice, although, as I've mentioned to you, I don't practice clinically anymore, but in some trauma patients, there have been times where I've whispered in their ears during surgery, and I've said to them, “Mr. Jones, I know that you might be awake, and I know that you might be experiencing this, but I cannot give you much anesthesia because you are so sick right now. And I'm going to do the best that I can.”

And I did that and I taught residents to do that, because when you -- when you review the literature on this, patients who have suffered anesthesia awareness said -- a lot of them just said, “I wish they knew that I was awake,” and this is one way -- you don't know for sure that they're awake, and we have monitors now that -- not entirely accurate, but, you don't know whether they're awake or not. So you can do it to everybody and -- and hopefully they are not awake, but that was my practice at least. So yes, I'm very familiar with anesthesia awareness.

Q Is it possible that Mr. Bucklew could experience anesthesia awareness? Taking into consideration, of course, that he would not be alive at the end of the experience to recount it?

A I don't think that's a possibility. If something wrong happened with the administration of the drug, and as we already discussed, I do not, especially with the dose that is used, I do not think that he would experience anesthesia awareness, no.

Q You talked about, I think there was three end goals in the context of anesthesia?

A Yes.

Q One of them was amnesia?

A Yes.

Q Do I have that right?

And you -- there was an amnesia agent. What is the purpose of the amnesia agent?

A The purpose is to block memory. And an anesthetic, by definition -- and when I say “an anesthetic,” I mean, one drug that produces the state of general anesthesia. So that drug has to have -- has to be capable of producing those three end points to be called a general anesthetic, and that's my medical and scientific opinion based on many years of thinking about this and doing research on that. As opposed to a drug that may cause amnesia, but it wouldn't produce necessarily the other end points of--

Q I -- I -- I understand.

A Okay.

Q But why do you want there to be an amnesia component to the anesthetic?

A Because patients don't want to remember their surgery.

Q Why do they not want to remember their surgery?

A Because it would be an unpleasant experience.

Q Because there would be some sort of suffering or some sort of painful --

A That's -- that's true.

Q -- component to it?

A Yeah.

Q So how do you -- so if you want to suppress that by making it so they can't remember, so doesn't that suggest that there is, in fact, some pain and suffering while the patient is under an anesthetic?

A No, it doesn't. You're -- you're trying -- there -- there would be pain and suffering if they were awake. But you're giving them a drug that makes them not awake and -- and removes that --

Q But also a drug that helps them forget it.

A That is -- that is -- that is true. Yes, it does because -- because the -- let's see -- so not, you know, we wish you could do this 100 percent of the time, but some patients, of course, we have difficulty with. And the trauma patient, I'm going to, again, give the example. You know, we have some choices, I guess, and I'm not saying necessarily in a clinical sense, but just in terms of how these drags work and why they're chosen, but, you know, I guess -- I guess the -- the -- the first goal would be: I don't want the patients to -- to remember this. I mean, there may be patients that are, quote, “awake,” but I don't want them to remember that --

Q Okay.

A -- part.

Q Why do you not want the patient to remember it?

A Because that's -- who would want to remember their surgery? Or their -- that -- that experience. I mean, that's -- that's the first --

Q And my follow-up question to that was, is it because there's a pain and -- component to the procedure?

A Yes. Absolutely,

Q Okay.

A Absolutely.

Q So why -- how do you reconcile that with your opinion that somebody who is unconscious does not experience any pain and suffering?

A Because as -- yeah, we're not -- we're sort of going in circles, here, on this. I can tell,

As you give an anesthetic, one of the first -- so of the three components that I described, blocking memory formation is one of the first ones to occur. And then very soon after, you -- patients become unconscious. Very soon after. But they're very close.

And then farther, higher doses, you finally block the movement response. So if -- if-- if I am saying to myself, well, all I want to do is, I -- I just want to block the memory, well, unfortunately, our drugs are not -- the drugs that we use do not provide me much wiggle room in that regard. So that is, if I provide just enough to block memory, then may not be enough to -- to produce unconsciousness. And I want to get past that. So I have to give a larger dose,

I'm not sure I have answered your question, but pain, I -- I -- I don't deny the fact, and I admit it freely, that pain and suffering can occur in awake individuals. No doubt about it. And that could be pain and suffering from surgery, it could be pain and suffering from other experiences. Whatever.

But in -- on my -- in my sort of opinion, as I'm a scientist and a physician, pain and suffering are words that we use to describe experiences that awake individuals have relative to these different types of situations or stimuli. So once somebody becomes unconscious, I don't consider them to be in the situation where they are -- or a state where they can

have pain and suffering because you have to be awake in order to have that. I can't -- I'm not sure I can make it any more clear to you.

Q So once -- you're -- you're assuming entirely that a patient -- or, in this context, the inmate is unconscious?

A (Inaudible response.)

Q So when we're asking specifically regarding any pain and suffering that an inmate may experience during the execution process, as soon as the patient becomes unconscious, the period thereafter is irrelevant.

Is that your opinion?

A That is my opinion, yes.

Q So the length of the execution process, the endpoint being when the inmate is declared dead, is a moot question -- or moot point for you; is that right?

A As long as you're maintaining the unconscious in a continuous basis, which, they are, based on my understanding of, again, how the drug works and how, you know, the timing and all that, yes.

Q So if Mr. Bucklew's hemangiomas continue to bleed when he was lying in the supine or whatever position he may be in -- as long as he's -- and blood is coming out of his mouth, as long as he is unconscious, he's not experiencing any pain or suffering in your opinion?

A That is correct.

Q And is it your opinion that as a medical fact, he would not be choking or he could not suffocate -- experience suffocation because he is unconscious at that point?

A That is correct.

Q And is this all based on the assumption that Mr. Bucklew is, in fact, what you're define- -- on what you're defining the far end of the unconsciousness spectrum?

A That is correct. And again, I base this opinion on -- I mean, we're -- I -- I realize, we're kind of focusing on -- and as we should -- on this particular inmate and the issues around choking and sensation. But remember, Pentobarbital is an anesthetic. And what kind of procedures can we do on patients with an anesthetic? I'll use myself on the example: I had heart surgery. They split my chest open, spread my chest, replaced my heart valve. Okay? Patients have had abdominal surgery where their incision, from stem to stern, for trauma patients, from here to here. In orthopedic surgeries. These types of procedures that go on for hours, are infinitely -- maybe that's little bit of a hyperbole -- but are much more capable of inducing suffering and pain than, you know, the choking and gasping and so forth sensations that we are discussing here.

And why are we able to do those types of procedures? Because this drug, like many of the other genera] anesthetic drugs, they're anesthetics. So if we're capable of doing those types of procedures on individuals, and I think that -- that the consensus is that those individuals are not suffering or having pain during those procedures, in the sense that we're talking about, which is that they're awake, then yeah, I think that you're -- once this Pentobarbital begins to occur, choking or the blood in the airway, that kind of thing, it's not that -- I mean, it's stimulating, we all have experienced stuff in our

airway, but it's not stimulating to the extent that these other procedures are. And, again, large dose of an anesthetic, I just -- it's -- I don't see it happening.

Q Do you agree that any length of any time in which an individual is choking is painful?

A If they're awake, would--yes. They would be in pain or -- or suffering. I'm not sure, again, we've already talked about this, I'm not sure pain is the right word, but they would be suffering.

Q Do you agree Mr. Bucklew, as a result of his condition being cavernous hemangioma, the difficulty or the challenge in accessing his IV lines, the uncomfort -- or discomfort he experiences when lying in a supine position, again, assuming he would be in the supine position, do you agree that Mr. Bucklew is more likely to experience a more compacted airway during the execution process?

A More likely compared to what? Just his normal state? Or just a normal individual?

Q Either one. Certainly his --

A Yeah.

Q His-

A It's more likely -- I think it's more likely that he would have those symptoms compared to a normal individual, because he already has those symptoms. And lying flat is more of problem for him, and -- and he says that and I don't disagree with that. Now, can he tolerate -- as I said earlier, can he tolerate that? Yes, he has been able to do that.

Q But lying in a supine position for an extended period of time would introduce additional stress or difficulty in his ability to breathe. Do you agree with that?

A Yes. That would be increasing his risk for that or -- or that possibility, yes.

Q And the challenge in finding an IV line, would introduce -- has a potential to introduce additional stress into Mr. Bucklew as well?

A Yes. I would agree with that.

Q And that additional stress has the potential to make it even more difficult for Mr. Bucklew to breathe?

A Yes. That could happen. Yes, I agree with that.

Q And as a result of these factors that we've discussed, it's possible Mr. Bucklew could experience a sensation of choking or suffocation?

A While he was awake, yes, that would be -- that would be possible.

Q So there's an increased risk of pain and suffering that you acknowledge exists up until the point of unconsciousness. Is that your opinion?

A I would agree with that. So -- and you -- you're probably not going to be willing to -- to -- to assign a numerical value to that, but -- because you're just saying increased risk, and so increased risk would be -- mean, going from 1 in 1,000 to 1 in 100 chance. I don't know what the number would be, but just because it's increased, doesn't mean it's substantial or likely.

Q Well, Mr. Bucklew has an increased risk of this, certainly in comparison to other individuals who do not suffer from cavernous hemangioma?

A That is true, yes. He has increased risk compared to a normal individuals.

Q And increased risk compared to individuals who don't have a Mallampati 4 airway?

A Yes. That's true.

Q If you were to able to determine that it takes significantly longer than 20 to 30 seconds for Mr. Bucklew to become unconscious from the administration of Pentobarbital, would that affect the opinions you've rendered in this case?

A I don't think so, I would say however, that -- so if-- if it took longer, than 20 to 30 seconds, it would certainly increase the amount of time that he -- there is a potential for him to -- to have, you know, the sensations of choking and so forth that he described.

But I have to leave it to the Court to decide whether that's a substantial -- substantial risk or not, or an increase in the risk, I just don't know. I don't have any -- I can't really give you an opinion about that, because I don't know what that -- from I guess a legal perspective, and I know that's a term that's used, I don't -- I'm not sure if that's substantial or not. I really don't.

Q A substantial amount...

A Of risk. That it would be a substantial increase in the risk for him or a substantial risk for him, compared to, you know, if it went-- if, instead of it taking 20 to 30 seconds, it took two minutes, is that a substantial risk or an increase? I don't know. Because a substantial is a -- is a term that -- that's open to interpretation.

Q Right. And -- and -- and maybe I should rephrase the question, so we can move away from the substantial risk. But if it appeared, in fact, was two minutes as opposed to 20 to 30 seconds, then that period of time in which Mr. Bucklew would be experiencing suffocation and/or choking?

A Well, that risk would be there. But you're -- I think you're assuming that he -- he will have, you know, if he does have choking sensations as the drug is being administered, and it takes two minutes for the drug to work, then yeah, I mean, it's going to be two minutes instead of the 20 to 30 seconds that I described.

Q Uh-huh, Right. And I'm not asking you to make a legal determination --

A Uh-huh.

Q -- of 20 to 30 seconds versus two minutes --

A Yeah.

Q -- in terms of what is an acceptable level of risk?

A Right

Q My question is more focused on your medical assessment, In terms of his -- during that additional minute-and-a-half or two minutes, would Mr. Bucklew be experiencing or there be an increased likelihood that Mr. Bucklew would be experiencing suffocation or choking?

A There would be an increased likelihood because of the reasons that I've already provided to you: Because he already has those symptoms, and, you know, we're going to -- if you're going to make it longer then there's an increased risk just because of the length.

Q I believe you stated in your report that if Mr. Bucklew started bleeding from his hemangioma, he would not notice; is that right?

A If he was unconscious.

Q Right.

A Yes.

Q So again, we're assuming he's unconscious.

A Yes. Right.

Q Is it possible that he could bleed to an extent that it would be coming out of his orifices?

A Yes, that is possible.

Q Are you aware that Mr. Bucklew takes certain nervous system depressants?

A I -- in review -- yes, in review of his records, I -- I saw that he is taking several different types of CNS drugs. Although, quite frankly, off the top of my head, I know that they've changed over time so I don't know specifically what he's taking right now, as of today.

Q What were the drugs, as of the time -- or what drugs are you familiar with that he's take in the past?

A I have to look at the medical records, I don't recall specifically off the top of my head.

Q Does Clonazepam sound familiar to you?

A That sounds like one of them, yes.

Q What about Tramadol?

A I think he took that, but I -- again, I --

Q Right. Sorry. I'm not trying--

A I know.

Q -- give you a memory test.

A I just don't remember exactly what drugs he's been on in the past, and that's now off of, and what he's on now, so...

Q Is it your opinion that-- again, assuming Mr. Bucklew is taking these depressants, that any interaction between these depressants and the Pentobarbital would be inconsequential?

A Yes. And that's based on my -- you know, the dose that's used, it's just going to be overwhelming. The, you know, the dose is overwhelming compared to any effects that they might have between the -- those drugs and the Pentobarbital.

Q What effects could the drugs have at a lower dosage of Pentobarbital?

A So basically, you could have what are called additive or synergistic effects where the two drug act together to produce more of an effect than the drugs acting separately.

Q Uh-huh.

A Or they could just be additive, where they just add -- you know, work together in the same amount, so the produce more unconsciousness or whatever effect that you're looking at. Those -- those are some of the interactions that you would have.

I know that -- well, that -- that's just, you know, that's the main -- I think the main effect. Which, again, when I -- in my report, I said basically, it's -- it's essentially going to be an additive effect anyway, I mean, you're using such a large dose that it's not -- it's not important. It's irrelevant more or less.

Q Can you turn to Paragraph 14 of your supplemental report.

A Uh-huh.

Q And I believe you state here that Pentobarbital is an anesthetic?

A Yes.

Q And by definition, anesthetics prevent awakening from stimuli including airway obstruction?

A Yes.

Q So by medical definition, Mr. Bucklew, if he was starting to choke, would -- that would not inhibit him from succumbing to the effects of the Pentobarbital?

A No. Not in -- not in this -- not in the dose of -- that's being used. So if -- if you could give a dose of Pentobarbital or whatever anesthetic you're using, and you could get into that fine, fine line, that level where, you know, somebody would respond to a type of stimulus, such as airway obstruction, then, yes, that -- that type of stimulus could wake somebody up. If you're at that very, very narrow window of-- of concentrations.

But that's a very low concentration of the drug, and -- and, of course, the Pentobarbital, in this setting, is at a much higher level. So they're not in that period for more than probably a second or two is my guess.

Q Could -- if a patient --

A Or a couple -- you know, maybe more than that, maybe ten seconds.

Q If an inmate is experiencing suffocation and/or choking, could it affect the distribution of the Pentobarbital?

A No. No. No. No. No. No. It wouldn't.

Q What if the suffocation or the choking was to such an extent that the inmate started convulsing?

A Convulsions, I don't know why you want to use that term, because you're not going to get convulsions in this type of setting because Pentobarbital is one of the drugs that you would use to prevent convulsions and so maybe you can clarify about why you think obstruction would cause convulsions.

Q Well, if the patient -- excuse me. If the inmate is experiencing some sort of a choking reaction or a gasping for air before the Pentobarbital has presumably taken full effect, as you've defined it, could that lead into some physical reaction or physical movement of the body?

A It could, but that's not what convulsion is. We don't use that term for that type of movement.

Q Maybe I was using that imprecisely.

A That's why I got thrown off base by your --

Q Well, that's why you're the expert, to keep me in line. I appreciate that.

So could the physical reaction, through the experience of choking, affect the distribution of the Pentobarbital?

A Well, I guess if the inmate was moving to sufficiently where it interfered with the flow of the IV, right? So, you know, I don't know where these straps are located, and it's obviously relative to where the IV is located, but I suppose if the individual was moving around or -- or -- or basically pushing up against the -- the strap where an IV was placed, then you could obstruct the flow of the fluid going through that. So that would be -- that would affect the distribution of the drug.

Q Is it possible that it could dislodge the IV?

A Yeah. I mean, if somebody's moving around, absolutely. If it's -- especially if it's a tenuous IV, so...

Q And then, of course, if the IV is dislodged --

(Whereupon there was a telephonic interruption.)

MR. FOGEL: Pardon me. If I'm not -- sorry.

THE WITNESS: It's okay.

BY MR. FOGEL:

Q If the IV is dislodged, that would necessarily impact the distribution of the Pentobarbital?

A That is correct.

Q Is an anesthetic the same thing as an -- and I'm probably going to mispronounce this -- anesthesia?

A No.

Q What is anesthesia?

A So anesthesia is a term that would be used to describe the -- the -- the state or condition that is produced by an anesthetic. So for example, Pentobarbital is an anesthetic, it produces anesthesia. And what is anesthesia? Again, going back to my three end points, it's immobility, it's unconsciousness, it's amnesia. The ability to -- to -- to do surgery procedures and have those end points, that's sort of what anesthesia would be.

Q Are you familiar with analgesics?

A Analgesics.

Q Analgesics, thank you.

And those are designed to prevent pain, I think we talked about earlier?

A That is correct.

Q And we've also talked about that anesthesia is also designed to cause amnesia.

Do I have that right?

A That is correct.

Q And it's your opinion that Pentobarbital would achieve all of these results? Unconsciousness, lack of pain reception, and amnesia?

A And immobility.

Q And immobility.

A Yes.

Q And how do you know this?

A The Pentobarbital would do that?

Q Uh-huh.

A Because Pentobarbital is an anesthetic, and you can give it in sufficient doses to produce that type of picture or that -- that state. Pentobarbital's used -- I don't think it's used -- as I said earlier, it's not used at all, clinically, for that particular, you know, in that setting. It could be used in animal studies or animal experiments or animal surgery; although, even now, veterinarians don't do it because it's such a long-action drug. At the dose that you need to give, it would last too long.

Q Understood.

A Yeah.

Q Understood.

So to what extent did you rely upon Mr. Bucklew's medical -- excuse me, the records from his prior surgeries from 2000 and 2003?

A I relied -- I think it was an important part of my analysis because one of the issues that came up initially, and maybe it's still -- it will be a factor, I don't know, but it has to do with distribution of the drug. That -- that there is a contention that this hemangioma would affect the distribution of the Pentobarbital. And so my -- the process that I went through to refute that is that well, he had that hemangioma back in 2000 and 2003, and it was a low-flow hemangioma, and he reacted normally to the anesthetics. And that is -- the that the documentation was that he was unconscious, he did surgery, he reacted normally. So I think that was an important piece of information to show that he doesn't rea- -- he would not react abnormally to anesthetics.

Q Did you take into consideration the fact that those procedures were 13 and 17 years, respectively -- 17--13 and 17 years ago, respectively?

A I did and I thought about, well, how -- how much larger has the hemangioma gotten, has it changed its characteristics? And it has not, based on my review of his medical records. So, for example, the hemangioma was slightly smaller when comparing 2010 to 20-- 17 -- '16, slightly smaller. The -- he had an angiogram done in -- I'd have to review the records, I forget exactly when the angiogram was done, but it was done at some point, and it showed that it was a low-flow hemangioma, so it showed there wasn't much blood flow it to.

The image study that he had done in 2016 used a -- what's called CTA or computer -- computer demographic angiography, I think I got that right, I may have it a little bit off, but CFT for short. They can use that technique to look at the blood flow of the hemangioma, there was low blood flow to the hemangioma. So the characteristics of that hemangioma, in that regard, have not changed over the years, so I don't see how it could have...

Q But aren't those procedures different because they were affirmatively trying to control for Mr. Bucklew's blocked airway? I -- I -- I can't recall, perhaps, if there was a kaleidoscope or some sort of tool that was used to control for his breathing?

A During?

Q The 2000 and 2003 procedures.

A No, I don't think so. I think they just used direct laryngoscopy.

Q Well, they used some sort of device to control for his blocked airway.

A But it's just the device that they normally use.

Q But that device would not be used in the context of an execution.

A There would be no reason to do so.

Q Right. So aren't there fundamental differences between how Mr. Bucklew reacted during those procedures in 2000 and 2003, as he would during an execution?

A No, I think you're -- you -- you, and perhaps, Dr. Zivot, are -- are -- are conflating and -- and putting together the issues around the airway management with his reaction to the anesthetic drugs, themselves.

Q And you're saying that he would react the same?

A Correct. Because as you well know, Dr. Zivot and -- and Dr. Wippold, and Jamroz, but primarily Dr. Zivot said, at least in some of (he initial reports that I read, that there would be an abnormal distribution of the drug. And that's just not true. And it doesn't make any sense to me in terms of (he anatomy or physiology of this hemangioma.

Based on my understanding of how these hemangiomas are -- their structure, and just to prove my point, the inmate had surgeries in 2000 and 2003, when the hemangioma was quite large. I don't know what it was compared to what it is now, but it was large enough that he was having treatment for it, and in -- reacted normally. So that is separate from the airway issue.

Q Right. Okay. And so that's the distinction, I think we're -- we're just talking past each other, His procedures in 2000 and 2003 do not tell you anything in terms of how he may or may not have experienced feelings of suffocation or be choking during an execution process?

A I wouldn't say they don't tell me anything, because he did have a large hemangioma then. Unfortunately, I don't know how large compared to what size it is now. But it was described in the records as being, again, large, I mean, that's sort of one of the terms that was used.

Q Right But they controlled for his airway --

A That's correct.

Q -- during the course of (he procedures, which, of course, they would not do during the course of the execution?

A That is -- that is correct. But it's -- but it's controlling -- they were controlling for his airway when he was unconscious, and, again, it just doesn't matter to me what's happening because he's unconscious in terms of the lethal injection process,

Q One of your conclusions --

THE REPORTER: Are you moving on to a new subject? I need a break.

MR. FOGEL: Okay.

(Whereupon there was a break in (he proceedings.)

BY MR. FOGEL:

Q Dr. Antognini, we were talking about the fact that choking may have under the distribution of the Pentobarbital. What about the bleeding from Mr. Bucklew's hemangiomas? Could that have an effect?

A No, I don't think so.

Q Even if the blood with was coming out of his orifices?

A No. It wouldn't affect the circulation of the drug. Well, so I'm -- I'm going to make sure, it has been -- it's getting -- been a long day, I may not be as focused as I should be. Can you repeat the question.

(Whereupon the record was read.)

THE WITNESS: Could the bleeding have an effect on the distribution of the drug, was the question --

BY MR. FOGEL:

Q Correct.

A -- I believe.

Okay. No. If -- I mean, if he had -- if somebody had massive bleeding from something, and by massive, I mean, we're talking about hundreds of MLs or thousands of MLs, that kind of setting, that of course affects the distribution of drugs. Because it's distributed by the bloodstream, so if you're bleeding -- but even bleeding from a hemangioma of this type, you know, wouldn't affect that because it's a low-flow hemangioma. The blood flow to it is low, relatively speaking. So you're not -- so there's not going to be a lot of blood actually going through that. Of course, it's in a sensitive area, I admit and agree with Dr. Zivot that in the awake condition, Bucklew could have choking conditions from the bleeding, but it's not enough to affect distribution of the drug.

I'm trying to think of a scenario whether either the choking sensations or the bleeding, itself-- I mean, there is a -- and I'm, you know, I don't mind saying this, you know, you might think it's pertinent or not, I mean, it's not because, again, we're talking about a massive dose of drug. But if somebody is choking, it could affect the mechanics of blood flow through the -- through the thorax, basically. But that's, again, sort of small compared to the overwhelming effect of it in terms of the dose of the drug that's being given.

And the main thing that's going to affect distribution of this drug, in my opinion, is the rapid onset of hypo- -- severe hypotension. And that doesn't actually help in your case in any way whatsoever. Because when that blood pressure drops from that Pentobarbital, it -- the one thing that -- that keeps -- that brings the blood concentration down of a drug -- I shouldn't say the one thing -- but the main thing in this particular time period, the one thing that brings the concentration of the drug down, is that it gets redistributed to other organs, so the brain is what we call a high-flow organ, the heart is a high-flow organ, it gets a lot of blood flow.

So the drug starts to go there first, but then, you know, there's blood flow to other tissues, so the drug gets -- we call it redistributed to other tissues. But that's not going to happen in this setting, because that severe hypotension that happens, the circulation is essentially going down, close to zero, and you're not going to redistribute that drug. So the drug that's in the brain now, normally if it was a low dose, it would be sort of washed away, and it's not going to happen in this setting. So it goes into the brain, and it slays there.

Q So going back to my original question --

A Yeah.

Q -- which is just --

A Yes. Yes.

Q -- regarding the blood -- the bleeding from Mr. Bucklew's hemangioma, which you've acknowledged is a possibility that could happen as a result of the execution, the answer to my question is, you do not think it could affect distribution of the Pentobarbital?

A Right. Correct.

Q You've also rendered an opinion regarding lethal gas?

A I did say something about that, yes.

Q And it's -- I'll read it directly from your opening report. And it's at paragraph 26.

A Yes, I see it.

Q You said, (reading):

"The use of lethal gas would not significantly lessen any suffering or be any less painful than lethal injection in this inmate." Why does lethal gas not hold any advantage compared to lethal injection?

A Well, essentially, because I think that the -- I use the term lethal gas but there are several -- several types of gases -- maybe more than several, there are a lot of types of gases that could be used for -- for -- to kill somebody, I guess. They're not necessarily ones that will be used or have been used in executions.

You know, the one that comes to mind is cyanide gas, and, you know, I -- I don't know if anyone's used nitrogen in an execution, I don't know the answer to that question. I -- I think somebody has, some state has done that, but I'm not positive about that. And those have effects that may not be pleasant either, but it would be short-lived, just like it is with the Pentobarbital.

So that's why -- I mean, I do -- I -- I, you know, drew a conclusion and I said I didn't think in my opinion that it would -- you know, using gas would not significantly lessen any suffering or be less painful. Because, again, their onset of action is going to be relatively fast, just like Pentobarbital's onset -- onset of action. So that's why I -- I drew that conclusion.

Q That's it? Simply because it would happen quickly?

A Correct.

Q You think there would be no difference?

A That's --

Q Did you take into consideration what position the individual might be sitting or lying in?

A No. I did not, no.

Q Did you consider the fact that using lethal gas would not require the use of accessing an IV line?

A I did not, I mean, I -- obviously, I know that. But I don't think that the -- inserting an IV line is, as I said, significantly increasing the -- the -- the amount of pain,

Q Right. I mean, we've -- we've --

A Yeah.

Q -- talked plenty --

A Right.

Q -- about your opinions --

A Yeah.

Q -- and understandings regarding accessing Mr. Bucklew's IV lines.

But what -- what are you relying upon, in terms of how a lethal gas execution operates, to form this conclusion?

A Let's see. Again, I -- I referred to I believe examples of nitrogen and of cyanide. Because I know -- of course, we all know cyanide has been used in the past, that was used in California and elsewhere. I don't know whether other gases that have been used in executions --

Q Sure. Putting aside --

A Okay. I know --

Q Okay. Okay.

A I just -- I want you to know I'm trying to answer your question in giving you the background of why it formed my opinion.

So I thought in mind, okay, well, how does cyanide work and how quickly does that work and what kind of suffering may be occurring? And I'm, quite frankly, thinking about, you know, maybe -- as I look back in my review of this, at this -- at that point, I did probably look at reports of cyanide, you know, using cyanide as a lethal injection, and -- and I think that those could be -- to -- to use a rather -- not -- maybe not the best term, but it could be kind of messy. In the sense that, you know, inmates can be -- can have convulsions from the -- from the cyanide, and that might be true for the nitrogen, so I'm -- I'm looking at, you know, the -- the pain and suffering that might occur from Pentobarbital compared to what my understanding of lethal gas would be and that's why I formed that opinion.

Q Right. And my -- my question is, what informed your understanding of a lethal gas?

A So for the cyanide one, I guess it'd have to be, I might have reviewed -- I -- I really don't remember. But I'm not trying to be evasive about this.

Q Is there anything in your materials reviewed that you could point to?

A No. I didn't put that in there. No, I did not. Now, as far the nitrogen part, just based on my -- my experience, my scientific experience -- not the right word. My scientific knowledge of -- of using nitrogen, when you go from, you know, air is 80 percent -- 79 percent nitrogen. When you go from 79 percent nitrogen, now to 100 percent nitrogen, you know,

you quickly achieve hypoxia and somebody would be unconscious very quickly and, you know, it depends on how quickly the gas is introduced and all of that.

So I -- again, I'm just saying sort of based on what I know, that's why --

Q And how do you know how quickly a gas is introduced?

A Well, I don't know that. I mean, it could be introduced very slowly and cause a lot of suffering, I guess. You know, you get -- you can get suffering from hypoxia, you know, because somebody can be awake and realize that they're not getting enough oxygen. So depending on -- on how it's used, you might get more suffering from nitrogen gas than you would have Pentobarbital. Or you might get less suffering, you know, it depends on how you would use it, I guess. And I'm not making any recommendations to anyone about how --

Q Understood.

A Yeah.

Q I'm just still trying to get at my first question, which is, how you -- what you are basing your conclusion on, that lethal gas would cause significantly less -- excuse me, strike that.

What you're basing your conclusion on, that the use of lethal gas would not significantly lessen any suffering or be less painful than lethal injection?

A Well, I already said to you, I looked at -- my recollection is, I suspect I looked at some information on -- on the use of-- of cyanide as a lethal gas, and then I just looked at -- or had my -- my understanding of what happens with hypoxia based on over the years. I mean, obviously, as an anesthesiologist, we're very concerned about hypoxia and we study hypoxia and all of that, and that's how I came to that conclusion. But it's not -- I -- I will admit that it's not perhaps as well founded as some of my other conclusions.

Q Are you relying upon any information that you were given by the Attorney General's Office --

A No.

Q -- in forming that conclusion?

A No.

Q Dr. Antognini, are you being compensated for your time today?

A Yes.

Q Are you being compensated for the time you spent in preparing your reports?

A I am.

Q How much are you being compensated an hour? Do you charge an hourly rate?

A I do. It's -- well, for the deposition, I think it's a -- it's a flat rate, I can't remember what it was, it's in my -- I think it's in my report. I believe, in the first one. I think it's $2,000 for a deposition appearance.

Q It's a flat rate?

A Yeah.

Q Okay.

MR. FOGEL: We don't have anything further at this time.

MR. SPILLANE: All right. I'll try and move quickly.

EXAMINATION

BY MR. SPILLANE:

Q You're a board-certified anesthesiologist; is that right, sir?

A Yes.

Q Do all board-certified anesthesiologists have expertise in setting central lines, such as subclavian or femoral vein lines?

A No. I wouldn't say that all of them do. I would say that -- that is part of their training, but if-- you know, just because they've trained -- been trained to do that, does not mean that they continue to do that in their particular practice, so I wouldn't say that all board-certified anesthesiologists would be experts in...

Q Well, I probably asked a bad question. I'll start out with this: Every board-certified anesthesiologist is trained how to do that or he wouldn't be a board-certified anesthesiologist?

A That's correct. That is part -- that's a part of training. But, you know, some people, their -- their practice may be that the/re doing outpatient surgery -- or anesthesia for outpatient surgery, so they may not place central lines ever.

Q What type of surgeries does one use a central line?

A It would be heart surgery. It could be somebody who's having a major abdominal surgery. It could be some type of orthopedic procedure, where there's going to be a lot of blood-loss, I guess. Or a spine surgery. And then somebody who's particularly sick, and you can't get -- you don't have good IV access, and you wanted to, you know -- if you're having problems with that, which we've already discussed, then -- then, you know, you would put a -- a central line in that kind of patient.

Q When you examined Mr. Bucklew, were you able to physically view his uvula?

A I did see his uvula, just the very top of -- of it. But I -- I did sort of waffle, whether it was a Mallampati 4 or 3, because I was able to see part of his uvula. And generally speaking, when you have a Mallampati 4, you don't see any of the uvula. But I still have nevertheless called it a 4, because the Mallampati score -- and maybe, I mean, I -- I think clinicians use that scoring system in maybe not the most consistent way. So for example, if I had somebody who's thin, but just has an abnormal, maybe have a very small chin or whatever, they may have a -- I look at them and I say, “Oh, they have a Mallampati 3 because I can -- I can see just a part of their uvula,” but if I have somebody like with this inmate, I mean, it's -- it's not just a question of being able to see, I mean, he has a large mass there, I would say maybe sort of maybe fib -- fib, I shouldn't say that in a deposition -- but I would move more toward saying a Mallampati 4, just

so show people, “Hey. This is a potentially difficult airway.” Which I don't deny, he's got a, you know, from a clinical perspective, it could be a challenging airway.

So to answer your question, I know it was more -- it was a “yes” or “no” question, but I wanted to provide some feedback, I did see part of his uvula.

Q Okay. And -- and as I understand it, and correct me if I'm wrong, if you see part of the uvula, it's generally not a 4; is that fair?

A That is -- that is correct.

Q Okay.

A But I did not say that in my report.

Q All right. That's what I --

A That was my recollection -- yeah, that was my recollection, that I did see part of his uvula.

Q Let me ask you about your conclusion of-- on pain and suffering. Those are two different things; is that fair according to your testimony?

MR. FOGEL: Objection.

BY MR. SPILLANE:

Q If you understand my question, you may answer.

A Yeah.

Q And if I stated it wrong, tell me.

A Yeah, I would say that they are two different things. So basically, pain is a -- suffering can occur from a variety of different types of situations or -- or stimuli, and pain is part of that. Pain, generally speaking, will cause suffering. But you have suffering from some -- some -- from something else that's not painful. So, you know, with all suffering, we have emotional suffering from things that happen in our family and all of that, but that's different than the suffering that occurs from a painful stimulus.

Q As I understood your testimony on direct, you testified that there would be no pain 20 to 30 seconds after the chemical entered the bloodstream in the IV; is that accurate?

MR. FOGEL: Objection. Misstates the witness's testimony.

BY MR. SPILLANE:

Q You may answer, if I got it right. If not, tell me.

A That is correct. That -- that 20 to 30 seconds after the injection started to enter into the -- actually into the bloodstream.

Q When you --

MR. FOGEL: Hold -- hold -- hold on. That's not even close to what you testified about. I mean, fine. I can redirect, but...

MR. SPILLANE: The record will reflect.

MR. FOGEL: Fine. That's fine.

THE WITNESS: Well, I don't remember what I said I mean, we can read it back, I'm happy to -- I'm trying to . be consistent, but that's --

MR. FOGEL: Understood.

THE WITNESS: Maybe I'm not using the right words.

MR. FOGEL: For 20 to 30 seconds from entering the bloodstream; right? We've been talking about unconscious the entire day, but it's different. But Mike, go ahead and ask your question.

BY MR. SPILLANE:

Q I asked about pain. You indicated, as I understood your direct testimony, that when the person is unconscious with this dose of Pentobarbital, they would not feel pain.

Did I get that correct?

A That is correct. That is my opinion,

Q So they would not feel pain 20 to 30 seconds after the chemical entered the bloodstream from the IV; is that accurate?

A That is my testimony, yes.

Q Let me ask you a little bit of how you got there. Did you think about blood concentrations when you made that conclusion?

A Yes.

Q Tell me what you thought.

A So I looked at -- as I said, I quoted that study in my supplemental report from Ehrnebo. And basically, what they -- what he did in that study is, he took humans and he gave 100 milligrams of Pentobarbital intravenously and then he measured the blood levels of that drug. And typically, what happens when you do that kind of study, you give the drug, and then you start taking blood samples and measuring the concentration of the Pentobarbital in the blood. And if you look at their -- his figure, which is figure 1, I think, it shows a typical high level and then it just starts to fall off and go down and decrease.

So one thing that you can do, as an approximation is, that you can look at those blood levels and say, “Well, if this is the concentration that you achieve with 100 milligrams of Pentobarbital, what concentration would you achieve with 5,000 milligrams?” Which is -- is 50 times 100.

Let me make sure I got that right. So as a first approximation, you could just say -- look at the peak level there, and say, “All right. Well, if they achieved -- or I should say, if you look at the blood levels, if they achieved in that study the average -- at six minutes after the injection, the average was about 2.9 micrograms per ML, you just multiply that by 50, and say, “Well, it would be about 145 micrograms per ML at six minutes.”

Now, mind you, in that -- in that particular study, that was the first time that they had taken a blood sample. If they had taken a blood sample earlier on, it would have been higher because that's what happens with these drugs, their concentration falls off as the blood is redistributed.

Now, I will admit to that -- that analysis is an approximation and, in fact, he might -- you can go on and claim that there's an error there, that I'm wrong. But I'm not wrong in the direction that would aid you, as I mentioned earlier. Because when you get that incredibly fast -- well, I shouldn't say -- when you get that rapid onset of hypotension, sudden or severe hypotension, that drug is not going to redistribute. So if you were to able -- if you were able to measure the blood levels on that setting instead of falling off like that study showed, it would -- it would be de-elevated. Because the blood pressure is so low that the drug is not being redistributed so the blood levels are staying very high.

Q How many micrograms per milliliter of Pentobarbital in the blood are necessary to achieve the high level of unconsciousness that you spoke about, near comatose? MR, FOGEL: Object to form.

THE WITNESS: So I -- can I answer? Or...

BY MR. SPILLANE:

Q If you understand my question, you can.

A So I -- I relied on the package insert that has a table in it that I referred to in my report, and they have some drugs listed there. And the first drug listed is Pentobarbital, and there -- there're five degrees of depression listed there. And No. 3 says, “Comatose, difficult to arouse, significant depression and respiration.” And then No. 4 is, “Compatible with death an aged or ill persons, and then -- or in the presence of obstructed airway.” And then No. 5, “The usual lethal level.”

So just taking No. 3 as an example of comatose, No. 3 says you need 10 to 15 micrograms per ML; No, 4 is to 25; and No. 5 is 15 to 40. Obviously, they -- they've given a range because it's going to be sort of individualized. And at six minutes, based on that study, just looking at the average, it would be about 145 I think is what I calculated. 50 times -- about 2.9. So that's ten times the amount that would be needed to achieve level 3.

Now, mind you, that was the concentration that -- that -- that calculation I just did, of 50 times 2.9, that was the using the concentration of Pentobarbital at six minutes. But the concentration of Pentobarbital in those individuals at, maybe, one or two minutes was probably, you know, I don't know for sure, I -- I did some calculations and I -- I can't remember off the top of my head, but it's higher. So if you, now, take that factor of 50 and multiply that, at that point in time, one or two minutes after the drug's been injected, now we're talking -- could be 200 or 250 micrograms per ML of the Pentobarbital. From this massive dose of the Pentobarbital.

All right. So we're at this very high level, and then, as I said, this sudden and/or this rapid severe hypotension and that drug is not going to get redistributed, so it's not going to fall off. So it starts out very high, and it stays very high. That's why this drug is a lethal -- is a lethal agent administered in the way that it does.

Q Is that calculation you just told me about part of the reason you concluded that this person would be deeply unconscious and not feel pain at 20 to 30 seconds?

A That is part of the reason.

Q Tell me the other reasons.

A Well, the hypotension is going to make somebody unconscious. So if you take a normal individual and you make them hypotensive, I mean, they can main- -- people can maintain unconsciousness -- sorry. People can maintain consciousness when they're hypotense, you know when nothing else is being given. But when you give an anesthetic like this and it causes the hypotension, and it's going to act synergistically, because you need blood flow to the brain to be able to maintain consciousness, and this drug -- and in addition to the effect it's having on the brain, it's decreasing blood pressure, so the blood flow to the brain is going to be decreased as well. So that's going to exacerbate the problem of maintaining consciousness.

And then finally, the inmate is going to stop breathing, their oxygen source is going to go down and they will become hypoxic, and then you can't maintain consciousness when you're hypoxic, so those factors all combine to produce death, and, you know, unconsciousness and death. So that -- that's how I envisioned what was happening in this scenario.

Q I want to clarify something we talked about earlier.

As I understood the earlier testimony, there might be a period when the person had some level of unconsciousness, where he could still experience pain or some level of-- perhaps, I'm using the term wrong, semi-unconsciousness, did you reach an opinion of how long that would last?

A I have an opinion about it, I -- but it's -- it's more based on my -- my understanding of the -- the drug and the kinetics, and not so much about the, you know, having done a calculation. Because in order to be able to -- to answer that question, first, we have to decide, okay. Well, what -- what is the period during which --

MR. FOGEL: Objection, The question was, did you reach an opinion? I think it's --

MR. SPILLANE: I think he said “yes,” and then kind of...

THE WITNESS: Okay. Yes, I did reach an -- I have reached an opinion.

BY MR. SPILLANE:

Q Okay, Let me ask you this: What -- what opinion did you reach?

A That it would occur rapidly. And by rapid, I'm -- I'm -- I'm going to estimate that it's probably going to be in the range of maybe ten seconds. I mean, that's just a -- a -- a -- I'm -- based on my working with these figures and how quickly this drug is getting in and so forth, that this period, as I think Dr. Zivot is describing, where, you know, the -- the inmate would be in this period where he would be able to maintain -- or sense that choking sensation, it's going to be ten seconds. But I think that's going to be within that 20 to 30 seconds that I described. It's not going to be in addition to the to 30 seconds. It's a ten second, let's say, a ten second window within that 20 to 30 seconds.

Q So I'm going to ask you the question, just a different way:

During the 20 to 30 seconds you described earlier, is there a period of ten seconds where he might feel something; is that what you're saying?

A Sorry, within that 20 to 30 --

Q Yeah, is it before? Or is it within? I didn't --

A Within. It's within.

Q It's within.

So in the 20- to 30-second period, there might be ten seconds where he could feel something; is that what you're testifying to?

A That is correct. But just to clarify, I mean, he could also experience before that ten seconds -- I mean, obviously when he's awake, he can experience as I've testified.

Q Right. Thank you.

I don't have think I have any further questions, Doctor.

FURTHER EXAMINATION

BY MR. FOGEL:

Q Clarify quickly: On that last question, matter of clarification, states lawyer asked you if you had reached an opinion on how long this state of mild unconsciousness, somewhere else on the spectrum besides this total unconsciousness, whether you had reached an opinion; is that opinion set forth anywhere in any of your reports?

A No.

Q And you also -- also talked about there might be some ten seconds, where he would experience this level of mild unconsciousness, some level of unconsciousness, somewhere away from the far end of the spectrum. Is this ten-second period identified anywhere in any of your reports?

A No. Not -- not a -- a actual quantitative number is not.

Q Okay.

MR. FOGEL: No further questions.

MR. SPILLANE: All right. That's all I have. Thank you.

(Whereupon the deposition of Joseph F. Antognini was concluded at 3:27 p.m.)

VANDERBILT CENTER FOR NEUROSCIENCE DRUG DISCOVERY

Craig W. Lindsley, Ph.D.
William K. Warren, Jr. Chair in Medicine
Center Co-Director and Director, Medicinal Chemistry
Editor-in-Chief, ACS Chemical Neuroscience

May 26, 2017

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I have received and reviewed the "ADDENDUM TO BOP EXECUTION PROTOCOL FEDERAL DEATH SENTENCE IMPLEMENTATION PROCEDURES" as well the available literature and case studies in the public domain. Specifically, I was asked to review the draft protocol and address the question:

"Will the proper administration of this draft protocol cause a humane death, or will it present a risk that its application is sure or very likely to cause serious illness and needless suffering, putting the agency at risk to losing legal challenges alleging the unconstitutionality of the protocol as applied under the 8th Amendment (cruel and unusual punishment)? Why or why not?"

In my expert opinion, based on deep knowledge of the pharmacology of pentobarbital sodium, the protocol as drafted *will* produce a humane death with limited suffering and pain. The total dose of pentobarbital sodium administered intravenously is 12-35x above the maximum tolerated dose administered to man (140-420 mg IV; many sources state a maximum IV dose in man of 150 mg (the draft protocol would then afford 33x above the maximum dose in man that elicits sedation/unconsciousness in 10-30 seconds)). At the doses administered (2.5 g x 2 IV), the person receiving the infusion will lose consciousness within 10-30 seconds after the first injection, and respiratory depression/heart failure will ensue within minutes. The person receiving the infusion will be unaware of any pain or suffering due to the rapidity of the effect. This protocol is more humane than the other double and triple agent injections still employed. Case histories that are available with single agent pentobarbital sodium detail highly consistent results and extremely rapid and peaceful passing (as relayed by witness accounts). The protocol states that "the lethal substances shall be prepared by qualified personnel" and "A suitable venous access line or lines will be inserted and inspected by qualified personnel…" If pentobarbital sodium of appropriate quality and IV preparation, along with proper IV lines in place, are adhered to, the draft protocol will provide a humane death. To guard against ay failure of drug administration, the draft protocol provides for: "If peripheral venous access is utilized, two separate lines shall be inserted in separate locations and determined to be patent by qualified personnel. A flow of saline shall be started in each line and administered at a slow rate to keep the line open. One IV line

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will be used to administer the lethal substances and the second will be reserved in the event of the failure of the first line. Any failure of a venous access line shall be immediately reported to the Director or designee." The draft protocol includes the proper safeguards that will further ensure proper administration of pentobarbital sodium (2.5 g x 2 IV) that will cause a human death. As such, my professional and expert opinion is that the draft protocol ***does not*** present a risk that its application is sure or very likely to cause serious illness and needless suffering, putting the agency at risk to losing legal challenges alleging the unconstitutionality of the protocol as applied under the 8th Amendment (cruel and unusual punishment). Of all the available options and protocols in use today, I believe this protocol to be the most humane.

Respectfully,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

IN RE: OHIO EXECUTION PROTOCOL LITIGATION) CASE NO. 2:11-cv-1016
VOLUME III

PRELIMINARY INJUNCTION HEARING
BEFORE THE **HONORABLE MICHAEL R. MERZ**
UNITED STATES MAGISTRATE JUDGE
THURSDAY, JANUARY 5, 2017; 9:00 A.M.
DAYTON, OH

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Gary Mohr
Stephen Gray

INDEX OF WITNESSES

* * * * *

Proceedings recorded by mechanical stenography, transcript produced by computer.

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*** *** *** ***

P-R-O-C-E-E-D-I-N-G-S **9:05 a.m.**

THE COURT: This is Case Number 2:11-cv-1016. I understand that our first witness this morning will be Dr. Antognini out of order?

MR. MADDEN: Yes, Your Honor.

THE COURT: Very well.

JOSEPH FRANCIS ANTOGNINI, PLAINTIFFS' WITNESS, SWORN

THE COURT: Sir, would you please state your full name and spell your last name for the record?

THE WITNESS: Joseph Francis Antognini, A-N-T-O-G-N-I-N-I.

THE COURT: Your employment, sir?

THE WITNESS: My employment, sir?

THE COURT: Yes.

THE WITNESS: I am currently employed with the Joint Commission. It's an accrediting agency for hospitals and other healthcare organizations.

THE COURT: Right.

THE WITNESS: Which I just started.

THE COURT: JCAHO, have I got that right?

THE WITNESS: The Joint Commission is its official title.

THE COURT: Your witness, Mr. Madden.

MR. MADDEN: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. MADDEN:

Q. What has been your occupation?

A. Most of my career has been spent as an anesthesiologist at the University of California, Davis. Prior to that, I was in private practice.

Q. What education and background do you have to hold that position as an anesthesiologist?

A. After graduating from college, I attended medical school at University of Southern California, and then residency at University of California, Davis, an anesthesiology residency. I finished that residency in 1987.

And then practice, private practice of anesthesiology from 1987 to 1991, and then moved over to the University of California, Davis, where I was a faculty member.

Q. Let's go back to your private practice experience.

A. Yes, sir.

Q. Can you tell the Court about that?

A. So that was a small community hospital in the Sacramento area, and I took care of patients at that hospital for a variety of different surgical procedures. I provided anesthesia for those patients. I provided anesthesia for patients having neurosurgery, orthopedic surgery, obstetrical surgery, plastic surgery, gynecological surgery, vascular surgery. I did anesthesia for

electroconvulsive therapy. And surgery that I did not provide anesthesia for was open heart surgery because they did not do open heart surgery there.

Q. After private practice, what kind of work did you do?

A. I went to the University of California, Davis, where I was a clinician. Did clinical work. Continued to do clinical work, and then I did research, teaching of medical students and residents.

Q. Did you do clinical work during this period?

A. Yes, I did. I continued to do clinical work at the UC Davis Medical Center. And then cases that I did very similar to what I did in private practice, that is, I did anesthesia for neurosurgery cases for orthopedics, gynecology, obstetrics, and so forth. But, again, I did not do anesthesia for or provide anesthesia for patients having open heart surgery.

Q. Now, you said you did clinical research. Did I get that right?

A. I -- most of my research was actually basic science research.

Q. Okay. And can you tell the Court about that?

A. So my interest was in anesthetic mechanisms, specifically where do anesthetics work to produce some of their outcomes, or the goals of anesthesia. And I was primarily interested in how they produced immobility, that

is, how they prevent people from moving as a result of a stimulus. So that was the focus of my work.

Q. Let's turn to your CV. Defendants' Exhibit 94. And what volume is that? III.

A. Okay. Yes, I have it here.

Q. Can you turn to your CV?

A. Yes, I have it.

Q. Looking at your CV, it seems you have written a lot of articles specific to a certain field. Can you explain that?

A. Most of my work was -- my research work was related to understanding the relationship between anesthesia and noxious stimulation, to try to determine, number one, where the anesthetics are working to produce the immobility that we see with anesthesia, but also to look at the other responses that occur during anesthesia from noxious stimulation.

So, for example, I was interested in how -- where anesthetics worked to produce the, or affect the response that occurs from noxious stimulation in terms of the heart rate and blood pressure. As an example, when you apply noxious stimulus, the heart rate will usually go up, the blood pressure will go up, and I was interested in looking at that to determine where anesthetics might work to do that.

So really a lot of what I did was to determine where

anesthetics were working to produce their effects specifically related to immobility.

Q. Now, why did you study that field?

A. It was just something that was very interesting to me, number one. It was also something that -- immobility's a critical end point for anesthesia, and it was very important in my mind to understand where the drugs are working to produce that. And it just happened to be a time in my career where I had that interest.

And also some of my mentors had been doing some work, not really related to these ideas, but the techniques that they were using were -- I could use myself in the area that I wanted to look at this. So it was just a great example of having the right timing in terms of having the interest but also having the resources and mentorship to be able to do that.

Q. And how did you conduct this research?

A. So most of my research was with using animal models. And so, of course, you get a protocol to approve -- approval from the animal care committee, and then you carry out the experiment, obtain your results. Obviously when you do an experiment, you have a hypothesis, and then you do the results -- or do the experiment and get results. Sometimes results confirm your hypothesis, sometimes they don't. And so once you get the results, you write the paper up. And

that is the sort of the final product of the process. You write the paper and then you submit it for peer review.

Q. It seems like you've written -- looking at your CV, it seems like you have written quite a bit of publications. Did you publish your work in peer review journals?

A. Yes. The vast majority of my work was published in peer review journals.

Q. Tell the Court about your peer review experience.

A. So, essentially, the peer review process is where you submit the paper to a journal and the journal will send the papers to reviewers. And those reviewers are usually going to be colleagues, or I should say people that are in the field, and they will look at the paper and they will make comments and provide those comments to the editor and editor-in-chief who will then make a decision about whether to reject the paper or to have you revise it and then resubmit it.

And, you know, sometimes my papers were rejected, and I'd send them somewhere else, and eventually they would get published one way or another. But that's the way the peer review process works.

In my career, I reviewed many papers. I was an associate editor for the premier journal in our field, *Anesthesiology.* So I was on the other side as well reviewing papers.

And I would just add that when you have your paper reviewed, you submit your paper, it's obviously a very personal thing to you and people are going to make critiques of it, and sometimes those critiques can be very painful to the heart, so to speak, but I would say that about 95 percent of the time my papers were improved because of the peer review process.

THE COURT: Well, many of us in the legal field wish that the publication of law reviews would adopt that model because it's even worse being reviewed by students who haven't quite gotten my view. That's what happens in the legal field.

THE WITNESS: I'm sorry. I can't help you with that.

THE COURT: I understand.

BY MR. MADDEN:

Q. So what has been the focus of not just your research but your peer review articles?

A. Well, as I said, most of these projects that I did, they were published in peer review articles. So, again, it was around the concept of where do the anesthetics work to produce some of the effects, and specifically immobility.

Q. Now, after your career in research, what did you do?

A. So in about 2010, I became -- moved over to more of an administrative role in the department and hospital, and I

became director of the operating room. So I had responsibility for about 550 people, nurses and technicians, the central sterile area, and so forth, and did that for about five years. And just recently retired from the university about six months ago to move down closer to family in Southern California.

Q. And after your retirement, what have you been doing?

A. My current employment is, I'm part time with the Joint Commission, and that's reviewing hospitals, going out and looking at hospitals to see how they are doing in terms of their processes and so forth for accreditation.

MR. MADDEN: Your Honor, at this time I move to have Dr. Antognini recognized as an expert in the field of anesthesiology, in particular in regards to the application of noxious stimuli during anesthesia.

THE COURT: Any objection?

MS. BARNHART: No objection.

THE COURT: So ordered.

BY MR. MADDEN:

Q. You mentioned earlier the end points of anesthesia. What does that mean?

A. There are three, in my mind, perspectives. There are three essential end points for anesthesia. One is amnesia. Patients don't want to remember their surgery. Two is unconsciousness. Patients don't want to be conscious during

their surgery. And three is immobility. That is, that the patients have to be still during the operation because the surgeon doesn't want to have to operate on a moving target. Those are the three essential end points.

Now, some people have argued that analgesia is an essential end point. I believe that analgesia is a very useful and often very important thing that we need or want to achieve during anesthesia and surgery, but it's not an absolute requirement.

And the basis of that essentially is that analgesia, in one way, can be defined as something that removes pain. Well, if you are unconscious as a result of the anesthetic, by definition you have removed pain essentially.

Q. We will get to that more in a second.

A. Yes, sure.

Q. Would you turn to page 4, paragraph 9 of your report? You say the distinctions of end points are important. Can you kind of elaborate on that?

A. Page 4, yes, got it here. So, again, I spent most of my career trying to understand the process by which anesthetics produce immobility. And so you need to -- it's important to understand that patients move during surgery. And they move at concentrations of anesthetics and doses of anesthetics that ablate consciousness, and yet they move because of reflexive actions.

So it's common for patients to move during surgery, and yet they are not conscious. It's all because of reflexive movements. So just because -- you know, if I were to walk you through an operating room and have you observe, you might be shocked to see, well, you know, patients are moving, but it's fairly common for that to happen. We don't want it to happen, but we have to be able to adjust the dose properly, and sometimes that can be difficult. And patients do move during surgery.

Q. You talk about these end points. Are all end points equal?

A. They are not equal in terms of what we're looking at. Obviously movement is different from consciousness. They are certainly not equal in terms of their sensitivity to anesthetics. That is, memory and consciousness is more sensitive to -- is more sensitive to the anesthetics than the immobility part.

And that's pretty much true, I think, if you look at either drug-induced effects on a CNS or trauma. I am sure some of you have been maybe hit in the head in your life and maybe even knocked out. I have had that experience. I -- in my experience, I was told that I was unconscious for just a minute or two, but I actually have no memory for about a five-hour period. So memory is actually even more sensitive than consciousness.

Q. Well, let's turn to page -- to Defendants' Exhibit 94. I think you have that. 177. Can you tell the Court about the illustration that you have in your report and what it means?

THE COURT: The page?

MR. MADDEN: Page --

THE COURT: That's the next page, okay.

MR. MADDEN: Yes, sir.

THE COURT: Numbered 5 at the bottom but numbered 1777 at the top.

MR. MADDEN: Thank you, Your Honor.

THE COURT: Yes.

BY MR. MADDEN:

Q. If you could --

MR. MADDEN: Your Honor, with the Court's permission, can he use the easel to illustrate this point?

THE COURT: Absolutely. I have got to say he may as far as I am concerned. Whether he can is up to him.

THE WITNESS: So one way of looking at this concept is to have a graph like such, and this -- the graph that I am going -- the graphical representation that I am going to draw here is based on data published in the literature. And the way that you can look at this is to look at percent of patients responding versus the anesthetic concentration. Or the anesthetic dose. And you can look at

these different end points. So you can look at, for example, if this is 100 percent of patients responding, you can look at memory and see that as you increase the anesthetic concentration, the percent of patients that have memory will go down like such. So this would be memory. And then consciousness would look something like this.

If you are looking at immobility, it would be shifted over like this. So this would be the movement. So one way of looking at this, in terms of how we would do this, is that imagine for a moment that, you know, all the people that are in this courtroom, and we started to put in some of the anesthetic gas into this courtroom, and gradually the anesthetic gas starts to build up and starts to affect people.

So if I were to go around -- and I am a scientist here. So I have a gas -- a mask on so I can't -- I am not breathing the anesthetic. If I go around and I start testing each one of you and say, so, for example, I will just focus on the consciousness part. I would go to you and provide or apply some type of stimulus to check to see whether you are conscious or not. So I might go to you and you are conscious at this particular concentration but you are not. She is conscious, you are unconscious, and so forth. And then maybe a quarter of you would be conscious -- or unconscious and maybe three-quarters would

be conscious.

And then I continue to build up the anesthetic concentration. I go around again and I check that, and now it flips to almost all of you are unconscious and so forth.

So that's the way that you can conceptualize this approach of understanding the relationship between the anesthetic concentration and these various end points.

BY MR. MADDEN:

Q. Now as to --

THE COURT: Just a question, Doctor.

THE WITNESS: Yes, sir.

THE COURT: What you have drawn on the board essentially reproduces what is in your report.

THE WITNESS: Yes, that's correct.

THE COURT: At page 5.

THE WITNESS: That's correct.

THE COURT: Thank you.

THE WITNESS: I do want to just mention one thing, though, and I believe this is important, is that when we do these -- when we look at immobility, movement versus no movement, we usually look at the concept of gross purposeful movement. So it's not just a simple reflex withdrawal. It's what we consider to be gross purposeful movement.

So this curve that I've drawn here, in terms of its shift -- and, again, it's not quantified here, but it's

quite a bit shifted to the right, that is, the curve for gross purposeful movement. If we were to say, say that any movement would be positive. That curve would be out like that.

So just to make sure I've made that point, in some of these studies looking at movement, again, looking at gross purposeful movement, if I were to stimulate you with a noxious stimulus and you had just sort of a simple, very simple withdrawal reflex, that would be -- and this is arbitrary based on the way people do these studies -- that would be considered a negative movement.

If you want to say, well, what concentration would you need to prevent all movement, that curve would be out like that.

So to clarify that, this curve here I should say would be gross movement and this would be any movement. And that part --

THE COURT: I'm sorry, are you applying the phrase "gross purposeful movement" to the third curve?

THE WITNESS: Yes.

THE COURT: Please put the word "purposeful" in there.

THE WITNESS: Sure.

So I think this is one way to understand the relationship between anesthetic concentration, or anesthetic

dose and these various end points.

BY MR. MADDEN:

Q. Okay.

A. So there is this shift outward in terms of this. So that was, again, the major part of what I spent my career is trying to understand the relationship among these different end points.

Now, I have not done the studies that are here. Other people did those studies.

THE COURT: The first two.

THE WITNESS: The first two, the memory and the consciousness. I never did studies for that. I had to -- I use the work of other people. But this curve.

THE COURT: And, again, gross purposeful movement.

THE WITNESS: This curve here, yes, gross purposeful movement and any movement, I did studies related to those end points.

MR. MADDEN: Let the record reflect that I am showing opposing counsel *Miller's Anesthesia, 7th Edition*.

And may I approach the witness?

THE COURT: You may.

BY MR. MADDEN:

Q. Let me refer you to page 518, Figure 20-3. Do you recognize that?

A. Yes, I do.

Q. And what is that?

A. This figure is from the chapter in *Miller* by -- it's the *Inhaled Anesthetic Mechanisms of Action*, by author -- by Misha Perouansky, Robert Pearce, and H.C. Hemmings. They had asked for me to provide to them a figure, basically just like that figure there, but it has a little bit, a drawing of the central nervous system on it to indicate where the drugs are working to produce their anesthetic effects. But they asked for that figure so they could include it in the chapter. And they were very kind to say courtesy of Joseph Antognini.

Q. Thank you, Doctor.

Now, where in the body does anesthesia produce immobility?

A. So, based on my work and the work of other people, it looks that it's -- immobility is produced by anesthetic action in the spinal cord.

Q. And what is noxious stimuli?

A. So noxious stimuli, stimulation essentially is applying a stimulus that causes or has a potential to cause tissue damage. So, for example, that might be a heat stimulus. It might be a chemical stimulus. It could be a mechanical stimulus, like a pinch.

There is one type, at least one type of stimulus that is not -- that can be painful but is not necessarily

associated with tissue damage. That would be electrical shock. And we often use that experimentally to apply a noxious stimulus. But, of course, I am sure almost all of us have experienced that in our lives where you plug something in and you get shocked, or you feel the shock of static electricity.

But those are the different ways which we apply a noxious stimulus.

Q. Have you ever heard of the term "Lazarus sign"? And what does it mean?

A. So the Lazarus sign and the Lazarus phenomenon is named, of course, from the Lazarus in the Bible, who was raised from the dead. And in this instance, it's given to brain-dead humans who have spontaneous movements or who have movements associated with noxious stimulation. So, for example, patients, brain-dead humans in the intensive care unit can sit up in bed. They can actually cross their arms over their chest. There have been reports of head turning, sometimes spontaneously. Other times in response to noxious stimulation of some sort.

And these -- because by definition these are brain-dead humans, these reflexes and these movements are the result of some of the circuitry in the brain stem and spinal cord.

Q. Have you ever observed physiological responses in the brain by dead humans?

A. In brain-dead humans.

THE COURT: Physiological responses.

BY MR. MADDEN:

Q. In the brain by dead humans.

A. I believe you mean brain-dead humans, yes. I have.

So in my career, I have done anesthesia for organ harvesting. And you might ask yourself, well, why does a brain-dead human need to have anesthesia? And the answer is that when you apply a noxious stimulus to a brain-dead human, you can get marked physiological responses. That is, you can get marked increases in heart rate, in blood pressure, and you need to be able to control that during the anesthetic -- during the harvesting of organs. So if they are going to take out the kidneys and the liver and so forth, you need to be able to control that. And I have seen that.

And that's very well-reported in the literature as well.

Q. Now, I want to talk about physical movements. Do complex movements by patients during surgery inter -- while anesthetized always indicate consciousness?

A. No.

Q. Explain that -- using the figure, explain that to the Court.

A. Well, I have an anesthetic concentration on a patient

here, or I should say anesthetic concentration there. You should see that none of the patients would be conscious based on this curve, but almost all of these patients, not quite where I have drawn the arrow -- I am trying to draw that straight. I am going to have to do it like this.

At this concentration, none of the patients would be conscious but 50 percent of the patients, about, would have gross purposeful movement. So movement can occur in 50 percent of patients even though all of them would be unconscious based on the data that we -- that we've used or I've used and others have published in terms of consciousness and memory.

So movement during anesthesia, from a surgical stimulus, does not equate with consciousness.

Q. So what type of movements are we talking about? For example, gross purposeful movement.

A. So basically when a surgical incision is made, the patient can move violently. They can move their arms around, they can attempt to sit up from the operating room table, cough, and so forth. So they can be pretty significant.

And, of course, it's difficult sometimes for us to be able to achieve the correct anesthetic level. Obviously it's not what we want, but it does happen.

Q. And just because you have gross purposeful movement

doesn't mean you necessarily have consciousness; is that right?

A. That's correct.

Q. How is an anesthetized patient during surgery capable of such movements?

A. I believe, again, based on the work that I've done and also the work that's documented, complex neurocircuitry in the spinal cord and brain stem, as I mentioned with the Lazarus phenomenon, those together lead me to believe -- and I think others -- that the complex movements occur because of the -- or the circuitry is there to generate those movements. So just because the patients are unconscious does not mean that they cannot move in a complex way.

Again, I refer -- go back to the Lazarus phenomenon, where brain-dead humans can move very -- in very complex ways. And this is, again it's -- there are many studies out there, many animal studies at least, that help to inform this area.

So as an example, there is something called the frog-wiping reflex. So if you take a frog and you apply noxious stimulus to the forelimb, a hindlimb will come up to wipe it away.

Now you take that frog and you pip it, so basically you've severed the connection between the brain and the spinal cord so there is no connection between the two. Now

you apply that noxious stimulus to the forelimb and the hindlimb will come up and wipe it away.

If you move the forelimb maybe down and you apply the noxious stimulus again, the hindlimb will come up and wipe it away at that new location.

So the hindlimb knows where the forelimb is even though the brain has been disconnected.

Now, frogs are not humans and humans are not frogs, but that type of work I think gives you an idea of the incredible amount of circuitry that's present in the spinal cord to be able to generate these complex movements.

Q. Now, you've already explained noxious stimuli. How is that different from pain?

A. Pain is the conscious awareness of a noxious stimuli. That's my sort of simplified version or explanation of it. So pain is what we all think about pain. That is, you know, you stub your toe; it hurts. It's tissue damage that -- or potential tissue damage that provides that emotional experience.

And I refer to the specific definition in my report, and this is from the International Association For The Study OF Pain. As in, quote, an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in such -- in terms of such damage.

THE COURT: You are reading from where?

THE WITNESS: This would be page 6 of my report, my declaration, which is on 1778.

THE COURT: I have it.

THE WITNESS: I am not sure that you asked about a noxious stimulus.

BY MR. MADDEN:

Q. What's the distinction between that definition --

A. Yes.

Q. -- and a noxious stimulus?

A. A noxious stimulus again further defined by the IASP is "a stimulus that is damaging or threatens damage to normal tissue."

So you can apply a noxious stimulus but pain is, again, the conscious awareness or that unpleasant sensory and emotional experience associated with that noxious stimulation.

Q. Can you explain to the Court what you mean by paragraph 12 of your report?

A. So I think we need to -- well, I am not saying what you need to do. I am just thinking in my own mind, it's important to make the distinction between a stimulus that's, you know, being painful and noxious. So as an example, if I were to go over to you and I had a hammer and I were to knock you in the hand with that hammer, you would say that hurts, and you would have a painful experience.

But if you were anesthetized and I did the same thing, and after you wake up, I'd ask you, did you feel any pain, you'd say no, I don't remember any pain. I didn't feel any pain.

So it's important to use the terminology correctly about applying, you know, the same pain or painful versus a noxious stimulation. Pain is -- and painful really should only be used when we're talking about somebody who is awake and conscious.

Q. Have you ever heard the term "minimal alveolar concentration" or "MAC"?

THE COURT: Alveolar I think.

THE WITNESS: Alveolar, that's correct.

MR. MADDEN: Thank you, Judge.

THE WITNESS: Yes, I have heard that term.

BY MR. MADDEN:

Q. And what does it mean?

A. The minimal alveolar concentration, or MAC, just signifies the dose that would be therapeutic or effective in 50 percent of the population. It's just a way of looking at the effective dose. So, again, looking at these curves, if I may go back to the figure here.

Q. Sure.

A. So the MAC -- the effective dose fits your MAC, would be where I have drawn this, this dotted line; that is, that

50 percent of the patients would display no gross purposeful movement and 50 percent of the patients would display gross purposeful movement.

Q. And what is the concept supramaximal noxious stimulation?

A. So when you do a study like this, you always have to be mindful of the amount of noxious stimulation, because during surgery, the amount of noxious stimulation varies. Something can be incredibly noxious and something else might be not quite so noxious. So the anesthetic amount that you need to prevent the end point, in this case gross purposeful movement, depends on the degree of stimulation.

So many years ago when this MAC concept was developed by Ted Eger and others, they were sure to look at that concept: Well, how much stimulation do you need. So they actually applied different noxious stimuli in graded amounts, and then they got to a point where if they applied more noxious stimulation, it didn't change the amount of anesthetic that was needed.

So let me give you an example. If I were to apply -- if I, again, use that example of a hammer and I just lightly touch your finger, you might be a little bit noxious and you might -- and I'd have to give you some anesthetic to prevent you from moving but not very much. But if I hit you harder with it, I am going to have to use more anesthetic to

prevent the gross purposeful movement.

THE COURT: The MAC is the amount needed to prevent the gross purposeful movement in 50 percent of the population?

THE WITNESS: Correct.

THE COURT: All right.

THE WITNESS: And just to clarify that, obviously we like to do better than just being 50 percent, you know, right 50 percent of the time, so we actually increase the anesthetic a little bit more to try to get a lot more of the patients to -- and sometimes we can't do that because some patients are very sick and we can't do that. But that's, you know, clinical things that we have to manage.

So just, again, to clarify with the noxious stimulation, so if I increase -- let's say I hit you with 100 grams of force per unit area and I need to provide a certain amount of anesthetic, let's say 1 percent, and now I increase that stimulus to 120, and I still only need to give you 1 percent, then I've reached the super maximum point.

BY MR. MADDEN:

Q. Now in a clinical setting during a surgical procedure, would you expect to see a spectrum of movement?

A. Yes. So there may be no movement at all or there may be violent thrashing about during the surgery, violent, we call it bucking. It's actually, say, a colloquial term in

the specialty of just coughing vigorously. So there could be a lot of that going on.

But movement of the arms and legs, we certainly -- it's important to strap patients down during operations because of these movements. It's not the only reason we strap them down, because patients can fall off the table when they move. Their arms can fall off when they move in terms of going off the armboard. I mean, obviously they don't literally fall off the body, but --

Q. Now, in relationship to the eye, is that a problem?

A. So during anesthesia, this is an important issue where patients, their eyes can -- their eyes can remain open. So when we give an anesthetic, sometimes their eyes will close, sometimes they will open. We almost always tape the eyes shut because if you don't do that, the eyes -- the eyes will dry out. The conjunctiva will dry out and you get what's essentially a corneal abrasion. So we have to tape the eyes in order to prevent that, or to minimize that risk. Even taping the eyes sometimes will not -- you can still get that problem, but it's definitely a problem -- more of a problem when you don't tape the eyes so the eyes can remain open.

Q. In --

A. In an anesthetized.

Q. -- an anesthetized person?

A. That is correct. And they can close initially with

induction and then open up; the eyelids will lift up as the muscles start to relax.

Q. Are you familiar with midazolam?

A. Yes.

Q. What is it?

A. Midazolam is a benzodiazepine. It's a relatively short-acting -- fast-acting and short-acting benzodiazepine that we use for a variety of different reasons in medicine and surgery. Primarily in my specialty for sedation in the therapeutic doses that we use.

Q. Now, are all benzodiazepines created equal?

A. No. There are differences in terms of their, what I would say their kinetic phase, that is, that some of these drugs act faster than others and some are shorter acting. So, for example, diazepam wouldn't act as fast as midazolam, and midazolam would probably, dependent on the doses compared to these other drugs, not last quite as long. But there are kinetic differences among these benzodiazepines.

But in terms of the clinical effects, they are pretty similar.

Q. What is the typical dose of midazolam for a regular, healthy person?

A. Again, it depends on what you are using it for. So if I were to use it on a patient who's going to have surgery, I'm going to use it for the sedative and anxiety-relieving

parts. So I might give 1 milligram, 2 milligrams. So elderly people require less. So if I had somebody who was in their 70s, I might only start out with 1 milligram IV. Someone that's younger, I might start out with 2 milligrams. So the range is going to be somewhere in that, but it could go up to 4 or 5 milligrams.

Q. What about doses greater than 5 milligrams?

A. Can you clarify what you mean?

Q. Yeah. In your practice, should doctors use caution when giving over 5 milligrams of midazolam?

A. They should use caution no matter what dose of midazolam they are giving.

Q. Is midazolam safe?

A. Midazolam is not a safe drug.

Q. And you know that how?

A. Because I've given it to patients and they've become unconscious even in small doses. So the main thing that you need -- that's important to understand here is that people use the term about some of these drugs, that these drugs are safe. And I'm not trying to scare or upset anybody in here that may end up having surgery very soon. Yes, these drugs are safe when used in the right hands.

But if you gave these drugs to somebody in the doses that I use, it would not be safe because they cause airway problems, they cause respiratory depression, and it is only

because we know how to manage those airway complications that we are able to make these drugs safe.

So midazolam in my mind is not a safe drug, and I think that's borne out by the literature in terms of the deaths that have occurred as a result of midazolam and other drugs that are used. Midazolam by itself or midazolam and opiates used together.

Q. What would be the primary purpose of a therapeutic dose of midazolam?

A. What would --

Q. What would be the primary purpose?

A. Again, it depends on the circumstance. If it's a patient about ready to have surgery, the primary purpose is to relieve anxiety and produce some sedation. If it's actually being used during a procedure, so, for example, a colonoscopy, then it would be to produce a heavy or very moderate or deep levels of sedation so that the procedure could be done.

So it's primarily being used for that purpose. Now, it can also be used for what we call induction of anesthesia or beginning the anesthesia basically. And in that case, we would be giving a lot more of the -- or more of the dose. We can do the endotracheal intubation or the airway management.

Q. When a therapeutic dose of midazolam is administered

intravenously, what is the onset?

A. The onset can vary, but it can be as quickly as 30 to 60 seconds. So it's been very common in my practice to provide the midazolam and within that time period, the patient will say, gees, I feel like I've just had a couple glasses of wine. It can be very rapid.

Now, in some patients it may not be that rapid. Again, it's sort of obviously a dose-dependent phenomenon. And, again, if you are young, you may not -- you know, it may not work as quickly, but it's certainly going to work within one to two minutes in almost everybody.

Q. Does midazolam prevent the formation of memory?

A. Midazolam, one of its most potent effects is to prevent the formation of memories. It's got very strong amnestic properties.

Q. Have you ever heard of the term "anterograde amnesia"?

A. Anterograde amnesia is a term to describe something that you are not going to remember in the future. That is, that if I were to give you some midazolam right now, you might be a little bit sedate but you would be able to ask questions. And then an hour from now you wouldn't remember that you had asked me those questions. So it provides the amnesia after you have given the drug as opposed to retrograde amnesia where it prevents -- ablates memories that were there before the drug was given, which midazolam

doesn't really do at all.

Q. Can midazolam cause unconsciousness?

A. Yes.

Q. Can midazolam cause the induction of anesthesia?

A. Yes.

Q. Explain that.

A. So induction of anesthesia is something that we do to get people anesthetized for surgery, and often what we need to do when we induce anesthesia is we need to place an airway device into the windpipe, and that's called an endotracheal tube. So the endotracheal tube is a plastic tube, it's about that long.

THE COURT: Indicating approximately 8 inches to a foot.

THE WITNESS: About a foot, yeah, 8 inches to a foot, and it's about the size of my finger. Obviously it depends on the individual but the size varies, but it's about the size of my finger. So you can imagine sticking a plastic tube like that down the mouth and into the windpipe is a very, very stimulating effect. It's probably more stimulating than some of the other stimuli -- certainly -- I shouldn't say probably -- it is more stimulating than some of the other stimuli that occurs during surgery. So it's a very stimulating procedure. I mean, you can imagine, we have all experienced aspirating something in our windpipe

and you cough severely. I mean, that's -- that's what it's going to feel like.

BY MR. MADDEN:

Q. And what are you basing this on when you say that midazolam can be used for this purpose?

A. So there are studies that have been published in the literature looking at the use of midazolam for anesthesia induction. And usually they are comparing midazolam or some other induction drug. So, for example, most of the time it's been thiopental. So basically they have looked at midazolam versus thiopental for these inductions of anesthesia.

Q. Is midazolam typically used for the induction of anesthesia?

A. No, it's not.

Q. Why not?

A. Because there are other drugs out there that are better suited I think for the -- that process. So one of the disadvantages of midazolam is -- compared to other drugs that we have -- is that you need to use more of it, of course, to achieve this. And then, of course, it's a short procedure. The patient's going to take some time to wake up, and that's not such a problem with the other drugs that we have. So people have not used midazolam for that purpose because of the other drugs that we've got.

Now, had midazolam been discovered many years ago, and you started -- in use many years ago, it probably would have gained a lot of traction. But because of when it was discovered and brought into use, there are enough other drugs coming on the market or already present where people decided, in our specialty, it probably wasn't particularly useful for that purpose.

But it could be used. If I have a -- if there are drug shortages, which we have a lot of, and maybe somebody's allergic to the drug you want to give, midazolam would be an appropriate choice.

Q. What are some of those other drugs that were -- that you are speaking of?

A. Well, it could be thiopental, it could be propofol, etomidate, ketamine. These are other drugs that we use for induction of anesthesia.

Q. And what would the typical induction dose be for midazolam?

A. It would be around 0.2 to 0.3 milligrams per kilogram. That's the dose that's in the literature. The package insert says you can go up to .6 milligrams. Of course, if you give a larger dose, you are going to have problems at the end with the patient waking up, but that would be sort of the dose range that you would use.

Q. Can midazolam ever be used for painful procedures?

A. Yes.
Q. Which ones?
A. Colonoscopies, as I pointed out. Endotracheal intubation is incredibly stimulating. So it can be used for that. It can be used as the sole drug in endotracheal intubation in the intensive care unit.

There again, other endoscopies like bronchoscopies for which it's been used, and so there have been -- you know, it can be used for a variety of different procedures.

Q. And what about cardioversion?
A. So cardioversion is a procedure where somebody that has an arrhythmia in the heart and you apply paddles to the chest and the back and you deliver an electric shock to the chest. And I've had that actually done twice to myself. But I don't remember it. Although they did not use midazolam in my case, but it can be used for that purpose, and it is a very stimulating procedure, so they have to anesthetize the person for that.

It's also been used in induction for C-sections. There is a report of that.

Q. Let me -- let me refer you to Defendants' Exhibit 76, at 1130. Do you have 76 with you, Doctor?
A. I don't know. I'm afraid I am not as adept at navigating these binders as I think you are. Are you talking about Exhibit 76?

Q. Yes.

A. Okay. No, I don't have that.

THE COURT: The record will reflect that the witness has been handed the binder that contains Defendants' Exhibit 76.

BY MR. MADDEN:

Q. And then page 1130 on the top right-hand corner.

A. Yeah.

THE COURT: You are directing the witness' attention to page 1130 of that, correct?

MR. MADDEN: Yes.

BY MR. MADDEN:

Q. Do you recognize that article?

A. I do.

Q. What is this?

A. This is a paper that was published in 1989 -- Crawford was the first author -- comparing midazolam and thiopental for induction of anesthesia in patients, female patients, by definition female patients having cesarean section.

THE COURT: An elective cesarean.

THE WITNESS: Elective, that's correct.

BY MR. MADDEN:

Q. Tell the Court about that paper, why you think it's relevant.

A. What they did, they did a study to compare the effects

of midazolam, and in this case it was a 0.3-milligram dose of midazolam with thiopental, which is a 4-milligram/kilogram dose. So what they did is they had two separate groups. One received midazolam; the other received the thiopental. And then they -- and I've noted some of the details on that, but there was basically the comparisons of the two drugs in terms of the effects on the mother.

And they looked at various end points such as systolic blood pressure and diastolic blood pressure and heart rate and so forth. But I think the point of this paper or the important thing to gain out of this paper is just to indicate the use of midazolam, its effect on noxious or its -- yes, its effect on noxious stimulation.

So something that we need to -- I think I need to explain about, something that's different about cesarean section compared to other types of surgeries, that obviously when you are doing a c-section, you, as we like to say, you have two patients there. You have the mother and the baby. So you have to be very careful about the drugs that you give because you don't want to overdose the baby. You want the baby essentially to be able to come out as quickly as possible so that there is a minimal chance, or you lessen the chance that the baby will absorb some of the drugs that we give.

So what we do in these c-sections, which is different

from other procedures, is that we actually would put the mother on the operating room table and then we prep and drape her. So we've sterilized the abdomen, and we have the drapes over her while she was awake, and the surgeon is gowned and gloved. So the sterile field's all set up. And literally the surgeon has the scalpel in his or her hand, poised, ready to go.

And what we do is we induce anesthesia. We actually give the drug, in this case it was either midazolam or it was thiopental, and then we use a muscle relaxant to relax the mother. And then we perform the endotracheal intubation. And once we confirmed that the endotracheal tube is in the correct place, that is, that it is in the windpipe, then we tell the surgeon "Go." And then the surgeon will make the incision and start to pull apart the tissues to get the baby out.

Now, what we -- at this point what we're doing as an anesthesiologist is that we are providing some anesthesia through the lungs. So in this particular case, as I recall, they used nitrous oxide. Yes. And nothing else. So basically it was nitrous oxide.

An important point to make about this is that once that tube is in place, you turn the nitrous oxide on. It takes some time for the nitrous oxide to start flushing through the system and get into the patient. So my estimate is that

for the -- probably for the first minute of this procedure, the only anesthetic the patient has on board in this study was the midazolam. So this is a -- the drug that was used in that one group to provide anesthesia for the endotracheal intubation and the initial part of the cesarean section.

Q. And what was the conclusion of that paper?

A. Well, none of the patients had any memory of what went on, and that thiopental and midazolam are essentially equivalent. I mean, I think there are some very minor differences, but they are essentially equivalent in terms of the effects on blood pressure and so forth. There are other studies that they published out of this group. They looked at the baby and effects and all that, but my recollection is that there was really no major effects one way or the other between the two drugs.

So obviously the intent here was just to look at the effects, as I said, on blood pressure and so forth, but within the context of how these types of operations are done, I think it's important to, again, point out that during the first minute or -- minute, approximately, midazolam was the -- the only anesthetic that this mother was getting, or that these mothers were getting.

Q. Let me refer you to page 8, back to your report, and paragraph, just -- paragraph 17. Can you explain what you were trying to -- what you were saying there to the Court?

A. So what I'm saying here is that midazolam can clearly produce unconsciousness, and that's been defined by multiple investigators. It reduces the amount of a potent, inhaled anesthetic that's required for -- to produce immobility. So in this particular study that I quoted, the midazolam dose that was given reduced the halothane requirements by 70 percent. So halothane is one of the drugs -- we don't really use it anymore, but it's one of the inhaled end effects. And when they gave the midazolam in the study, they only used to give 30 percent of halothane with regard to not having the midazolam on board.

Now, I further go on to say that midazolam has not been used -- it's not clinically warranted to administer a huge dose of midazolam to see whether or not it would produce complete, or could be used as a complete anesthetic for a long surgical procedure. As I've already indicated, it certainly can be used on very, very short procedures, such as endotracheal intubation and cardioversion and so forth. But whether it could be used on a long surgical procedure is unknown because, again, we're not able to really do the study to do that because it's, for the most part, not clinically warranted or ethical.

Now, again, getting back to the issue around drug shortages and other things like that, you never know what's going to happen in the future. There may come a time when

midazolam will be something that we'll take another look at to do that, and we'd have to do that work, but right now we don't know about the immobility part in humans.

However, there is an animal study that was published by Nishikawa, and their conclusion was that you could -- in the mouse, it did provide a complete anesthetic. I don't have that paper in front of me. I am not sure if it's included here. But I know that there was some concern about the -- that paper.

That paper looked at some genetically altered mice and some mice that had been administered other medications, but almost all studies like that will always have a controlled group, which is a group of mice that are what we call wild type; that is, that they are sort of your normal, average mice, or whatever the species is. And that's part in that paper.

And those mice, when given midazolam, the investigators were able to achieve anesthesia, general anesthesia. That is that they were able to prevent movement to a noxious stimulus.

Q. In your experience, is it ever warranted to administer extremely high doses of midazolam, for example, 500 milligrams, to a patient?

A. Given the current choice of everything else that we have here, no, it would not be warranted to do that to a

patient.
Q. Is there any evidence that -- which demonstrates that midazolam can produce the end point of immobility as it relates to noxious stimuli?
A. Could you repeat that, please?
Q. Yeah. Is there any evidence which demonstrates that midazolam can produce the end point of immobility as it relates to noxious stimuli, stimulation?
A. So clinical experience, I would say yes. Again, these drugs have been used in some settings for clinical procedures. But I would also, again, refer you to the paper I just mentioned, that there is evidence in animals that it can produce immobility.
Q. So there would be a difference between consciousness -- as you explained before, there would be a difference between consciousness and immobility?
A. Correct. Yeah, I hope I -- maybe you should ask the question one more time to make sure.
Q. Yeah. I am referring to immobility as opposed to consciousness.
A. Yes, okay.
Q. Would 500 milligrams of midazolam produce a state of unconsciousness comparable to levels of anesthesia considered adequate for a variety of medical procedures?
A. Yes, in my opinion, it would.

Q. And how do you come to that?
A. Well, again, I just, I look at what's been published out there in terms of the effects of midazolam, and there are a variety of different studies, some of which I have quoted here, looking at consciousness. And, again, it's used during procedures. So there are studies that I could certainly refer to if you desire, but --
Q. No, that's okay.
A. -- the work is out there.
Q. To your knowledge, is there any human studies where humans were given 500 milligrams of midazolam to study the results?
A. No. To my knowledge, no.
Q. And why not?
A. Again, it's not clinically or probably ethically warranted to do that because we -- I'm not sure I could say it's ethically unwarranted because there may be some reason why an investigator might want to do this. Obviously, the investigator would have to go up to the IRB and ask, and make that proposal, and there may be some valid clinical reasons to do so. But to my knowledge, no one's ever done that. And those studies have not been published.

THE COURT: And the abbreviation IRB stands for Institutional Review Board, correct?

THE WITNESS: Correct, yes.

BY MR. MADDEN:

Q. In those extreme dosages, how would you expect midazolam to affect a person?

A. I would expect midazolam to -- when you say extreme doses, I am going to say 5 milligrams. I would expect the individual to become unconscious, and they would have no memory for that period and probably for even after they started to wake up from it. They would not have memory for quite a long time. I can't give you an estimate how long that would be, but it could be for several hours or more after that large dose. So they'd be unconscious for a significant amount of time and have --

THE COURT: That's the anterograde amnestic effect as opposed to retrograde, right?

THE WITNESS: Correct, that is correct.

BY MR. MADDEN:

Q. Have you ever heard of the term "black box warning"?

A. I have.

Q. And what does that mean?

A. So many drugs that we administer in medicine can have serious complications or side effects. And sometimes the FDA will put these warnings in a -- at the top of the package insert and they will put a black box around it. So, therefore, the term "black box warning." And it's to alert the clinician about the serious complications that might

occur from that particular drug.
Q. Does midazolam have that warning?
A. It does.
Q. And is that warning given to just any drug?
A. No. No, it's not. Only to drugs, again, that have some serious side effects.
Q. What are those side effects for midazolam?
A. So the side effects are going to be respiratory depression. It can be unconsciousness and death because that's what has occurred as a result of the administration of midazolam. Now, the black box doesn't specifically mention all of these, but that's the clinical experience, that these drugs will produce these effects.
Q. Are you aware that Ohio's lethal injection protocol calls for 500 milligrams of midazolam?
A. Yes.
Q. And is that a therapeutic dose?
A. No, it's not.
Q. And how much more is that than a therapeutic dose?
A. Well, again, depending on its intended use, it could be -- if my therapeutic dose for a patient is 2 milligrams, then 500 milligrams would be 250 times that dose. If my intended dose for a patient is, let's say, 20 milligrams because I am inducing anesthesia, or 25 milligrams, then 500 milligrams would be 20 times the therapeutic dose.

Q. What would you expect to happen to a person who's given 500 milligrams of midazolam?
A. They would become unconscious and they would, again, have lack of memory for a long period during the action of the drug.
The important thing to also point out is that the duration of action of midazolam is going to be a lot longer with 500 milligrams. So if you gave 25 milligrams of midazolam to somebody, it might have an action of -- again, dependent on the end point you are looking at, it might have an action of 30 minutes, 60 minutes, something like that.
If you give 500 milligrams, it's going to have a lot longer duration because you've achieved a much higher concentration of the drug. It's going to take longer for that drug to wear off.
Q. What is the -- can you say that with a degree of medical certainty?
A. Yes.
Q. What is the risk that a person given 500 milligrams of midazolam would experience noxious stimuli?
A. Well, I just want to make sure I clarify that. Do you mean what is the risk that they would experience pain?
Q. Yes.
A. I think the risk is very, very low. Because the drug produces unconsciousness, and when you apply a noxious

stimulus, they may have some physiological responses to that noxious stimulation, but I do not believe that they would have the experience of pain that we normally associate with, as a conscious person.

Q. Thank you, Doctor, for correcting me on relating the difference between noxious stimulation and pain.

Have you ever heard of the term "ceiling effect"?

A. Yes, I have.

Q. And what is it?

A. It describes the -- generally describes the effect of a drug that, as you increase the dose of the drug, you don't get any additional clinical benefit from the drug. So, for example, you might give a drug that you are using to control the blood pressure. And so you start to give the drug, and the blood pressure starts to come down and then it reaches a certain point, and then you give more of the drug and the blood pressure doesn't go any further down. So you have reached, in that case, it's really more like what you call a floor effect because it's an effect that's going down. But maybe it's a drug that you are giving to increase the blood pressure. So you increase the blood pressure, and it reaches a certain point. And you give more, and you don't see that effect.

And that can be one way of describing a ceiling effect. There are other reasons why that might occur. There is

something called tachyphylaxis, which is not really germane here, but that can also give you a similar pattern. But, in essence, the ceiling effect describes the phenomenon where you give more of the drug and you don't see any more of the response that you are looking for.

Q. In paragraph 10 -- in page 10, paragraph 20, you talk about the pain from stimulation caused from paralytics. Can you tell -- talk to the Court about that?

A. So when you give -- when you induce anesthesia in a patient, you know, typical anesthesia, general anesthesia that we all are, I think, familiar with -- obviously, maybe I am a little bit more familiar with it than you are because I have done it so many times, but I am sure many of you have had surgery and had anesthesia for that procedure. But basically you have the patient on the operating room table. You have an intravenous line in place, and you give the induction drug, which, you know, we can say it's propofol or something like that. And we need to control your airway. So we are going to place that plastic tube into your mouth. So we will give a muscle relaxant to relax the muscles in order to be able to place that -- that plastic tube.

And we often will use rocuronium. So we start with, let's say, propofol and then we give rocuronium. Rocuronium in its configuration is irritating to the vein. So people have described -- and I have certainly seen this movement

occurring when you give the rocuronium. So the arm will flinch or move up.

This -- these investigators looked at this phenomenon describing that movement, and, again, it's thought to be secondary to vein irritation. They did not indicate any signs or find any signs of awakening. They were actually looking at the BIS number, and they did not see any change occurring despite the fact that movement occurred. So the BIS didn't change despite movement occurring.

Q. Are there any drugs that have a similar effect?

A. Yes. There are other drugs that will cause vein irritation. Certainly in my specialty, yeah, there is -- Propofol can be very, very painful. Etomidate. In fact, propofol, which is the white drug that you're probably familiar with, the one that was used with Michael Jackson, that's very irritating. We actually will use lidocaine mixed with the propofol to help mitigate that response. But it's very painful.

Sometimes patients will have a lidocaine allergy and we can't do that so we have to give the propofol just as it is, and these patients will complain and sometimes complain significantly about the amount of pain that they experienced from the propofol. But it's just one of the things that we have to do essentially, and we have to talk the patient through it. But it happens fairly commonly when we can't

provide the lidocaine. Even with the lidocaine, we can still get pain on injection.

Etomidate is another drug that's painful on injection. Diazepam, Valium, when it's given intravenously is painful on injection. Those are the ones I am most experienced with.

Of course, I know within the context of this setting potassium chloride can be painful when given to an awake human.

Q. But if the person has been rendered conscious, would they feel it?

THE COURT: Conscious or --

BY MR. MADDEN:

Q. I am sorry. Unconscious, would they feel that?

A. In my opinion they would not. Again, we have to think carefully about separating the idea of pain versus noxious stimulation. So I do not believe that they would experience pain in the way that we normally think about pain. Would they have a physiologic response to that? It could certainly happen. If you were measuring the blood pressure and the heart rate, yes, those values could go up, but that doesn't mean that they experience the typical emotional experience that we all think about when we think about pain.

Q. In that same paragraph you talk about the stimulation caused by potassium chloride. Can you talk about that to

the Court?

A. So it's been well described that potassium chloride when injected intravenously can cause pain. And, again, it's irritation of the vein setting off some of the nerve fibers and activating nerve fibers in the vein, and it can be very painful.

Q. Would --

A. Go ahead.

Q. Would the noxious stimulation caused by potassium chloride be long or short in duration?

A. In what setting?

Q. If administered intravenously.

A. Well, if it's administered as a slow infusion in a clinical setting, it would last for a significant amount of time.

Q. What about administered quickly?

A. Well, if administered quickly -- and this certainly has unfortunately happened either in a clinical setting by mistake or obviously there have been some homicides out there where healthcare workers have administered potassium chloride quickly to a patient, but if administered quickly in a large enough dose, the drug gets to the heart and the heart will stop essentially. And after it stops, then there is no more blood flow to the heart or to the brain. And then the person would become unconscious.

So, again, dependent on the --

Q. Be unconscious or dead after the potassium chloride reaches the heart?

A. Well, once the heart stops, they are going to be clinically dead if nothing else is done. But they would be unconscious. So there is pretty good data out there about how long does it -- how long can you maintain consciousness after the heart's stopped, and it varies. It's probably around ten seconds.

Now, there may be -- there are some old reports many, many, you know, hundreds of years ago, and not to get into too gory of a subject, but when the guillotine was used, there were some experimenters who actually would ask the condemned person to attempt to speak after the head was severed. And they actually timed how long after the head was severed to see when the individual was still able to move their mouth. And my recollection it's -- in that setting, it was around ten seconds. And I think other literature, more modern literature suggests that it's probably around that period of time once the heart stops, you are going to lose consciousness within about ten seconds.

So if you look at the time from when the drug is first injected to when the heart stops and they lose consciousness, you are probably talking about maybe 20 to 30

seconds is my guess.
Q. And would you expect that 500 milligrams of midazolam would render the inmate unconscious to withstand that noxious stimulation, that noxious stimulation in that short duration?
THE WITNESS: Judge, do I have to pay if I drop that water?
THE COURT: No.
THE WITNESS: I'll be careful.
Can you repeat the question?
MR. MADDEN: Could I have that question repeated.
THE COURT: And would you expect that 500 milligrams of midazolam would render the inmate unconscious to withstand that noxious stimulation, that noxious stimulation in that short duration?
THE WITNESS: I will answer the question if I could just rephrase it a little bit in terms of 500 milligrams given to a person?
BY MR. MADDEN:
Q. Yes.
A. If midazolam at 500 milligrams is given to a person and then potassium chloride was injected, I would not ex -- I would predict that the individual would be unconscious and unable to feel and experience the pain that we normally associate with the injection of potassium chloride.

Q. With that 1 to 25 seconds?

A. Correct, for that period of around -- up to around 20 to 30 seconds after the injection, yes.

Q. There's been a lot of testimony here about air hunger. Can you tell us your understanding of air hunger?

THE COURT: There's been a lot of testimony in the case before this hearing. I don't think we have had any testimony during the course of this hearing about air hunger. Just, again, counsel are much more familiar with what's happened in prior proceedings than I am, but --

MR. MADDEN: If it's your understanding that air hunger is not at issue here.

THE COURT: I am not saying it's not an issue. I am saying that I don't have a recollection of any discussion of air hunger during this preliminary injunction proceeding, which is not to say it's not an issue.

MR. MADDEN: Okay, okay.

THE COURT: Your witness, you know.

BY MR. MADDEN:

Q. Can you tell us your understanding of air hunger?

A. So air hunger is -- just to explain this a little bit in terms that you can relate to, air hunger in a way is going to be similar to how I described pain versus noxious stimulation. So air hunger is the conscious awareness that we have when we can't catch our breath. And some of the

clinical conditions in which that occurs would be pneumonia, congestive heart failure, pulmonary edema. These are conditions where you get water on the lung.

You could have chemical damage to the lungs that causes air hunger. You could also have a physical obstruction of some sort that causes air hunger. So that is if you have a -- you have aspirated something and you can't catch -- you know, you can't breathe very well around that, that would cause that sensation of not being able to get your breath. And that's what you experience as an awake person.

Q. And are you concerned that a cessation of -- cessation of breathing like that would be stimulating to a patient enough to cause them to awake from 500 milligrams of midazolam?

A. I would not expect that to. The -- not breathing or the apnea would not be stimulating in the sense of waking somebody up from 500 milligrams of midazolam or many of the other drugs that we use in our specialty.

Q. Do all anesthetics produce the cessation of breathing? Is that a common problem with all anesthetics or a side effect of all anesthetics?

A. One of the most important concepts I learned in medical school is never say never and never say always because someone's going to find something. So I won't say, you know -- the common anesthetics that we use, I would say they

all produce some type of respiratory depression. Now, do all anesthetics do that? There may be some experimental anesthetics out there that I am not aware of that don't have that problem, and certainly there's some anesthetics that have less of a problem, but the commonly used anesthetics and sedative drugs all cause respiratory effects and respiratory depression in some way to some degree.

Q. Now, much has been said about the ceiling effect as it relates to midazolam. Can you talk about that a little bit?

A. So the ceiling effect I just don't think is particularly germane here because it really depends on the end point that you are looking at and whether a ceiling effect is beyond that end point.

So there may be some effect that you are looking at where there is no -- that is, that you might be looking at a particular end point like sedation. I will just use that as an example. And the ceiling effect of the drug is actually beyond that -- that point. The effect of the -- at the receptor level in terms of leveling off is beyond the concentration that you need or the dose that you need to be able to produce a particular end point.

In this setting, what we're concerned about in terms of giving a large dose of midazolam is, does it produce unconsciousness. And in my opinion it does. And so whether there is a ceiling effect beyond that is really not

important because it produces the desired effect, that is, that you want to -- in this particular case, just like in the clinical work, you are interested in producing unconsciousness. So it does produce unconsciousness.

So if a ceiling effect occurs beyond that in terms of something that happens at the receptor level or if a ceiling effect occurs because you are looking at the electroencephalogram and when you give more of a drug you don't see any additional effect, I don't think that's particularly important because, again, you are looking at does it produce unconsciousness. And the answer is yes.

And so I don't think it's that important.

Q. Yesterday Dr. Stevens gave testimony on his theory regarding the ceiling effect and how he arrived at his conclusions. Can you give an opinion in response?

A. So I think that the ceiling effect and the way that he approached this as an academic exercise, I think I'll be quite honest, it's pretty much exactly what I would have done in the sense that, you know, I think he used some of the appropriate data out there and put together that process in a reasonable way.

Of course, there were some -- there was a math error in one version, and I think perhaps at odds in terms of another issue related to that; but, nevertheless, I think that was an appropriate way to look at this as a -- from an academic

exercise.

And as he mentioned yesterday, it's certainly a ballpark figure. But I think that there is a lot of uncertainty in the way that you arrive at this type of analysis or do this type of analysis. And it's related to the variability of the data where you draw the lines to the ways in which the data were obtained. So, for example, the different types of cells that were examined, the different methods, different temperatures, obviously many of these studies were done at room temperature. And, of course, we give drugs to patients at body temperature.

But the variability of the data I think is instructive. And I'd be happy to go further into that.

Q. Yeah. Why don't we show you what is the Expert Exhibit 1 from plaintiffs.

THE COURT: Before we do that, we are going to take our morning recess for ten minutes.

MR. MADDEN: Thank you, Your Honor.

THE COURTROOM DEPUTY: All rise. This court stands in recess.

(Recess from 10:27 a.m. until 10:42 a.m.)

THE COURT: Mr. Madden, you may resume your examination.

MR. MADDEN: Thank you, Your Honor.

BY MR. MADDEN:

Q. Let me refer you to Plaintiffs' Expert Exhibit 1, page 20 of 32. I think it's expert page -- no, 20 of 32. Okay?

THE COURT: Page number again, please.

MR. MADDEN: 20 of 32.

THE COURT: All right. Thank you.

BY MR. MADDEN:

Q. Looking at Figure 5. Do you have any opinions about -- of this particular figure?

A. Yes, which I will elaborate. So one of the -- as I mentioned earlier, the approach that Dr. Stevens took, again, as an academic exercise, I think it would be pretty much the same approach that I would take.

However, there is -- it's important to understand that there is some uncertainty involved in arriving at these types of calculations. And one of the issues has do with the variability of the data and what those data mean, which I could best explain if I could go up to the poster and explain that.

MR. MADDEN: With the Court's permission.

THE COURT: Of course.

THE WITNESS: May I remove this exhibit?

BY MR. MADDEN:

Q. As long as you put it back.

A. So I am just going to make a very simplified drawing of one of the -- of Figure 5 here, folks, for explanation. And

I am just going to draw part of it because I only need to do that to explain the idea that I am trying to -- I want to explain in terms of variability. And I'd like to explain this in a very -- in a way that hopefully you'd be able to grasp what I am trying to explain here.

By an example, suppose I was interested in what's the average height of the people that are in Dayton, Ohio, right now. Well, I could go out, and I am not sure how many people are in Dayton, Ohio, right now, and measure the height of all those people. But I have a plane to catch tonight. I can't do that.

Maybe what I'll do is I'll measure the height of all the people in this courtroom. So I measure your height, your height, and so forth. And I develop an average. I put those together, divide by the number of people in the room, and I get an average. And there is going to be some variation in that average, variation. And that's essentially what this "T" refers to. It refers to the amount of variation in the data.

The dot itself represents the average. But when I've measured the height of all the people in this courtroom, have I truly gotten an accurate estimate of the height of the people in Dayton? Well, statistically speaking, no, I may not have. And one of the ways you can look at this variation is that the true height of the people, the true

average height of the people in Dayton is somewhere in between the "T" mark that you see here. And because of the way that these drawings are drawn, the "T" goes down like that on each of these. Just for purposes of clarity, omit that. But you have the variation going down like that.

So the important thing to understand here is that you might look at these black dots and say, well, the ceiling effect occurs here because that's where you begin to see the leveling off. And based on the data that is available, you could say that. But what if the true value for this data point is there. That is, when I say the true value, again referring to my example, the true average height of people in Dayton. And the true value over here for this data point may be up here. So, in fact, you can't draw a straight line. There is no ceiling effect.

So there is this inherent variability in data. You know, again, I haven't really said this, but what does science try to do? It tries to explain the world. That's what we are trying to do here. Can we explain the world? Can we, based on our studies and experiments, predict -- make predictions about the future, that is, this is the way things work?

And when you do these types of experiments, you have to understand there is variability there. And so drawing a straight line based on that, yes, there is a chance that

that's where that ceiling effect occurs, but there is a chance, a fairly significant chance I think, that the ceiling effect may be different.

The other thing that I want to point out is that these graphs are drawn on what we call a log scale. So I am just going to put in some numbers here. Number 1, 10, 100, and then 1,000. These are the drug concentrations. So this is only going from 1 to 10. This goes from 10 to 100, and this is from 100 to 1000.

So dependent on where this line is drawn -- and so what was done is that you draw -- you say, well, this is where the ceiling effect first occurs. So it's going to be at around 100 because that's where you begin to see the leveling off. But there are no data points between 1 and 100. The experimenters didn't do that study. So had they done that study, maybe they would have said -- would have seen that at 50, it would be right here, all right? So then the ceiling point actually occurs at 50.

So, again, I don't disagree with the approach that Dr. Stevens takes on this. Again, I would have done the same thing. In fact, I have done this type of calculation myself for other reasons. And it's a reasonable approach to try to estimate this so-called ceiling effect.

Now, there is other issues here where you are going against some in-vitro studies to the clinical situation,

which is -- also has issues, but just based on the variability issue, it's important to understand there is variability in data in making that type of assumption. Yes, it could be correct, but there is a chance that it's not going to be correct. And that's just sort of the nature of statistics.

Q. Thank you, Doctor.

Now, in your -- one of your, either your report or your addendum, you state that you believe Dr. Stevens makes an error in his calculations. Can you tell that -- can you explain that to the Court?

A. Yes. So the math error was corrected. I believe that there is another error, and I understand he may --

Q. When you are talking about the math error, what are you referring to?

A. Well, I am sorry. In his report, for this case -- I apologize -- the math error was corrected. It was in a previous report, so I apologize. That's, I guess, not germane to this particular.

Q. Okay. What was the other error that you noticed?

A. So, again, if I may, I think it's best if I could go to this, so --

And I believe it would be useful if I may refer to the Arendt paper that is important in this discussion, if that's permissible.

THE COURT: Yes, sir.

Mary, that's A-R-E-N-D-T.

THE WITNESS: Correct. And I am not sure where that is, if it's even in these documents.

BY MR. MADDEN:

Q. What would you be looking for?

A. The Arendt paper, A-R-E-N-D-T, from 1983.

Q. Try, see if it's DX 76.

A. You know what, actually -- I have Dr. Stevens' report here. He has a figure that's probably important -- that's an important figure so I can actually excuse that so -- I think part of this explanation I will just do from my chair and then I will go up there if I need to.

When you administer drugs to people, or to animals for the most part, many of the drugs are bound to proteins in the blood. And we talk about a bound drug and then the free drug. So the free drug is the drug in this plasma or in the blood that is actually not bound to anything. It's just floating around free. But many of the drugs are actually attached to proteins such as albumin. So that's called protein binding.

In the case of midazolam, about 95 percent of the drug in the blood, in the plasma, is protein bound, so it's actually attached to albumin. In order for that drug to get into the brain, it has to be in the free form. So the way

that you can think about this -- and I was thinking about this, this morning and reflecting on my experience when I went to, on Tuesday morning, to the Air Force Museum. And I was very interested in the planes that they had there, Air Force One and so forth. And when you walk into those planes -- and I am sure many of you have done this -- they have Plexiglas partitions, so that would be -- the walkway through those planes is very narrow. It's only about that narrow (indicating).

And they actually have that set up on the outside just to inform you this is how narrow it is. So if you can't fit through that, then you are not going to be able to get through the plane.

So imagine the plane is the brain. And you walk up to that and you've got all this -- you know, it's cold outside. You have got all this bulky clothing on. You can't fit through that. You have to take that bulky clothing off in order to fit through the brain. It's the same concept -- I am sorry -- for you to fit through the plane, it's the same concept. The drug cannot pass in general from the blood into the brain until it's in its free form. So you have to -- it has to get off from the albumin. And then it gets into the brain.

So that's an important thing that needs to be done when you are doing these calculations, and Dr. Stevens did that

appropriately. He accounted for the protein binding.

He then referred to a figure from the Arendt paper, which is Figure 9, which is on page 25 of his report. And it's in the book. It's page 1842. And it's called figure 9 in his report.

THE COURT: What page of his report did you say it was on?

THE WITNESS: 25 of 43.

MR. MADDEN: No, I think you have a different -- I think you have a different -- you may have to let me -- is this the paper you are speaking of?

THE WITNESS: Yes, page 23 of 32 in this particular version.

THE COURT: Page what?

THE WITNESS: 23 of 32.

THE COURT: Thank you. Okay.

THE WITNESS: And it's Figure 7 in this particular report.

THE COURT: Okay.

THE WITNESS: Okay. So what these investigators did is that they gave you a large dose of midazolam, 10 milligrams per kilogram, and then they measured the concentration of the drug in the -- and Dr. Stevens in his rebuttal report pointed out my error in saying total blood concentration. And I -- probably what I did -- and I don't

have -- since I don't have the full report, I only have what's here in front of me.

BY MR. MADDEN:

Q. I can give you the full report.

A. Thank you. If you would, please.

I'm sorry. I'm looking for something here.

So he referred to a measurement of midazolam in the blood in multiple sites here. So I think I just sort of carried over the use of the term "blood," but I think we would both agree that it's really the measurement of the drug in the plasma, which is important here.

Well, I don't personally think it's that important whether you refer to blood or plasma, but it is the same thing. It is in the plasma, that is actually where it was measured, where they removed the red blood cells and looked at the plasma concentration of the blood.

So again I am referring to figure 7, and in that figure, you have a curve that describes the plasma concentration of the drug and then a figure that describes the concentration of the drug in CSF. So something that's --

THE COURT: CSF for the record.

THE WITNESS: I am sorry, cerebral spinal fluid.

THE COURT: All right.

THE WITNESS: So what's important to see there or

understand is that there really are no proteins to speak of, and there's a limited amount of protein in cerebral spinal fluid. So when the drug, the free drug crosses over into the brain and it starts to bathe and get into the CSF, there isn't really much protein binding of the drug because there isn't really much protein in the CSF. So the concentration of the drug that's in there is basically the free drug concentration.

And the drug -- the concentration of the midazolam in this figure that's drawn from plasma, that is the total drug concentration in the plasma, the bound, protein bound and the unbound. So what he did is that he made a correction for the protein binding, and then he looked at this figure and said, well, on average the CSF concentration is about 14 percent of the plasma concentration. And therefore I am going to make that correction as well. And that is not the right way to do that. He basically doubled -- made an accounting or counted for that issue twice instead of just the one time. So he could have done one or the other but I don't think he should have done both.

Now, in the grand scheme of things, do I agree it's an error or not? No, I don't think so simply because, again, given the variability that I have already explained here, and dependent on how you look at the data, you might get a ceiling effect of maybe 5 milligrams of midazolam or 500

milligrams of midazolam. It depends on where you draw these lines and so on and so forth.

BY MR. MADDEN:

Q. The point is that it's unclear?

A. Yeah. Again, it's just unclear about how valid these data are -- or I should say how valid this analysis is in terms of being certain that that's where the ceiling effect occurs.

Q. Now, in your report at paragraph 23, you state that the ceiling effect obfuscates the issue. What did you mean by that?

A. Well, again, it's -- from my perspective is that -- again, we don't know what happens clinically to somebody who receives 500 milligrams of midazolam because we don't -- as clinicians, we don't administer that dose. But we do administer doses of .2 to .3 or more of midazolam to patients for the procedures that I described earlier. And those patients are unconscious. So there is evidence out there that these patients are unconscious.

So why even think about or deal with the ceiling effect. The question from the practical perspective in my mind, these drugs produce -- or I should say midazolam produces unconsciousness that's sufficient for the procedures that I have just described, such as for the colonoscopies and for endotracheal intubation, the c-section

study that I referred to. To me that's the important data to understand what would happen with a larger dose.

Q. There's been some testimony about barbiturates and benzodiazepines having a different atomic structure. Do you believe that's relevant?

A. Not particularly. Again, trying to point out structural differences can sometimes be instructive, but as an example that I gave in my own field of anesthetic structures, you can have two molecules that are vastly different in the structure and yet they produce general anesthesia.

In my field you can have two molecules that are quite similar and they might produce completely different affects. So I gave you the example of flurothyl, which is a halogenated ether as I recall, that instead of producing anesthesia that produces convulsions, which is certainly the opposite of a general anesthesia.

So trying to draw conclusions from structural similarities or structural dissimilarities is, again, you have to be careful about how you do that. It's not an all or nothing. It's not like you can hang your hat on that at all.

Q. I want to get to paragraph 28 of your addendum.

A. Could you refer to me where that would be in my --

Q. Yeah. I think it's -- attached to your --

A. I have lost my place so you are going to have to tell me.

Q. 1811.

THE COURT: The same document, Defendants' Exhibit 94, but at page 1811.

THE WITNESS: Yes, okay. Thank you. Yes, I have it.

BY MR. MADDEN:

Q. How does midazolam and opiates affect breathing?

A. So these drugs affect the respiratory centers in the brain stem and brain to depress the drive to breathe. They can also affect the ways in which the airway's maintained, so the airway can tend to collapse a little bit. And this is particularly true, not just for midazolam and opiates but for anesthesia in general. There is airway collapse.

So when I use that term, the way that you can think about it from a non-medical perspective is that -- I mean, we're all familiar with the idea of seeing people snore, right? If someone falls asleep and the back of their tongue kind of goes -- or their tongue goes to the back of their throat and they start to snore. And general anesthetics have that effect, as do sedative drugs such as midazolam and opiates. So two primary effects, decreasing the drive to breathe, which is related to carbon dioxide primarily and pH. But also the collapsing. Again, I use the term of

collapsing the airway where the airway starts to get smaller, again related to the muscles relaxing and the tongue falling back.

Q. Let me refer you to paragraphs 29 and 30.

A. Yes.

Q. Is that the same as air hunger?

A. Not necessarily. So air hunger is the, again, the concept or the idea that you feel that you have that sensation that you need to take a breath. But what these drugs do, such as midazolam and opiates, they remove that drive or decrease that drive and remove that feeling. And that's how these drugs -- why these drugs are so lethal for any use.

As I said, even small doses of these drugs can kill patients if you give them -- when midazolam first came out, that was what was so serious was that these drugs were -- midazolam was to be given to patients, especially elderly patients, in combination with opiates, and patients weren't being monitored. They were just sort of, I will give you some drugs, give you these drugs, and then the nurse or doctor walks away. And then they come back in a few minutes and the patient is blue because the patient has stopped breathing. So these are -- have powerful effects on that.

So the concept of air hunger as being a stimulus doesn't make any logical sense to me. That is, if these

drugs, such as midazolam and opiates -- and we know it's well-documented that these drugs produce respiratory depression and apnea, which is the cessation of breathing. It's -- we know that happens.

And the Judge just yesterday referred to the problem in this area about opiates and other drugs like that and the problem. You know, why do people who take heroin, why do they die? Because they take the drug to become unconscious. They stop breathing, and they die.

If these drugs caused air hunger to the extent that they woke the person up and the person said, oh, my God, I feel like I need to breathe, then they wouldn't kill people, right? Their respiratory -- respirations would go down. They'd get that air hunger sensation and they'd wake up and start breathing again. Well, that's not what happens. They get respiratory depression. They stop breathing. They don't wake up.

Even though all the things that normally would cause -- I shouldn't say all the things, but some of the things that would cause this air hunger, that is the increase in the carbon dioxide, the decrease in the pH, those things are occurring in these patients or these individuals. But -- and that normally would cause air hunger, but it doesn't in them because that's the effect of the drug.

Just as a way of an example, when I talk about the

effects of this carbon dioxide as a very potent stimulus for breathing -- and we are all familiar of the concept of breathing into a paper bag. If you do that, you start to rebreathe your carbon dioxide, and that really gets to -- you have that sensation, I got to take a breath, and you start breathing faster.

So carbon dioxide is a very exquisitely strong stimulus for breathing. And these drugs take that away. So I don't see air hunger as being an issue.

Now, there have been -- and I may refer to my report here. There is further discussion about the choking, snorting, and gasping that I talk about related to the air hunger issue, which these were eyewitness reports. I have not obviously personally witnessed an execution, and I hope that I never have to, but when I see some of these descriptions, the first thing that comes to my mind is that these are, number one, descriptions in reports by, for the most part as far as I can tell, people who are not medically trained and may not understand, you know, what's going on.

And I said this earlier in my testimony. If I were to take some of you or any of you on a tour of the operating rooms and intensive care units and show you what patients can do, you would see that when you give these drugs, they cause this respiratory depression. They cause this airway collapse. And we have to be there to try to basically

manage the airway.

So, yes, if you give these drugs without any intervention, some of these people are going to attempt to breathe, but they have got a collapsed airway and so they are going to (indicating sound) like that, as they attempt to breathe. I am not sure how that's going to go into your --

THE COURT: She's good. She'll get it.

THE WITNESS: Okay. But that's essentially what you would see. And we're there to manage that.

BY MR. MADDEN:

Q. Do those actions in an operating room indicate that the inmate is in pain?

A. I am sorry. You have used the word "inmate" and then "operating room."

Q. I mean, in an operating room that a patient is suffering pain?

A. No, it does not indicate that at all. Again, these drugs are very powerful. And dependent on the type of drug that you are using, they may not be unconscious. So let me give you an example, specifically with opiates.

You can give opiates. It could be fentanyl, Sufentanil, Dilaudid, whatever. It doesn't really matter too much. You are at the end of an operation. You've given these drugs. The patient's starting to wake up and, you

know, you say, "Mr. Jones. Open your eyes, Mr. Jones," and he opens his eyes, and you take him into the recovery room. But you give him so much of the opiate that he is really not breathing very much. And, in fact, he may not be breathing at all. And you say, "Mr. Jones, take a breath," (indicating). You know, he'll take a breath, and he will open his eyes, and he will breathe. "Good job, Mr. Jones. Take another breath." And he will take another breath.

If you don't stimulate him, if you are not there to tell him to keep on breathing, he will just lie there and maybe he will be awake a little bit or maybe he will be asleep, but he really won't be breathing. So these drugs really remove that sensation of air hunger. They are very powerful in that regard. That's again the basic mechanism by which they produce respiratory depression and death.

Q. Now in the testimony yesterday, consciousness was referred to as all or none. In your professional experience, in a clinical setting, is that accurate?

A. No, it's not. Consciousness is -- even in a nonclinical setting, it's a spectrum. It depends on what end point you are looking at. And this is I think critical to understand. And as I told you early on, I will say things that may be helpful to your case or may not be helpful to your case. But consciousness is a spectrum, and you have to decide what do we look at when we're determining

consciousness.

We're all familiar with that term here today, right? We're all awake and hopefully most of you are listening to what I'm saying. Maybe you are not. That's fine. But you are awake. That's what we typically think about consciousness.

When you give these drugs, you provide some type of stimulus to the person, and you determine whether they are conscious. So typically that stimulus would be a verbal stimulus. You'd say, "Mr. Jones, open your eyes." They open their eyes. Maybe you give them a little bit more drug. They don't open their eyes to verbal stimulation, but you do the tactile stimulation and the tactile stimulation is enough to open their eyes. And maybe give more drug and you provide a little bit of a shove or something like that and they open their eyes. A shaking let's say. And then finally you have to pinch them. And if they respond to the pinch, by moving their arm, you have to decide, well, is that consciousness or not.

Somewhere in that spectrum you have to decide where -- where do I have consciousness and where do I have a reflexive movement of some sort. And I will say to you that it's arbitrary. You know, one person might say, well, if they move, that's indicative of consciousness. Another person might say, well, if they move to a noxious

stimulation but otherwise don't respond in any other way from the verbal stimulation or anything else, you might say, well, that's unconsciousness.

I have my own opinion about this, which is that I think if patients do not respond to tactile stimulation, to verbal stimulation, they are unconscious. If they respond to only noxious stimulation, they are -- I am sorry. If they respond to verbal stimuli and maybe to tactile stimuli, they would be conscious. But if they don't, they would be unconscious. But you could say, well, I am going to actually say that they are conscious if they respond to a noxious stimulation. I think that's for the Court to decide, I guess, in this setting.

Q. Is it absolutely -- Dr. Bergese yesterday testified that neurologists or a doctor would need to do a consciousness check. Do you agree with that?

A. Do a consciousness check in what setting?

Q. That only a doctor would be qualified to do a consciousness check.

A. I disagree with that because there are some consciousness scales and tests that are done routinely by nonphysicians. So, for example, the Glasgow coma scale, the GCS. Glasgow -- being the town in Scotland -- coma scale has been in use for many, many years to assess the level of consciousness in -- primarily in head trauma patients. So

it goes anywhere between 3 and 15.

There is the RASS score, R-A-S-S, and then there is the OASS, which is the Observer Assessment of Sedation Scale, and they are not all the same but they look at very similar things. But many of these are done by nonphysicians: nurses, for example; and I believe EMTs do use the Glasgow coma scale out in the field to assess consciousness.

Because it's important, what had happened before these became in -- into use is that one person might say, oh, they are unconscious or they are comatose, and there was very imprecise terms being used. It was very important to be able to track a patient through the course of hours to days about what's their level of consciousness. So the Glasgow coma scale was used.

In any case, that's a long-winded answer to your question about can nonphysicians -- or is a physician required or neurologist, and the answer is no. They are common to have these checks done by nonphysicians.

MR. MADDEN: Just a second, Your Honor.

THE COURT: Of course.

MR. MADDEN: Your Honor, I have no further questions.

THE COURT: Cross.

MR. MADDEN: Excuse me.

Your Honor, we are going to wait to admit the reports.

Is that fine?

THE COURT: That's fine.

MS. WOOD: Your Honor, before we do cross, can we take a short, ten-minute recess to set up the projector?

THE COURT: I don't think it will take ten minutes.

MS. WOOD: Five minutes.

THE COURT: Why don't you go ahead and set up the projector. I have a couple of questions for Dr. Antognini which may or may not be --

MR. SWEENEY: Do you want me to wait, Your Honor?

THE COURT: No. My question was I thought from the courtroom deputy that you guys had brought a table in to do that with instead of displacing Mr. Madden. But apparently not.

MR. SWEENEY: I don't know that it would --

THE COURT: You keep setting up, and I have got some questions.

THE WITNESS: Yes, sir.

THE COURT: You were in the courtroom yesterday when I raised the question about the opioid crisis in Ohio.

THE WITNESS: Yes.

THE COURT: And I think you were here when I mentioned the book *Dreamland*.

THE WITNESS: Yes.

THE COURT: So one of the things that comes out of the book -- and I am only asking these questions, not because they are necessarily relevant except that they are things that are in my head that need to be -- I need to make sure that -- whether they are relevant or not.

So in the book, there is a -- and it's a journalist's book; it's not a medical one. There is a lengthy discussion of the pain scale and how over the last however many years hospitals and physicians have become much more attentive to how much pain a patient is suffering and frequently ask people to rate the level of their pain. In fact, as an observer, I witnessed this many times in March and April of this year as my wife was recovering from knee replacement surgery. The medical people would ask, "What's the level of your pain?"

The suggestion in the book and what I carry in my head from having done many years of Social Security Disability work in which pain is an important question is that we don't have an objective measure of pain. Will you agree with that?

THE WITNESS: In general I would. Let me just say some of the conundrums around the issue of pain.

I have personal knowledge that, my own personal knowledge, there is only one person in this whole world that truly experiences pain. That's me. The rest of you might

be faking it. I don't know. My pain is a personal experience, and you cannot really have a true objective measure of that when it's such a personal experience.

Now, you can develop some objective material -- I use that term a little bit loosely -- but you can observe people and say, well, if I was having that stimulus and I see the person crying, I'd say, I'd probably be crying, too. So I can -- I can do that.

And we have pain scales that go from 1 to 100 depending on the scale. We have -- actually in the hospitals, you will see little drawings of a happy face and then a not so happy face and then a crying face and that kind of thing. You can look at those types of -- use those types of criteria.

But it's very difficult to -- to objectify because I can tell you, you apply a noxious stimulus to somebody and it might be a 2 out of 10 for you but it's an 8 out of 10 for her. So it's variable for a variety of different reasons, and it's difficult to objectify or to make objective.

THE COURT: Essentially you've confirmed my understanding. Thank you.

THE WITNESS: Sure.

THE COURT: Are you ready, Mr. Sweeney?

MR. SWEENEY: We are, Your Honor, I believe.

Ms. Wood would be starting off with the cross.

CROSS-EXAMINATION

BY MS. WOOD:

Q. Good morning.

A. Good morning.

Q. My name is Nadia Wood.

THE COURT: You need to get closer to the microphone if you can.

MS. WOOD: Can you hear me now?

THE WITNESS: Yes.

BY MS. WOOD:

Q. Can you see the screen?

A. Yes, and that is, as I pointed out to my attorneys, we have the incorrect CV. It's not the most up-to-date CV that I have. I am sorry. Maybe I should -- I should wait for the question.

THE COURT: Wait for the question.

THE WITNESS: Yes, sir.

MS. WOOD: Can everyone else see the screen, Judge?

BY MS. WOOD:

Q. So to clarify, you are no longer a director of perioperative services, correct?

A. That is correct.

Q. Are you still a clinical professor of anesthesiology?

A. I am a volunteer clinical professor. I actually forget the exact title, but it's a volunteer clinical professor.

Q. And how much time do you spend in the operating room?

A. I am not in the operating room anymore.

Q. So are you currently practicing as an anesthesiologist?

A. No, I am not.

Q. And when did you stop doing that?

A. About a year ago.

Q. Okay. And in reviewing -- in preparing for -- preparing your report and preparing for this hearing, are these the materials that you relied upon and reviewed?

A. Yes. The -- I did ask Mr. Madden about what I needed to include in here because, again, I'm not that familiar with this process. And he said only those materials that inform your decision or your opinion. So there are probably -- in fact, I know that there are other papers that I refer to but I did not include in here. So I don't have those off the top of my head, what they were.

MS. WOOD: And for the record, this is Plaintiffs' Expert Exhibit 4, page 928. Also filed as ECF 852-1, PageID 25823.

BY MS. WOOD:

Q. So to go back to your CV, you are not currently practicing as an anesthesiologist, correct?

A. That's correct.

Q. But you had a lot of publications, right?
A. Right.
Q. I believe Dr. Stevens mentioned you had about 127 listings. Is that about right?
A. Correct. Of peer-reviewed publications. I had other publications, but those are the peer reviewed.
Q. And most of those are concerning animal studies, right?
A. That's correct.
Q. And in animal studies, you just testified that you were studying immobility?
A. Yes. I didn't -- yes.
Q. You were not studying unconsciousness of those animals?
A. That's correct.
Q. You didn't follow up with the animals and see if they recalled the experiments afterwards?
A. In almost all of these experiments, the animals were killed at the end. So there wasn't that opportunity, and even if there was, of course talking to a goat, you can talk to a goat but you won't get much of a response, so --
Q. So you don't know -- you were only focusing on whether the animals were moving, not what they were experiencing; is that right?
A. That is correct, yes.
Q. Okay. And you were studying general anesthetics in animals, correct?

A. Correct, yes.
Q. And you did not study midazolam, though, in your studies, did you?
A. I did not. Not in a -- I reviewed my CV. The only paper I think I have for midazolam was a computer study that we did, a computer modeling study which didn't obviously involve, you know, injecting midazolam into a patient; it was a model study. So I have not studied midazolam in the experimental setting.
Q. So you had no studies on midazolam, correct? Or except for that one computer modeling?
A. Right, that's correct.
Q. You didn't write any chapter books on midazolam; is that right?
A. That is correct. I don't -- not directly for midazolam, no. I'm sure that some of the work that I did, I did reference midazolam some more with that writing, but not the chapter -- I didn't write any chapters or anything like that that was devoted to the benzodiazepines or the midazolam.
Q. So benzodiazepines were not the primary focus of your study or research at all?
A. No.
Q. Now, this is your current license; is that correct?
MR. MADDEN: Objection, Your Honor.

THE COURT: Grounds?
MR. MADDEN: It has personal information on here.
MS. WOOD: It's available on the website publicly.
THE WITNESS: That appears to be correct.
BY MS. WOOD:
Q. Your activities indicate that your current activities in medicine are again administration, again not practicing medicine.
A. That is -- it says administration for a year, yes, that's correct.
Q. And are you a board-certified member of anesthesiology?
A. Yes.
Q. Are you familiar with the organization guidelines on expert testimony?
THE COURT: Go back one slide, please. What's the source of this slide?
MS. WOOD: It's public information, publicly available on California website.
THE COURT: Which California website?
THE WITNESS: Medical Board of California, so you can search for --
THE COURT: My question was to her, not to you.
THE WITNESS: Oh.
THE COURT: I'm sorry. Which website?
MS. WOOD: State of California has license search,

and you can go and search professional licenses. And I put in here Mr. Antognini's name, which license, and it does say current, and Dr. Antognini confirmed that it is accurate information.

THE COURT: So this slide is presently where in the plaintiffs' exhibits?

MS. WOOD: Well, this is just an illustration, Your Honor.

THE COURT: It is not an illustration. It's a document being used for cross-examination of a witness. It's not an illustration such as the ones that were created in court by Dr. Stevens and Dr. Antognini. This is an exhibit being used to cross-examine the witness, and it's not in the plaintiffs' exhibit book and it needs to be because after a while, this hearing's going to be over and I have got to be able to refer to stuff, and I am not going to make you leave your projector here.

MS. WOOD: Can I just ask about the information in support of his license without having the slide up?

THE COURT: Not anymore because you have already used the slide. So let's get that slide printed out and number it as a plaintiffs' exhibit. And I'm not trying to suggest --

MS. WOOD: I understand.

THE COURT: -- anything improper about that except

that it's not in the book.

MS. WOOD: Can we do it during the break?

THE COURT: Yes.

MR. KING: Your Honor, Jim King. I just have a question because typically an impeachment exhibit doesn't have to be identified, especially if it's not introduced, but you would like that in this case?

THE COURT: I certainly would.

MS. WOOD: Your Honor, I may have several exhibits that I was not intending to admit into evidence.

THE COURT: Certainly not a problem, but just to make sure when they are on the screen that they are identified for the record and that they are later put in the book.

MS. WOOD: Okay. We will do that.

BY MS. WOOD:

Q. Now the next slide, you said you were board-certified in anesthesiology; is that correct?

A. That's correct.

Q. And you are a member of the American Society of Anesthesiology; is that right?

A. I have not paid my dues since July. So, quite frankly, I am not quite sure if I am a member yet or not. It has to do with if I paid my dues or not, so I am not sure how to qualify that. I have got to do that.

Q. You have been a member?
A. Yes, I have.
Q. And what I am showing you now is American Society of Anesthesiologists Guidelines For Expert Witness Qualifications and Testimony. Are you familiar with those guidelines?
A. I am generally familiar with them. I have not read them. I can see them, and that sounds about right, yes.
Q. And they state "to limit uninformed and possibly misleading testimony, experts should be qualified for their role and should follow a clear, consistent set of ethical guidelines." Is that right?
A. Yes, that's correct.
Q. And under --

THE COURT: Correct in the sense that she has correctly read what's on the screen?

THE WITNESS: Yes, that is correct.

MR. MADDEN: Judge, I object to this whole line. This has not been in the exhibit book for -- so that I could go over this with my client before this cross-examination. I'd object to this whole line of questioning. One, it's not relevant. His ethics don't go to bias. It doesn't have any relevance.

MS. WOOD: It's absolutely relevant.

MR. MADDEN: Well, then why didn't you put it in

the book? Why didn't I get an opportunity to look at this and go over it with my client beforehand?

THE COURT: All right. So the objection is overruled. Counsel may continue with the examination, but this is subject to the same thing as the prior one. I want the whole set of guidelines marked as an exhibit, provided to Mr. Madden.

And go ahead.

MS. WOOD: Will do.

BY MS. WOOD:

Q. These expert witness qualifications promulgated by American Society of Anesthesiologists state that you must be actively -- or should have been actively involved in the clinical practice of anesthesiology at the time of the event.

A. Yes. So --

THE COURT: Just answer the question that she asked.

THE WITNESS: Okay.

THE COURT: Has she read that accurately?

THE WITNESS: She's read that accurately.

THE COURT: All right.

BY MS. WOOD:

Q. And the event in question, the forthcoming executions have not happened yet; is that right?

A. To my knowledge, no, they have not.

Q. But you have ceased being actively involved in the clinical practice of anesthesiology about a year ago; is that right?

A. That is correct. May I respond to that further?

THE COURT: No. Just answer the question that's asked.

THE WITNESS: Okay.

THE COURT: We -- as you can see, there are some problems.

THE WITNESS: Yes, okay.

MS. WOOD: Let's talk about things that are actually in the exhibits.

BY MS. WOOD:

Q. Let's talk about the BIS monitor.

A. Sure.

MS. WOOD: And what I am showing now is a page from *Miller's Anesthesia* that we have been using. It's *Miller* -- on the bottom it is marked as *Miller's Anesthesia, 8th Edition*, 2015, page 1528.

BY MS. WOOD:

Q. And it shows -- it's on top, page 1527. And it shows a BIS index range; is that right?

A. Yes, that figure shows that.

Q. And are you familiar with this index range?

A. Yes. I have used it in the operating room and I have used it in the lab.

Q. And it shows that in order to state -- to attain a state of general anesthesia, you need a BIS below 60; is that correct?

A. That is the way that that is written there, and that is correct. That's maybe --

Q. I am just asking --

A. That's fine. Okay.

Q. This is, again, from *Miller's Anesthesia*, page 1520, 8th Edition, 2015. It talks about how BIS monitor has been studied extensively in clinical trials and used widely in anesthesiology practices; is that correct?

A. Yes.

THE COURT: Are you asking him if you read it correctly, or asking him if that is an accurate description of reality?

MS. WOOD: Just what it states, Your Honor. I would hand him the book but then you wouldn't be able to see it.

THE COURT: Right.

MS. WOOD: For the sake of convenience, I am just putting it up on the screen and reading it.

THE COURT: Understood.

BY MS. WOOD:

Q. So the *Miller's Anesthesia* --

THE WITNESS: May I just interject something if I may?

THE COURT: Give it a shot.

THE WITNESS: I want to make sure that my responses accurately reflect that I agree that the counsel here is reading the material correctly.

BY MS. WOOD:

Q. Okay. *Miller's Anesthesia*, same page, same slide, talks about three known exceptions. And it says three exceptions are the anesthetics ketamine, sito figure, nitrous oxide, and a third one that I probably can't pronounce.

A. Dexmedetomidine.

Q. Thank you. So they are known exceptions to the accuracy of the BIS monitor; is that correct?

A. There are known exceptions to that, but these are not the only ones.

Q. And the next slide is the manual for BIS monitoring, which also talks about exercising cautions when using with ketamines and nitrous oxide to produce unconsciousness. Is that correct?

A. You have read that correctly.

Q. Now, in your report, you talk about -- that's Plaintiffs' Expert Exhibit 6. In your report, and that's

Plaintiffs' Expert Exhibit 6, Bates page number 1013, paragraph 40, you talk about how BIS monitor may be inaccurate in some drugs; is that correct?

A. Yes.

Q. And you list ketamine and nitrous oxide; is that correct?

A. Yes.

Q. And then you conclude that because the BIS resulting from midazolam is greater than the BIS resulting from other anesthetics, that should not be equated with midazolam having less effect on consciousness; is that right?

A. That's what I wrote there, yes.

Q. But we just saw that ketamines and nitrous oxide are known exceptions, correct?

A. They were some of the known exceptions, but not the only ones.

Q. Neither one of these mentioned midazolam, did they?

A. No, they did not.

Q. *Miller's Anesthesia* does not mention midazolam as a known exception, does it?

A. No, it doesn't.

Q. The BIS monitoring manual does not mention midazolam as an exception, does it?

A. No.

Q. Do you have some other reason to believe that midazolam

produces inaccurate BIS values?
A. Yes, which I can refer to.
THE COURT: Well, we'll leave it at yes unless Mr. Madden desires to bring out the explanation of the yes on his redirect examination.
MR. MADDEN: Judge, I would just like to note that the plaintiffs' experts were given much more leeway on how they answered questions. We weren't trying to keep Dr. Bergese to yes and no, and he was given an opportunity to respond.
THE COURT: You would prefer that he respond now?
MS. WOOD: I would object.
MR. MADDEN: I would just --
THE COURT: Just make note of it, Tom. It's easier.
MS. WOOD: You get a redirect.
BY MS. WOOD:
Q. Let's talk about how benzodiazepines provide no pain relief. In your report, you said that benzodiazepines possess analgesic properties; is that correct?
A. I did. Yes, I said that -- wrote that.
Q. The record that's the Plaintiffs' Expert Exhibit 4, Bates page number 898.
Now, *Miller's Anesthesia, 8th Edition*, 2015, at page 842 states, "Benzodiazepines lack analgesic properties and

must be used with other anesthetic drugs to provide sufficient analgesia." Is that correct?

A. Yes, you have read that correctly.

Q. And the rest of the sentence says, "However, as maintenance anesthetic drugs during general anesthesia, benzodiazepines provide hypnosis and amnesia." Is that correct?

A. You have read that correctly.

Q. So benzodiazepine's primary purpose during general anesthesia is to provide hypnosis and amnesia; is that correct?

A. I would say that is one of the actions of the drug. I am not sure that you could say it's the primary purpose, but I'll just say it's one of the actions, or those are some of the actions of the drug.

Q. Let's look at some of the studies you cited. One of the studies you talk -- you cited in support of analgesic properties of midazolam was Yegin, 2004, and that was again back in your report, paragraph 16.

A. Um-hmm.

Q. This Yegin study, in addition to midazolam, used another drug, didn't it?

A. Yes, it did.

Q. So that study did not use midazolam alone, did it?

A. No, it did not.

Q. Let's look at another study you relied on. Again, back in your report you said you cited Gehrke to the study?
A. Yes.
Q. To support your contention that benzodiazepines produce analgesic properties, correct?
A. Yes.
Q. This Gehrke study -- this is a quote from the study -- says, "The use of an opioid morphine or fentanyl or neuromuscular blockers was allowed at the discretion of the attending doctor." Is that right?
A. Yes.
Q. So in that study midazolam was not used alone either; is that correct?
A. I'd have to review that study. I believe there might have been a small group of patients that might have received midazolam itself but I don't know. I'd have to review the study.
Q. So this is the study and this is the quote from the study that talks about the use of an opioid?
A. That's correct. But as you see there, it says, "was allowed at the discretion of the attending doctor." So if the attending doctor said I'm not going to use anything but midazolam -- I'd have to review the paper to see whether some of the patients received midazolam only.
Q. So would it be fair to say that the study did not focus

on the use of midazolam as a sole drug because it did not exclude other drugs, including opioids?

A. Well, as a sole focus, that is probably a true statement, yeah.

Q. Again, in the Gehrke study -- again, this is from the front page of the study -- talks about the reason why midazolam became popular is because it's due to its better amnesia properties; is that correct?

A. You have read that correctly.

Q. Now, this is on how to do anesthesia induction, *Miller's Anesthesia,* page 1655, again 8th Edition, 2015. It talks about the standard induction of anesthesia for intubation purposes.

A. Yes.

Q. And the quote says that "The most common technique for induction of general anesthesia is the standard IV induction which entails the administration of a rapid-acting IV anesthetic followed by an NMBD."

A. Um-hmm, yes.

Q. In this case, an NMBD, would that be a neuromuscular-blocking drug?

A. That's correct.

Q. So normal practice for induction of anesthesia would be to administer an IV drug with a neuromuscular blocker; is that right?

A. That is correct.
Q. And that blocker will prevent somebody from moving during intubation; is that correct?
A. That is correct.
Q. And if midazolam is used as a drug along with a neuromuscular blocker, they may have trouble recalling the procedure; is that correct?
A. That is correct.
Q. So if somebody doesn't remember what happened during their intubation, that doesn't mean they did not experience pain during that intubation, does it?
A. No, it does not.
Q. I believe at one point you mentioned having conversation with Mr. Madden on midazolam but then Mr. Midazolam -- Mr. Madden not being able to recall having that conversation; is that right?
A. That's correct, yes.
Q. If you were to, say, hurt Mr. Madden in some manner while he had midazolam, would he be in pain?

MR. MADDEN: Objection.

THE COURT: Hang on. I'll allow it.

THE WITNESS: So could you repeat it, please?

THE COURT: Yes. The question is, if you were to, say, hurt Mr. Madden in some manner while he had midazolam, would he be in pain?

THE WITNESS: I think the answer depends on the dose of the midazolam, whether he would have that awareness and experience of pain. I think the answer probably depends, you know, if it's the usual therapeutic dose, then he probably would have pain at that time.

BY MS. WOOD:

Q. Now, let's look at some other studies that talk about how the use of midazolam in emergency endotracheal intubation is not because of its analgesic properties, it is because that physicians rely on it for its amnesic properties. In fact, this is -- this is a Sagarin 2003 study that says midazolam is a fairly potent amnesic agent, correct?

A. Yes.

Q. And you don't disagree with that statement, right?

A. I do not.

Q. And the study, "continues that physicians are overly optimistic in counting on the amnestic properties of midazolam to ensure that patients do not recall the unpleasant experience of neuromuscular paralysis and oral intubation." Is that correct?

A. You have read that correctly. I wouldn't necessarily agree with that statement, but you have read it correctly.

Q. All right. Let's talk about the use of midazolam in c-sections, that Crawford study you discussed. What I have

up on the screen now is Plaintiffs' Expert Exhibit 6, page 1012. It's paragraph 36 that discusses Crawford 1988 study on use of midazolam to induce anesthesia for a c-section; is that correct?

A. Yes, that's correct. You are referring correct, yes.

Q. Now, this study is -- was published in 1989, which means it's about 28 years old; is that right?

A. Yes.

Q. I will remind again that according to anesthesiologist practices, your presentation, your testimony should reflect scientific evidence and accepted practice and is prevailing at the time of the event. That study is 28 years old, right?

A. Yes.

Q. Let's look at the current practices of cesarean sections and how they are performed now.

A. Yes.

Q. *Miller's Anesthesia*, page 2345, 8th Edition, 2015, it says that at present most cesarean deliveries in developed countries are performed with neuraxial techniques, correct?

A. You have read that correctly. I am not familiar with the literature on whether that's a true statement or not, but you have read it correctly.

Q. And neuraxial means spinal anesthesia, spinal blocks?

A. Correct.

Q. And *Miller's Anesthesia*, page 2345 talks about how general anesthesia may be needed for cesarean delivery because of its rapid and reliable characteristics, correct?
A. You have read that correctly.
Q. And it talks about emergent situations, correct?
A. Correct.
Q. Now, this study, the Crawford study, these were elective cesareans, right?
A. Correct, yes.
Q. You would not normally see elective cesareans under general anesthesia except on very rare cases today, would you?
A. Again, I don't know the literature. There are some patients, female patients, obviously pregnant, that would elect not to have a spinal anesthetic or epidural. They want to have a general anesthetic. And there might be some other reasons why you wouldn't be able do a spinal anesthetic on them. So you still would do a general anesthetic on an elective c-section, but not -- not a very large percentage. It would be a pretty small percentage.
Q. So it's uncommon?
A. Yes, it's uncommon.
Q. So this is, again, *Miller's Anesthesia*, page 2345, that talks about induction --
THE COURT: 2345, right?

MS. WOOD: I'm sorry. 2345.

BY MS. WOOD:

Q. And here *Miller's Anesthesia* talks about commonly used drugs for induction of anesthesia for cesareans. Now, this is today. This is the current edition of *Miller's Anesthesia*, and it says, "At present Propofol is the most commonly used for induction of general anesthesia for cesarean delivery." Is that right?

A. Yes, you have read that correctly.

Q. And the next slide shows every drug that is used in the induction of anesthesia. It's the same page, 2345, and I realize that the whole thing is unreadable, but I put boxes around the relevant drugs. It cites sodium thiopental, etomidate, and ketamine as the three drugs used in induction of cesarean sections today. Is that right?

A. Yes, you have read that correctly.

Q. This does not list midazolam there, right?

A. I do not see midazolam there, although I haven't read through the whole thing, but I take your word for it.

Q. Now, let's look back at the Crawford study. The Crawford study, "Mothers, until the division of the umbilical cord, anesthesia was maintained with nitrous oxide." Is that correct?

A. Yes.

Q. You don't know the rate of that oxygen flow, do you?

A. I do not, no.
Q. Increasing the flow of the oxygen would result in faster distribution of oxygen in the bloodstream; is that right?
A. I think you mean to ask, does it increase the flow of nitrous oxide, because that's probably what you are getting to.
Q. Nitrous oxide. I apologize.
A. That's fine. Yes, it would increase the flow of nitrous oxide, that's correct.
Q. And that nitrous oxide, depending on the flow, would be slower or faster distributed to the patient and all the tissues?
A. That's correct.
Q. So depending on the flow, the patient may be out faster; is that right?
A. That's correct, yes.
Q. But you don't know the flow. It's not listed in this study?
A. No, it's not.
Q. So your estimation on how long it took for that patient to become anesthetized because of the nitrous oxide is based on speculation?
A. Yes.
Q. Now, as soon as the umbilical cord was divided, that

means it was clamped and the baby was no longer connected to the mother, right?

A. Yes.

Q. At that point the study says, "After division of the umbilical cord, meperidine -- "

THE COURT: M-E-P-E-R-I-D-I-N-E, Mary.

BY MS. WOOD:

Q. "-- in that amount intravenously was given the patients in both groups."

A. Yes, you have read that correctly.

Q. So as soon as the baby was separated from the mother, the mother received meperidine which is a narcotic analgesic; is that right?

A. Yes.

Q. So midazolam was not a sole drug in that study either?

A. No, no, it's not.

Q. And, in fact, the requirements for this narcotic analgesic were higher in the midazolam group. This is back to the Crawford study.

A. Um-hmm.

Q. Even though the weight of the woman was significantly lower than the thiopental group. Is that right?

A. I'm just looking at what you've written -- what you have there. So let me look at that.

That's what that statement says. I'd have to look at

the actual data to make sure that it's statistics given here, but you've read that correctly.

THE COURT: Perioperative means postoperative?

THE WITNESS: No, it means around the time of the operation. So usually it's going to be during the operation and afterwards.

THE COURT: Thank you.

BY MS. WOOD:

Q. And we can -- the perioperative refers to this moment right here. This is after the division of umbilical cord, correct?

A. Yes.

Q. So mother's still on the table. She still has an open incision; is that right?

A. Yes.

Q. And at that moment, as soon as the baby is gone, she is given a heavy narcotic?

A. Yes.

Q. And this study, the Crawford study, the Yegin study, and the Gehrke study are what you use in your report to support your contention that midazolam has analgesic properties, correct?

A. Yes.

Q. In none of those studies, midazolam was used alone, correct?

A. I am not willing to say yes to that because, again, in some of these studies, when you look at a study, you have to be very careful that you are looking at -- it may be a small group of patients that did not receive a particular drug. And I refer back to the basic science paper with the mice where there was a group, a control group, wild type, that did not have -- that was normal.

So you have to make sure that there is no subgroup in these studies that would -- that you might be missing. Because some of these studies -- and maybe I could have done a better job of pointing that out -- but some of these studies do have subgroups of patients where they have received only a particular drug or only a particular intervention.

So I am not willing to concede on those until I have had a chance to review them.

Q. Didn't you review them before you wrote the report?

A. I did, but I just can't recall off the top of my head where they would be in this particular --

Q. Do you see here, do you --

THE COURT: Let him finish his answer.

THE WITNESS: So getting back to the point of the meperidine, I mean, I can address, for example, the issue of -- excuse me. I'm stuttering -- meperidine, which, if you allow me to do, I can.

THE COURT: Go ahead.

THE WITNESS: The umbilical cord is tied probably, you know, it depends on the length of the operation, how long it takes to get the baby out -- but it's probably going to be somewhere around maybe two to three minutes after the incision. So in terms of my approach to this, meperidine usage is not important because I was only considering the period between the induction and when the endotracheal intubation occurred and then the beginning of the nitrous oxide.

Clearly, meperidine has analgesic properties and was given to these women, and I would not conclude that midazolam has analgesic properties in a study where meperidine had been given in conjunction with. And when I say in conjunction, at the same time. Meperidine was given after the midazolam.

So that's why I couldn't say, for example, that midazolam provided analgesia for a period of five minutes because the nitrous oxide is already starting to work and they have been given meperidine. That's why I estimated that it probably could be no more than 30 to 60 seconds.

But it's an estimate, again, to the issue you bring up about the flow of oxygen and flow of nitrous oxide. We don't know what the flows were in that particular study.

But there was -- according to the study, there was no

nitrous oxide during intubation, and there was no meperidine during the intubation. It was only midazolam and then the muscle relaxant.

BY MS. WOOD:

Q. The muscle relaxant would keep the mother from moving and the midazolam would keep her from remembering the experience, correct?

A. Yes.

Q. And in this study, there was no follow-up as to awareness of what they recalled from intubation, right?

A. They did not report it, no.

Q. And in this study, again, you don't know the nitrous oxide flow rate. So your estimate on how long the midazolam was a sole agent on board is only an estimate?

A. Yeah.

Q. Okay. Let's look at this graph that Mr. Madden has showed you, and this is from same graph from the latest edition of the *Miller's Anesthesia*?

A. Um-hmm.

Q. On page 618. The text underneath the graph talks about how this graph explains inhaled anesthetic action; is that correct?

A. Yes.

Q. And, in fact, that axis on the bottom, the X axis, it says it's a MAC fraction, and MAC stands for minimum

alveolar concentration; is that right?
A. Yes.
Q. That only applies to inhaled anesthetics, correct?
A. This particular figure, yes, applies to inhaled anesthetics.
Q. What about a concentration of MAC, the alveloar concentration that a person has left in the lungs, right?
A. What about it? What was your question?
Q. MAC.
A. Yes.
Q. Does that have any application to IV drugs?
A. The concept of MAC in terms of an effective dose 50, I believe, does have application to intravenous drugs, yes.
Q. Even though it stands for minimum alveolar concentration?
A. That's correct. It's a -- the concept of these types of curves, you could draw these types of curves based on the data that's available using intravenous drugs. Instead of using MAC, you'd use what's called MIC, the minimum intravenous concentration. So this is a conceptual drawing that could be applied in the setting.
Now whether the curve -- how the curves relate to each other certainly might be different, and I have not actually done that, but they certainly could be different.
THE COURT: Excuse me just a minute. It is almost

noon. How much more examination -- first of all, what's -- what is your flight time?

THE WITNESS: 6:10, so I have time.

THE COURT: So shall we recess for lunch?

MS. WOOD: We can do that.

THE COURT: We shall do that then.

THE COURTROOM DEPUTY: All rise. This court stands in recess.

MR. MADDEN: Judge, am I not allowed to eat lunch with the witness or anything like that?

THE COURT: No, you can have lunch with the witness.

MR. BOHNERT: Should he not be discussing the testimony, though?

THE COURT: No, he can't discuss the testimony.

(Lunch recess at 11:58 a.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N 1:35 p.m.

THE COURT: Ms. Wood, you may resume your examination.

MR. BOHNERT: Your Honor, if I might just very quickly, a housekeeping matter.

THE COURT: Sure.

MR. BOHNERT: One, we literally -- just yesterday this change was issued, and we just got a notification of it yesterday. So it's a document that we'll be using. The

Florida Department of Corrections just changed their execution protocol yesterday. And so we wanted to -- you know, it's not in the exhibits obviously because it just happened yesterday, so I wanted to give you a copy of it, as well as everybody.

THE COURT: Are you going to mark it as an exhibit?

MR. BOHNERT: Yes, we will, with the right person. I just wanted you to know.

THE COURT: Yeah, okay. Good.

MR. BOHNERT: And the other thing would be, I just wanted to clarify with rebuttal witnesses, we would be able to call a rebuttal witness based on things that have come up during this course of this hearing who was not identified previously on our exhibit, or our witness list; is that correct?

THE COURT: Well, the question is, is that rebuttal witness a person whose testimony could not reasonably have been anticipated on the basis of the filings of experts up to this point in time? I don't want to try to resolve that now. Think about that and be prepared to show me what you have.

MR. BOHNERT: It would be a lay witness to rebut the allegations and the accusations of bias and things of that nature that the State has levied against our other lay

witnesses.

The main question is there may have to be a fight over a subpoena to have a journalist testify, and I don't want to have to -- I want to know ahead of time whether I need to engage in that subpoena fight, and we will.

THE COURT: Who is the witness?

MR. BOHNERT: The witness I'm talking about on that is a man named Kent Faulk who witnessed the Smith execution in Alabama. He is a journalist, witnessed in his role as a journalist, but the media organization's position is: Our story speaks for itself. We stand behind the reporters, and we don't let our reporters testify.

MR. MADDEN: That is not rebuttal, Your Honor. That's an additional witness.

THE COURT: I agree with Mr. Madden. That's an additional witness. That's not a rebuttal of any particular witness, a bias on the part of any witness who has already testified. It's an additional comment on, in the words of Bob Dylan, "Don't speak too soon for the wheel's still in spin."

MR. BOHNERT: It was my understanding that Mr. Madden had -- did cross Mr. Hahn and essentially was impeaching him on the basis of bias, which would then be incumbent upon us perhaps to rebut those allegations that the testimony, the recount of that execution, was somehow

affected by Mr. Hahn's bias as Mr. Madden was.

MR. MADDEN: Your Honor, he is using a witness to rebut his own witness. We call rebuttal witnesses to rebut the testimony of the other side's witnesses. This is not a true rebuttal, and he knew coming into this hearing that we were going to question the bias of his witnesses who represent these inmates. That was obvious. And this is not rebuttal.

THE COURT: At least as obvious as the nose on my face. So, yeah, you are right. Mr. Madden's still got the better part of the argument.

MR. BOHNERT: Thank you.

THE COURT: Which reminds me to ask you, Mr. Bohnert, have you heard anything from the District Court from the Middle District of Alabama about your subpoena?

MR. BOHNERT: I have not.

THE COURT: Nor have we.

BY MS. WOOD:

Q. Good afternoon, Mr. Antognini.

A. Dr. Antognini.

Q. Dr. Antognini. I apologize.

A. Thank you.

Q. Before we took a break, we were looking at page 618 of *Miller's Anesthesia*, which is your illustration of MAC fraction and percentage of response; is that correct?

A. Yes.
Q. And it's a similar illustration to what you had drawn earlier today on the board, right?
A. Correct.
Q. And just to reiterate, the X axis on this graph is a MAC fraction, which is --
A. Correct.
Q. -- the concentration in the lungs?
A. It is the concentration of the anesthetic coming out of the alveolar part of the lungs, so that would be one way of looking at it, yes.
Q. And the text underneath the graphs, underneath that illustration in *Miller's Anesthesia,* talks about this illustration, illustrates sites of action that underlie anesthetic interaction.
A. Correct.
Q. And do you agree with that?
A. Yes.
Q. And further down in that text, underneath the illustration in *Miller's Anesthesia*, it says, "Immobility occurs by anesthetic action on the spinal cord." Is that correct?
A. Yes.
Q. And do you agree with that?
A. I do.

Q. And is that -- that applies to inhalant anesthetics; is that correct?
A. It does. Although I do have literature, a paper published out there on the -- on thiopental, which is an intravenous anesthetic that has predominant -- or has actions in the spinal cord in terms of producing immobility, not quite as strong, it looks like, as with the inhaled anesthetics but --
Q. So you said before we went on the break that these curves in this illustration would be different for intravenous drugs; is that right?
A. We do not have the data there. My -- my opinion, scientific opinion, I guess, would be that they would be similar to this. But we do not have data for every single intravenous drug that we use relative to these end points.
Q. So there is no graph like that for midazolam, is there?
A. Not to my knowledge, no.
Q. And you haven't studied the application of midazolam and its effect on immobility or on consciousness; is that right?
A. I have not, no.
Q. So for IV drugs in general, for midazolam specifically, these curves as to where -- when and where the amnesia and consciousness and mobility occur would be in completely different places?

A. Not necessarily. We don't know, but again based on the limited data that we have, the anesthetic, intravenous anesthetic such as propofol all have actions in the spinal cord to blunt the response to noxious stimulation, so that's why I would, in my mind, extrapolate to those actions being important in terms of producing mobility.

But we don't have nearly as much information and data up there on the intravenous anesthetics relative to these end points and this graph that I have there. We don't have as much information for the intravenous anesthetics as we do for the inhaled anesthetics. And there is a very simple reason why, and that is because it's much more difficult to do these studies with IV drugs because with the inhaled drugs they are easy to measure coming out of the lungs. But you have to do blood measurements with the intravenous drugs, and those are very difficult to -- not difficult, but they are very tedious, so --

Q. So you don't know where these curves would be for midazolam?

A. No.

Q. Not in relationship to each other or the concentrations of drugs?

A. Not in relationship to what?

Q. Not in relation to concentration.

A. Let me think for a moment about that question. At this

time I cannot recall all the -- you know, some of the studies, if they exist, the important studies. I'd have to review some of the literature to be able to answer your question, but as I sit here I can't really say yes or no to that. I don't know.

Q. And earlier you said that this MAC concept, even though you were talking about inhaling drugs, there is an analogous scale for IV drugs; is that right?

A. Could you rephrase? I am not sure I follow you.

Q. Is there an equivalent scale or description or MAC fraction to -- for IV drugs?

A. Well, there are --

Q. Let me --

A. I'm trying to answer your question, and I can. I just want to make sure -- so there are similar, I wouldn't say figures, but there are data that look at the probability of amnesia or consciousness relative to the concentration of certain IV drugs, so, for example, midazolam and propofol, that kind of thing.

Q. But you said MAC 50 measures movement. You said MAC 50 --

A. Correct.

Q. You said MAC 50, at MAC 50, 50 percent of the people will move and 50 percent of the people will not; is that right?

A. Right.

Q. Is there such a number for an IV drug at which you can say 50 percent people at this concentration will move and --

A. Yes, there is data.

Q. For movement?

A. For movement.

Q. Specifically?

A. Yes.

Q. And do you know that number for midazolam?

A. I don't know -- for midazolam, I am not sure that number exists. I know it's for propofol. I believe that number's out there. I don't know if it exists for midazolam. The closest I think that we probably have for that would be that as I cited in my work here or my report, if you give midazolam to patients who are getting halothane, you need to use a lot -- you can use a lot of halothane --

THE COURT: H-A-L-O-T-H-A-N-E, Mary.

THE WITNESS: -- to produce immobility. But we don't have that for midazolam in humans. Now the study that I cited with mice, you know, we have those data, but we don't have them for humans.

BY MS. WOOD:

Q. The genetically modified mice, that study?

A. No, the normal mice, the normal mice that were in that study, the control mice.

Q. Let's look at another quote from *Miller's Anesthesia* on page 1530. It discusses inhalant anesthetics and how they act to produce mobility primarily through their actions in the spinal cord, correct?

A. I see you have read that correctly.

Q. Do you agree with that?

A. Yes, I would. I do.

Q. What about *Miller's Anesthesia's,* page 837, where it states benzodiazepines exert their action through $GABA_A$ receptors. Is that correct?

A. Yes.

Q. Do you agree with that?

A. I do.

Q. *Miller's Anesthesia* doesn't mention anything about spinal cord with respect to benzodiazepines, does it?

A. Do you know -- I'm sorry. I am not allowed to ask questions. So GABA receptors are --

Q. It's yes or no.

A. Could you repeat the question?

MS. WOOD: Could you please read the question back to the witness.

(The following portion of the record was read: *Miller's Anesthesia* doesn't mention anything about spinal cord with respect to benzodiazepines, does it?)

THE WITNESS: It does not mention anything about

the spinal cord in that specific statement there.
BY MS. WOOD:
Q. Do you disagree that benzodiazepines act on GABA receptors?
A. I completely agree that GABA -- I am sorry. Benzodiazepines act on GABA receptors because GABA receptors are present in the brain and spinal cord.
Q. And were you here for Dr. Stevens' testimony?
A. Yes.
Q. And do you agree with his testimony that once you run out of GABA, benzodiazepines stop working?
A. I agree with -- I am not sure you characterized his testimony correctly, but I agree that you need to have GABA present, with the GABA receptor obviously, in order for the benzodiazepines to work.
Q. So what do you think happens once a person runs out of GABA?
A. Again, I don't think you are asking the question the right way, but I understand what you are trying to ask. You don't run out of GABA. It's just that the GABA that is used as a receptor, you know, once you occupy the receptor, there may be more GABA there but you have occupied all the receptor sites. In that case, you would not get further action from the benzodiazepines basically, if you added more of the benzodiazepine.

Q. So adding more dosages of midazolam would not produce more effect, would it?
A. It would not produce more effect at the -- at the receptor, that is correct.
Q. So wouldn't you agree that's the ceiling?
A. That would be one way of arriving at a ceiling effect. That is a ceiling effect at a GABA receptor. Now, how that translates into an effect at a clinical level can be completely different.
Q. So you agree that a ceiling effect exists; is that right?
A. Exists for?
Q. Midazolam.
A. At the receptor level, it does, and also there are -- if you look at, for example, the EEG effects, it also appears to exist for the EEG as well.
Q. So do you disagree about the dosage at which ceiling effect occurs?
A. I don't think we really know completely the dosage at which the ceiling effect occurs.
Q. But it does occur?
A. For -- for the EEG end point, it seems to occur based on the data that we have. But that is only at doses of benzodiazepines that have been given clinically, you can begin to see a ceiling effect. But if you were to give

more, that ceiling might rise a little bit. It probably wouldn't rise very much because obviously that's the definition of a ceiling effect.

Q. What do you mean, the doses given clinically?

A. Well, because the dose that we have given clinically, 1 to 2 milligrams, may go up to 5 milligrams or 10 milligrams. For induction dose, it may be as high as 20 to 25 milligrams, but we have not gone beyond that.

You can begin to see some of that ceiling effect occurring probably within the range -- so some of these studies -- I need to clarify this. Some of these studies gave the drug as an infusion and not as a bolus. So from a -- what we talk about a pharmacokinetic perspective, it's difficult to compare some of these studies in that way. So basically I would say that there appears to be a ceiling effect occurring in terms of the EEG.

So as an example, I would not expect a large dose of midazolam -- based on the current information that we have now, I would not expect a large dose of midazolam, and by that, I mean something beyond the usual clinical dose, for example, something beyond 20 to 25 milligrams. Based on the current understanding in the data out there, I would not expect midazolam to have much further effect on an EEG.

So to put that in context, and just to echo what I think Dr. Stevens said, if you give something like

pentobarbital, you can create what's called isoelectricity on the EEG. It's basically flat. And the data suggests that you cannot do that with the benzodiazepines.

Q. So your testimony is that there is -- you begin to see a ceiling effect at therapeutic doses; is that right?

A. I know that's a yes-or-no question. I'll say yes, you begin to see it at therapeutic doses, and therapeutic doses, of course, is a broad range at, like I said, sedation at 2 milligrams; at induction of anesthetic, let's say 20 to 25 milligrams.

Q. So at doses of 20 milligrams or less, you begin to see a ceiling effect?

A. On the EEG you do, yes.

Q. And the EEG is what's linked to the BIS monitor; is that right?

A. That is correct, yes.

Q. So you would see the effect of on the BIS monitor you couldn't get below a certain number no matter how much midazolam you would administer; is that right?

A. I'm not willing to go completely that far simply because if you look at the published data, again, people have not pushed -- given more in terms of the midazolam beyond that. It looks like it's starting to level off if you look at the available data, but, again, we don't have those data.

So I am not trying to sort of waffle here. I am just trying to answer the question to the extent that I can on my understanding and knowledge of the literature.

Q. So based on the data that you do have, at what BIS number would begin to level off?

A. It looks like -- based on the data that I have seen, it looks like it begins to happen where the BIS is starting to approach around 60, but you can get BIS levels below 60 in some patients but it probably starts to occur at around 60, a BIS of 60.

Q. So some patients, not the mean?

A. No, not the mean.

Q. I would like to go back to the slide for *Miller's Anesthesia,* page 842. It talks about benzodiazepines lacking analgesic properties.

A. Um-hmm.

Q. Do you disagree with that statement?

A. I do disagree with it, and I disagree with it in terms of its generalness. So it kind of depends on how you define analgesia. Typically, we define analgesia in a clinical setting in terms of drug administration, does the drug reduce pain. So I've already testified as to what I think pain is. And does a drug reduce pain.

Well, you have to ask yourself, what dose are you administering? So you might give a dose of a drug and apply

a painful stimulus and there is no reduction in the pain. And so you might say, well, that drug lacks analgesic properties. It doesn't act as an analgesic.

Or then you give a larger dose and, lo and behold, you are able to find that it does reduce pain a little bit. Another way of looking at this problem that we face is that you might apply a painful stimulus, mildly painful, and give a drug, and the pain is reduced. But now you increase the stimulation, you make it more noxious, and the drug does not reduce the pain because now you have a stronger stimulus.

So that statement up there that benzodiazepines lack analgesic properties I think was written within the context of the usual therapeutic dose that we give, you know, in terms of sedation.

And I don't think there is enough literature out there to fully answer that question. Furthermore, this is an unreferenced statement, and it's -- when I looked at that, obviously, it was put into the report in rebuttal. I went back through several editions of *Miller*, all the way back to 1990, and that statement is -- it's the same statement basically from the 1990 edition on to the latest edition. And that's been through several coauthors -- several authors or the same authors except for the last one where the investigator or the authors basically, with permission of the previous authors, updated that chapter but left that

statement. They left a lot of other things in there.

So you can interpret that in different ways. You might say, well, it was true back in 1990 and it's true today, but I think there have been some studies out there that suggest that midazolam in certain instances can provide -- or has analgesic properties, which is a term that I used, and --

Q. And aren't those studies the one you referenced --

THE COURT: Let him finish his answer.

THE WITNESS: And the studies that I cited, I recognize, for example, when the drug was given in these studies intrathecally, in the spinal cord area, that was it was given in conjunction with bupivacaine, which is a local anesthetic. In those studies, the midazolam prolonged the period of analgesia.

Now, my colleagues, both clinical and scientific, may quibble with my statement that midazolam has analgesic properties. They may say, well, that's not a really true test of analgesia. And that could be a fair assessment, I suppose.

But my interpretation is that midazolam, in certain circumstances, will provide analgesia and, therefore, I think to say that they lack analgesic properties is probably too broad of a stroke and that I feel justified in saying that there are some analgesic properties of midazolam.

And I think that's also been borne out in some of the

basic science studies where it appears to be an action in the spinal cord. Now, it's -- does midazolam provide strong analgesia? There is no evidence that it provides strong analgesia. I would agree with that. But it does have some analgesic properties as I look at the literature.

BY MS. WOOD:

Q. And you mentioned in certain circumstances, right? It provides analgesia in certain circumstances.

A. Well, for example, the circumstance of, as I just mentioned, in the case of spinal administration. Now, there is another -- another concept here that I think might help to illustrate and give you an idea of my thoughts about this, but I would be able -- if I could use the board to draw -- make a drawing.

THE COURT: I think it's close to being volunteered. If you want it, Ms. Wood, we'll let him do it, but otherwise not.

MS. WOOD: No.

THE COURT: All right.

BY MS. WOOD:

Q. I would like to go back to the spinal analgesia that you mentioned. That was in conjunction with another drug?

A. Correct.

Q. Okay. Could you name the studies showing that BIS levels for midazolam approach 60? Because there were none

in your report.
A. There was the study by Glass and there's a study by Lui.
Q. And those were the studies that were addressed in Mr. Stevens' rebuttal?
A. Correct. I can certainly refer to the data in those studies if you want.
Q. So going back to the circumstances, what you have identified in your report, the Plaintiffs' Exhibit 4, page 898, you talk about analgesic properties of midazolam. We discussed the Gehrke study, which was intratracheal intubation where they have not ruled out the use of opioids, correct?
A. Again, I did not review that paper again during the lunch period and all that so I don't -- my recollection of reviewing it when I included it was there was at least some -- some of those patients did not receive the midazolam, but that's my recollection.
Q. Would you agree that in the Gehrke study that patients did not receive midazolam alone?
A. I am sorry. I may have misspoken. I believe in that study that some patients received midazolam only. That's my recollection and that's why I included it. But I can be wrong on that, so --
Q. And the Yegin study, at the bottom there is the study

where midazolam was injected with another drug --
A. Correct.
Q. -- in the spinal cord. Okay. We have not talked about cardioversion?
A. Yes, that's correct.
Q. When patients are administered cardio shock --
A. Yes.
Q. -- even if they are sedated, do they come out of that sedated state?
A. They do. Often they do.
Q. So it wouldn't surprise you to know -- to hear about studies that report on the delivery of shock causes arousal, contraction of upper limbs, crying, mumbled comments?
A. No. And when you do cardioversion, you want to use a dose of the drug where they do come out of it very quickly, so --
Q. So these patients are sedated. They are not anesthetized. Would that be a fair statement?
THE COURT: Cardioversion patients.
THE WITNESS: For cardioversion.
BY MS. WOOD:
Q. Cardioversion.
A. For the most part, yes, I would say that they are sedated. They are not completely anesthetized.
Q. Now, let's look at *Miller's Anesthesia* again. This

version, this edition of *Miller's Anesthesia* on page 283 talks about how the papers on consciousness and anesthesia were published more than a decade ago, but it was not until the 7th Edition of *Miller's Anesthesia* that consciousness made its formal appearance in *Miller's Anesthesia*. Is that right?

A. You read that correctly. I am not that familiar with that particular chapter of *Miller* so -- but it says there indeed it is only the 7th Edition of *Miller's Anesthesia* that consciousness made its formal appearance.

Q. And you said you went back through prior editions of *Miller's* on a different topic?

A. Yes.

Q. And would you agree that the 7th Edition was published in 2010?

A. I think it was, but I'm not positive. But I'm not -- I have no information to suggest otherwise.

Q. So it's only since 2010 that, as the book states, that there has been an explosion of exciting data on newer biology of consciousness in anesthesia?

A. That's what it states, yeah.

Q. And would you agree with that?

A. I agree that it states that. I am not sure that's an accurate assessment of the field, but --

Q. So there is -- would you agree that there's been a lot

of research in the past few years into this area?
A. Yes.
Q. But that has not been your focus of your research; is that right?
A. That is correct.
Q. And you left the active clinical practice of anesthesiology in the past year?
A. That's correct.
Q. Now, in the same -- on the same page, that's page 283, *Miller's Anesthesia* distinguishes between such things as consciousness versus responsiveness. It gives an example that an individual may fully experience a stimulus, e.g., the command "open your eyes," but not be able to respond when a patient is paralyzed but conscious during surgery?
A. Yes, that's a correct statement. I mean that's what it says. And I do not disagree with the idea, or the idea or the fact that if you give a muscle relaxant without any sedation, sedative drug or anesthetic, people will be unable to move but they will be fully awake. And I have never claimed otherwise.
Q. And it also talks about awareness, how in clinical physiology the term "awareness" is used inaccurately to include both consciousness and explicit episodic memory. Is that right?
A. Explicit episodic memory, is that what you are looking

at?

Q. Yes. Right up here. Would you agree with that?

A. I agree that that's what it says. I'm not sure I agree with the intent of that sentence. But that's, that's my own opinion. I'd have to look at that more closely.

Q. Okay.

A. This is a -- I understand that this is an evolving field, so the understanding of consciousness and especially from not just in our specialty but also in just the neuroscience of consciousness in general field.

Q. We were talking earlier how cardioversion patients are sedated rather than anesthetized, correct?

A. Yes.

Q. *Miller's Anesthesia* distinguishes between general anesthesia and sedation; is that right?

A. Well, I cannot point you to a specific area, but I am sure that they do. I'm sure that it does. As you know, there are two volumes of *Miller*, probably close to 2,000 pages of it. I am certainly not going to be able to recall everything in it. But I could read here and, yes, it looks like they do include moderate conscious sedation and deep sedation and general anesthesia in that particular graph you have there.

Q. So *Miller's Anesthesia*, page 2629, talks about how general anesthesia is when a patient loses consciousness and

is unarousable even with painful stimuli; is that correct?
A. Yes, correct. Yeah, that's what it says.
Q. Do you agree with that?
A. Again, this is a -- it's a rather general statement because the statement says when the patient loses consciousness. So, again, as I've tried to make clear, consciousness is really part of the spectrum, sort of different levels of consciousness. And then likewise unarousable. I don't know exactly how they are using that term, but I will accept, I think, these terms in their sort of pedestrian way in which they are used and then, you know, I would agree with that.
Q. Would you agree if a painful stimuli is applied and the patient wakes up, they are not anesthetized?
A. If they -- if a noxious stimulus is applied and the patient wakes up, if they do not experience the pain of that stimulus then, and they do have -- they don't have memory of it, then I think you can sort of think about, well, did they actually experience the pain and the emotional aspects of that.

So, for example, with the cardioversion, you know, the patient wakes up, let's say, after the cardioversion and they have no memory of it and the stimulation is very short lived. I'm not sure that you can say that they suffered or had any emotional or conscious experience of that just

because they woke up from it.

Now, if the stimulus was continued, continued to be applied, then, of course, yeah, they probably are going to have that emotional experience that we think about.

But quite frankly, the cardioversion example is one where you are basically, again, because of the way that we administer these drugs, you purposely give just enough drug so that the patient will be unconscious based on your assessment of the patient. And they will have no memory of the procedure, but they will wake up immediately afterwards. Because you want to try to avoid, if you can, the -- at all times you want to try to avoid the patient being oversedated.

And I think I talked about this earlier, that you always try to match the drug and the drug dose to the amount of noxious stimulation. So with the cardioversion, it's very -- literally very short. It's probably, I'm not even sure how many milliseconds, but it's less than a second. So you want to match that with the amount of sedation that you have on board.

So that's why you give that, the doses of drugs that you do.

Q. So you are basing your assessment of what is general anesthesia on a subjective experience of a person, do they remember, do they feel pain; is that right?

A. That is part of it, yes.

Q. It's not an objective criteria, such as unconscious, unarousable even with painful stimuli, which is what the textbook says?

A. Well, for a cardioversion, since that's what we are focused on here, for a cardioversion, you would administer the drug and get the patient to a level of anesthesia or level of sedation. I am not saying that you always have to get to anesthesia with cardioversion, but you are going to get them pretty deeply sedated to the point where they are not responsive. So you call out their name. You maybe might touch their eyelash or something like that. Maybe do a sternal rub, the usual things. You may not do all of those, but those are some of the things that you would do. And when you're at that point, then the -- if it's a cardiologist, the cardiologist can flip the switch and deliver the electric shock.

Now, many times the patient will wake up from that. Sometimes they don't. They are still sedated. But your goal is to try to get them to the point where they wake up right afterwards.

Now, there is a downside to that. I am maybe getting into some clinical issues that are not particularly germane here, but sometimes when you give these drugs -- I am sorry. Sometimes when you do the cardioversion, the first shock

doesn't work. So the cardiologist has to do it again, maybe at a higher level. So sometimes you have to -- the first dose of drug that you give, you are going to make another higher dose because you are concerned that maybe the first shock won't work. So sometimes these patients wake up afterwards, you know, right after, sometimes they don't, so --

Q. If cardioversion patients were anesthetized, would they wake up from cardioversion?

A. If they had a level of general anesthesia that I would use during a typical surgery, they would not wake up.

Q. So anesthesia, under general anesthesia, they would be unresponsive to a noxious stimuli such as cardioversion; would that be right?

A. That's correct.

Q. But under sedation they do respond to noxious stimuli; is that right?

A. They do. They wake up.

Q. In your report you talked about coma versus general anesthesia; is that right?

A. Yes.

Q. There is a difference between the two, right?

A. So coma is really a -- compared to general anesthesia, it's a deeper level of unconsciousness. Maybe that's not the best word to say, unconsciousness, but it's a deeper

level of brain depression. In a normal individual, you wouldn't want to achieve a coma-like state with an anesthetic.

Q. That's why anesthetic value for a BIS is between 40 and 60, right?

A. They -- in general if you are using the BIS monitor, you would want to get to the level around 40 to 60. You wouldn't want to get below that because there is probably no benefit to the patient. In fact, there is evidence out there that it might be detrimental.

Q. So whether we are talking about general anesthesia, that's not as deep as a coma; is that right?

A. Based on I think what you have up here and also the general understanding of general anesthesia, that's correct. General anesthesia, that's a level -- at the clinical level, let's say, is not as deep as a coma induced, or anesthetics overdose that causes a coma-like state.

Q. And we established that under general anesthesia, patients generally do not respond to noxious stimuli; is that right?

A. Well, when you say don't respond, what kind of responses are we talking about?

Q. I believe I am talking in general. In general anesthesia, a patient is unresponsive to noxious stimuli. We have just discussed this a few minutes ago.

A. Are you talking about movement responses or --

Q. I'm sorry. I believe the word is -- that *Miller's Anesthesia* is using is unarousable.

A. Okay.

Q. They are unarousable even with painful stimuli?

A. During general anesthesia?

Q. Yes.

A. Yes, that's correct.

Q. So we don't need to go as deep as coma to get unarousable state in response to painful stimuli; is that right?

A. That is correct. For a typical surgery, you would not need to go as deep as coma to be able to prevent the patient from becoming unarousable.

Q. We can stop at the state of general anesthesia?

A. That's correct.

Q. And now looking at *Miller's*, page 1531, there is a table on box 50-1 that talks about emergence. What happens when people come out of general anesthesia, right?

A. Yes.

Q. And some of the signs of emergence from general anesthesia, again on the same page, would be things like swallowing, gagging, or coughing, correct?

A. Yes.

Q. You agree with that, that those are some of the

symptoms?
A. Right.
Q. Grimacing?
A. Yes.
Q. Defensive posturing?
A. Um-hmm. I agree that that's there.
Q. Return of muscle tone.
A. Yes, correct.
Q. And you agree that these are some of the symptoms that a person emerges from under general anesthesia?
A. Those can be present, yes, during emergence from general anesthesia, that's correct.
Q. And even a later phase of emergence even closer to awake, it would be symptoms like eye opening, responses to some oral commands, and awake patterns on EEG; is that right?
A. That's correct.
Q. And you agree that those are some of the symptoms?
A. Signs and symptoms.
Q. Signs.
A. Probably signs would be a better word to use here than symptoms.
Q. So you talked earlier that in the operating room you see people move; is that right?
A. Yes.

Q. And when that happens, what do you do as an anesthesiologist?

A. That depends on the situation. So I might provide -- the optimum thing to do is to provide more anesthetic. Sometimes you can't do that. Maybe the blood pressure is low or there are other reasons why you can't do that. You might give opiates, analgesics, like fentanyl. Or you might have to give more muscle relaxant, which is not the best thing to do because basically there may be conditions where the situation where you just can't provide more anesthetic to the patient, their blood pressure's too low, and if you give the fentanyl, that will often cause the blood pressure to decrease.

But you can give muscle relaxant, and the reason we do that is -- in the circumstances that we do that, we believe that the anesthetic concentration, despite the fact that it's low, is sufficient to block memory formation and to also prevent the patient -- or to make the patient unconscious. But even with the BIS, even if you are using the BIS monitor, obviously the muscle relaxant is going to be able to block -- I mean, the patient clearly, they move. That's why you gave that. So, yes, there are those situations occur.

Q. So if you see movement in surgery, that may indicate emergence, return of consciousness; is that right?

A. It could.
Q. And you said your first response was to give more anesthetic; is that correct?
A. That is correct. In the operating room, that would be my first -- first thing I would try to do.
Q. What about if somebody came in with a lot of pain, say a trauma victim? In that situation, would you administer benzodiazepines for pain management? Before inducting anesthesia?
A. In a trauma patient, I probably would not.
Q. And why not?
A. Well, obviously, I guess it's going to depend on the extent of the trauma what we are talking about here. But some patients who have major trauma, you have to be very careful about all the drugs that you give to the patient. And it may have effects on the blood pressure, especially if you do that before you get the patient in the operating room. You don't want to give somebody a sedative drug outside the operating room and then realize that their blood pressure's decreased and you have to rush them back to the operating room to manage them.

So it kind of depends on the clinical circumstances, but in general, in my practice in the past -- and as you have already so nicely pointed out, I am no longer practicing clinically -- but in the past I would avoid

giving sedative drugs to trauma patients, at least in the -- outside the operating room.

Q. So you would treat their pain first; is that right?

A. I might not treat their pain at all.

Q. You wouldn't use anesthesia?

A. I would use anesthesia, but I wouldn't give them any pain, like a fentanyl or anything like that. I mean I could. It depends on the situation. But often I wouldn't. I would just give the induction drug.

Q. Does inducing anesthesia on somebody who is in pain take more drug?

A. In my experience, no.

Q. Do you -- do you -- would you still do induction using benzodiazepines under those circumstances?

A. Circumstances of?

Q. Somebody who is in severe pain.

A. I would -- I would not use midazolam as an induction drug in some of the circumstances you brought up. Now, I have used midazolam many years ago as an induction drug. I have not used it since as an induction drug. I have used it only as a sedative drug.

So and I certainly would not use midazolam as an induction drug in the situation that you are describing here.

Q. Somebody in severe pain, you would not use midazolam

for inducing anesthesia?
A. I would not, no, because we have other drugs that are better.
Q. Going back to the exhibit from your report, it's a plaintiffs' exhibit, Exhibit 4, page 928, also has been filed as document ECF Number 852-1, PageID 25823.
We are going back to things you reviewed and relied on. You said earlier you did not look at any accounts of any executions; is that right?
A. I do not know what I -- maybe we will have to read back the testimony. I did look at some accounts of executions.
Q. Just tell me what you recall from those accounts.
A. Okay. I am trying to recall.
I cannot remember. And it may not be a surprise to you that I have -- as I mentioned in my report, that I am involved in at least one other, two other cases in similar circumstances, and I have reviewed some of the witness reports in those. And I am sorry. I just can't remember if they are related to those cases or they are related to this case, so I am not sure I can give you anything more than that.
Q. Do you recall learning that some witnesses to the execution report movement for a prolonged period of time?
A. I do recall that, yes.
Q. Do you recall inmates showing gasping or taking

breaths?
A. Yes, I recall reading about that.
Q. And do you also recall reading some inmates being able to mouth words or say words after the drugs were administered, several minutes after?
A. I do believe there was one report, and, again, I don't know -- the reason I am being hesitant is I cannot remember if these were reports that were newspaper reports, whether eyewitness reports, but I do remember that, yes. I do remember it, but, again, I don't know the providence of that off the top of my head.
Q. And have you considered any of that information in drafting your report?
A. No. Well, maybe -- let me think about that. I shouldn't say no.
MR. MADDEN: Judge, I object to the line of questioning. I think it's important that she refer him -- if she wants to speak about executions where midazolam was used in 500 milligrams on a three-drug protocol, maybe that would be relevant, but talking about executions where it was part of a -- mixed with hydromorphone. That's a totally different -- in fact, their witness even said that it has a synergistic effect. It's not even used as an anesthetic. So I think they are conflating and need to be specific about which executions they are talking about and what were the

drugs used.

MS. WOOD: May I response?

THE COURT: Please.

MS. WOOD: Mr. Madden opened the door on direct by generally discussing execution reports and generally discussing the bias of witnesses in making those reports with his witness.

THE COURT: Well, I don't have any problem ultimately with the witness being examined on what he -- what execution reports he's looked at. Understanding Mr. Madden's point that the fact that the protocol may be entirely different certainly has an impact on the weight, but it may not make it totally irrelevant, so overruled.

BY MS. WOOD:

Q. Let's go back and look at the signs of emergence that we just went over a few minutes ago.

A. Okay.

Q. In looking at these signs that you agreed are actual signs of emerging consciousness, those are consistent with the reports that you recall; is that right?

A. Some of the signs that were observed, based on my recollection, are consistent with emergence, that is correct.

Q. But you don't treat them as emergence of consciousness, do you?

A. Treat them where? I am not sure.

Q. In your professional opinion, do you believe that these are signs of emerging consciousness?

A. Again, can you make sure -- just to make sure we're understanding each other, can you point to which emerging signs you are talking about? Which signs?

Q. Return of muscle tone, swallowing, gagging, coughing, defensive posturing.

A. So those are -- can be interpreted as emerging -- signs of emergence. And that in a clinical situation -- well, again, it kind of depends. If you were at the end of the operation, then you wouldn't treat that. The patient is emerging. You want the patient to wake up.

If it was in the middle of an operation, then you would treat it in some other way. As I said, either with more anesthetic or with fentanyl or maybe again not what you would like to do, but maybe with a muscle relaxant. Generally we like to avoid that, but it certainly has happened.

Q. So just to reiterate, you didn't -- you don't know how this protocol would be carried out in practice; is that right?

A. What protocol?

Q. The execution protocol. You don't -- you have never observed an execution?

A. I have not.

Q. You don't expect to observe Ohio's executions, correct?

A. I do not.

Q. So you don't know how the team members administer IVs, for example?

A. I do not know by direct knowledge. I just have the protocol that I've read.

Q. And your report relies on the protocol being executed perfectly; is that correct?

A. Absolutely. And I've said this to Mr. Madden. If these drugs that are going to be administered intravenously are not administered in a properly flowing IV, then there are going to be significant problems. And, you know, the Court's got to decide on that issue, whether that's -- where that stands and all that, but that's absolutely the case. You have to have a properly functioning IV.

And my understanding in some of these protocols, and I am not sure, I can't recall with Ohio, I believe they have to have two IVs, but you have to have that or else it's going to be significant problems.

MS. WOOD: Thank you. I have no further questions.

THE COURT: Redirect?

MR. MADDEN: Can we have a short break so I can talk to counsel?

THE COURT: Of course. Five minutes.

THE COURTROOM DEPUTY: All rise. This court stands in recess.

(Recess from 2:29 p.m. until 2:40 p.m.)

THE COURT: Mr. Madden.

MR. MADDEN: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. MADDEN:

Q. Dr. Antognini, you were asked a lot of questions about and shown specific quotes from *Miller's Anesthesia*; is that accurate?

A. That is correct, yes.

Q. And what have you told me about *Miller's Anesthesia* as compared to articles?

A. Yes. I will begin to answer that question with a story, and I know -- I'm not trying to make light of the situation here, but I think it nicely illustrates my approach to that. When I was in medical school, my roommate and I were at a lecture, and the professor finished his lecture and my roommate went up to him and said, well, Dr. -- Professor So-and-So, you said this in your lecture but the book says that. And the professor replied, "The book is wrong."

Q. Why was that?

A. The reason why you have to be careful about relying on

textbooks is that many statements in textbooks are unreferenced. Also many chapters, the usual process for books, is that you gather coauthors -- and as an editor I have edited a book myself, and there is often a scramble just to get the authors to submit their articles on time, or their chapters on time. So there really isn't very much peer review in many books.

And I think with *Miller*, I have been an author in a chapter in *Miller's* and it didn't undergo really strict peer review like a journal article would.

So I always take what's in a textbook with a grain of salt about whether all of the statements in that book are valid or supported.

Now, obviously in a textbook of that size, you are going to find statements that would support your position or maybe statements that don't support your position. But it's kind of a hit and miss on whether it's truly valid or not. So, you know, using a textbook -- and I know that you have used a textbook; the other side has used a textbook -- but it's not a particularly great source of information, or accurate information necessarily. It can be, but not necessarily.

Q. You were questioned extensively about the Crawford article.

A. Yes.

Q. It's Defendants' Exhibit 76 at 1130. Let me refer you to the -- is there anything -- first, is there anything that you would like to explain about that article?

A. So the concluding -- let's take a look at this here.

MS. WOOD: Sir, Your Honor, can we have a moment?

THE COURT: Yes.

(Pause.)

THE COURT: In general, Dr. Antognini, is *Miller's* an accepted text in the field?

THE WITNESS: Yes. It's probably the -- the most accepted textbook in the field in my -- in my estimation.

BY MR. MADDEN:

Q. Is there anything you would like to explain about that article, the Crawford article?

A. Well, I still stand by my earlier testimony that this is evidence that midazolam can be used during a noxious procedure, and I've provided the qualifications there.

I know that the other attorney brought up the issue about the date, publication date of this. And I think it's important -- I think it's important, maybe, I am not sure if the rest of you would think it's important, but I think it's important to understand that the clinical validity, I guess, or the clinical usefulness of a drug, you know, something that was published 20, 30 years ago doesn't invalidate the actions of that drug in terms of its use during noxious

procedures.

So the fact that this drug was used in the study, you know, 27 years ago or whatever doesn't invalidate the fact that the drug can be used for those types of procedure. Is it clinically used now? No. But it's not used for cesarean sections to my knowledge to any great extent.

Q. Did you --

A. But it can be used, and if you just read and just look at the article and you look at the concluding paragraph, "We conclude that midazolam is a suitable alternative to thiopental for induction and maintenance of anesthesia for elective cesarean section."

Q. Doctor, are you currently licensed in the state of California?

A. I am licensed to practice medicine in the state of California, yes.

Q. And so if there is any insinuation that you were not, could you make it clear for the record that you are?

A. My license is active and there is no prohibition on it.

Q. Is there anything else you would like to note about this document?

A. No, I don't think so.

Q. Doctor, you were asked about the guidelines for expert witness' qualifications and testimony. Is there anything that you would like to speak about that?

A. So I think that we need to be a little bit mindful of how some of these guidelines were promulgated regarding expert testimony. In particular, the other slide that was shown, and I may have to have flip them back and forth for this, but it says here that, the underlined part, to limit uninformed and possibly misleading testimony, experts should be qualified for the role and should follow a clear and consistent set of ethical guidelines.

I fail to see what -- how my testimony or involvement here has been unethical, which I can elaborate on in just a moment. But, anyway, maybe for some reason the other side was billed in that case, but I don't see my involvement here as being unethical so --

But if you go to the next one that was shown. "The physician should have been actively involved in the clinical practice of anesthesiology at the time of the event."

I believe the attorney -- and we'd have to read back the question -- but I believe the attorney, and this is sort of paraphrasing, said, so you are not actually involved -- these executions are in the future so you are not actually involved at the time of the event. I think that was the wording. By that definition, no expert witness could do that because we're not present in the future. So I think that's a bit of a red herring.

"The physician's testimony should reflect scientific

evidence and accepted practice standards prevalent at the time of the event in question."

Again, these guidelines were promulgated regarding the cases of malpractice. So if I'm testifying in a malpractice case, I -- it's the position of the ASA that you should have been clinically active at the time of the malpractice case. So, for example, if something untoward were to happen to a patient today somewhere, and then a year from now a lawyer were to contact me and ask me, Dr. Antognini, would you be willing to testify as an expert witness in a malpractice case, I would say, well, no, I'm not -- I wasn't clinically active at that time. So I am not -- you know, I am not going to testify.

Now, I may be able to provide some testimony to them, but, you know, this issue I think comes up, and I don't think I would do that.

But this case is not about medical malpractice, and so I don't think that it necessarily applies. In fact, I don't think it applies at all.

Q. Have you been asked to, by the Ohio Attorney General's Office, to give any opinion about -- have you been asked about, by the Ohio Attorney General's Office, to give opinions about the effects of midazolam, correct?

A. I have, yes.

Q. And have you been asked in any way by me or any of the

lawyers here to provide specific information about an execution that will -- that will take place in the future?

A. I have not. And as I said, made clear to you, I in no way want to -- I don't want my testimony, my written report to be construed in any way as to aid anybody, any person or entity in the performance of an execution. That's up to the system to decide whether these will occur and which -- and the manner in which they will occur. I am just providing expert testimony on the pharmacological aspects of these drugs as I see it.

Q. Let's get back to *Miller's Anesthesia*. Does *Miller's* speak to extreme dosages of midazolam?

A. To my knowledge, it does not, but, again, it's a big book and I am not sure that it says anywhere about extreme doses, as you say, and especially doses at 500 milligrams.

Q. In fact, wouldn't you agree with me that *Miller's Anesthesia*, any time it's making any reference to any drug is almost always specific to therapeutic dosages?

A. That is correct. Again, that's a big book. I can't say always, but generally, any medical textbook, when it talks about drug administration, is always going to be talking about therapeutic doses.

Q. And it would do little good to teach doctors and young -- young persons attempting to become doctors about massive dosages that would kill people; is that correct?

A. That is correct. I mean, you might talk about that in the context of trying to explain a particular point, but in general in terms of trying to explain and talk about therapeutic dose, no, you would not talk about it. The high dose -- except to the extent that higher doses can -- are going to be more lethal, even in the clinical setting, than a lower dose.

Q. You were asked questions about the BIS. Is there anything you would like to add to that?

A. Well, I would like to talk about the BIS monitor and the values because the issue came up about you can't achieve a BIS below 60. And that's not true. You can. Now on average -- with midazolam. On average you may not be able to -- based on the clinical studies and the use of a therapeutic does, you may not be able to do it on average, but some patients definitely do achieve BIS numbers below 60.

And also, midazolam -- you know, based on the literature, midazolam does not cause a consistent change in the BIS. And the data that were in those papers point that out, which I can point out here.

Q. Yes. I would like to refer to Defendants' Exhibit 76 at page 1171. Do you recognize this, Doctor?

A. Yes. That's the paper by Peter Glass and others.

Q. Did you rely upon this document in rendering your

opinion?

A. I did.

Q. Let me refer you to page 1175. Are there any relevant information on that -- is there any relevant information as pertains to midazolam on that page?

A. Yes. So if you look at -- so we're looking at the Glass paper, 1175. It's their page 840. So there is four figures on that. The Figure Number 3 shows the bispectral index compared to the midazolam concentration. And it shows the sedations for on that figure, but also, again, the relationship between the BIS and the midazolam concentration.

And as we've discussed, the usual BIS levels that you are looking for in general anesthesia are going to be between 40 and 60. And if you look at that figure, you can see that there are a number of the dots that fall below 60. Not all of them. Again, that's why we are looking at average, and average is I don't think above -- I'm not sure where it is in terms -- it depends where you are looking on it at the graph, but there are definitely patients that had BIS numbers below 60 -- I am sorry. Volunteers that had BIS numbers below 60 with midazolam.

Q. Is there anything else, any other charts in that paper you would like to refer to?

A. Yes. I also in looking at the paper -- and then, by

the way, looking at this paper, but not just for this but I have looked at this paper for many times over my career. So Figure 5 is the relationship between BIS and probability of a positive response, and this is, in this case, probability of consciousness.

And this is -- as I recall, it's a logistic regression analysis. It's a statistical analysis of the data to provide the context here of what was going on with the BIS relative to the probability of consciousness.

And you can see that the -- there are two -- two curves there. Actually, there are three curves: The curve for midazolam. The curve for isoflurane is a curve to the right, or curves to the right. And then you have the curve for propofol. I'm sorry. I am alternating between wearing my glasses and not. But the curve for midazolam and the curve for isoflurane basically overlap. They are right on top of each other.

Q. What does that signify?

A. So that, based on that study, it signifies that relative to the BIS and the probability of consciousness, that midazolam and isoflurane have equal potent -- maybe that's not quite the right word -- but have equal effects in terms of being able to depress the BIS.

This is just a statistical analysis of the data. I'm not -- you know, again, if you look at the actual data

points, the midazolam never got below a BIS of -- in any patient, it looks like the low of the BIS was probably around 50 in any individual patient.

And the other thing that I would point out is that the curve for propofol is shifted to -- to the left. So what that means, if you think about it, is that if you were to draw a line between -- across from the 0.5 level all the way across, you could see that because of the shift of that curve with the propofol, that that line, that horizontal line that you -- and I use .5 because that's our 50 percent level. When you draw it across there, it intersects that propofol line at around a BIS of maybe around 62 or so. I'm not sure. But it intersects the other lines with a BIS of around maybe 70.

So just, again, to my point about there being different effects, these anesthetics having different effects on the BIS. Propofol obviously in this study appears to be different from isoflurane and midazolam based upon the figure that they had drawn there in terms of the effects of BIS and the probability of consciousness.

Q. Now, does pain stimuli always mean that a patient is emerging?

A. I'm sorry. That -- I'm not sure I understand.

Q. Does pain stimuli always equate to the patient emerging?

THE COURT: I don't understand the question.

MR. MADDEN: Maybe I wrote that down wrong.

BY MR. MADDEN:

Q. Would -- you were questioned -- you were questioned about these things, coughing and eye opening, in *Miller's*. Does that -- are all these always indicative of a patient emerging?

A. No.

Q. Can you explain that?

A. Well --

THE COURT: Just so the record's clear, we're talking about page 1531 of *Miller's Anesthesia, 8th Edition*. Go ahead.

THE WITNESS: I want to make sure it's -- emerging from anesthesia is not, I'm sure, the best way of looking at this. Now, are they shifting from a deeper level of anesthesia to a lighter level of anesthesia, and I think the answer to that is that is possible, but if they are showing signs of coughing, then that may occur, that there is a shift. Now, are they emerging from anesthesia? Are they regaining the possibility or the function of consciousness? That kind of depends on what level of anesthesia that they are at.

There's no question that there is a relationship between consciousness, un -- I should say unconsciousness

due to anesthetics and noxious stimulation. That is, noxious stimulation can shift those curves, as I talked about.

I think -- I believe -- I don't think that I really have all the data up there, that it can shift those curves and that you can -- that patients will be at a lighter level. I'm not sure a lighter level of anesthesia is the best way of looking at it, but that they will be less -- let me think about the best way to word this. That they are not as deep in terms of their brain depression. So their brain is depressed. Their central nervous system is depressed, and the painful stimuli will cause them to be less depressed from the anesthetic.

Now, again that doesn't mean that they are actually emerging from anesthesia and regaining consciousness, but depending on the anesthetic level, they could be getting close.

BY MR. MADDEN:

Q. Briefly explain the MIC, the MIC and the MAC in the application of the MAC to your opinions about midazolam.

A. So there are studies out there that look at intravenous drugs in terms of some of these responses. And you can develop sort of similar types of relationships in terms of how much drug do you need to provide amnesia, how much do you need to provide consciousness, and how much do you need

to provide immobility. And there are similar -- you can develop similar curves or relationships, as I have here.

So my recollection, I'd have to look at those data to be able to figure out, to determine what the relationships are, but my recollection is that the amount needed to ablate consciousness and ablate memory is significantly less than what it is for preventing movement.

Now, but we don't have any of those data for midazolam. We don't have the -- the data obviously, based on studies like the Glass paper for consciousness, and I'm not sure we have it for the amnesia part, but we don't have it for the immobility part.

Q. Let me refer you to your exhibit, page 16, that's Defendants' Exhibit 94 at 1780.

A. Okay.

Q. Please explain your reference to the Gehrke study and why you cited it there. And --

A. Do we have that actually here somewhere? Can I refer to it?

THE COURT: Yes. If the defendant -- the witness does not have Defendants' Exhibit 94, the clerk will provide it.

MR. MADDEN: I think he wanted to see the actual, the Gehrke study.

THE WITNESS: The actual paper.

THE COURT: I don't know.

BY MR. MADDEN:

Q. I don't have it.

A. Okay, that's fine. So I don't -- I do remember obviously the paper to some extent and that they used midazolam for endotracheal intubation, and I believe that there was a group of patients that did not receive any other drugs besides midazolam, but I'd have to refer to the paper to make sure. That's my recollection.

Q. Do you recall the question that you were asked about the Gehrke study? And if so, do you want to respond about it?

A. I do not recall the specific question. All I can say, in developing this, I thought I was pretty careful about including studies where midazolam was given by itself after that particular procedure, at least in some set of patients in that paper. That's my recollection.

Now, the general results may have been applied, or the conclusions may have been applied to the general results. I am sorry. The general results may have been applied to the conclusions, but my recollection is that there is a subgroup that received just midazolam alone, and I think the point I was trying to make, that if that's correct -- again, that's my recollection -- that these investigators saw fit to use midazolam by itself in some patients for endotracheal

intubation.

Q. You were also questioned about the Yegin study. Do you recall that? Paragraph 16.

A. Yes, I see that. I do recall that paper, yes, generally.

Q. And is there anything that you want to -- in response to your questioning about that?

A. My recollection is that it was just, as I said, that the drug was given intrathecally, or in the spinal cord, in combination with a local anesthetic, and that the analgesic period was longer when midazolam was used as opposed to when it was not used. Again, supporting my belief or contention that midazolam seems to have some analgesic properties.

Again, it's related to, you know, what dose are we talking about. And, you know, in this case, it had to be given with another drug. But in my mind, it had no analgesic properties whatsoever, I don't think you would see that type of effect where it belongs to an analgesic, but that's my opinion.

Q. Are there any other -- strike that. In paragraph 40 of your report, explain why midazolam is an exception to the BIS.

A. Is that my supplemental report?

Q. Yes.

A. I'm sorry. Explain what?

Q. Why midazolam is a exception to the BIS.

A. Well, I wouldn't say it's -- it's not an exception. It's just that for any of the drugs that we use in the operating room for which the BIS is used, the BIS does not provide necessarily accurate information.

Q. Explain that.

A. Well, just a little context. If you think about what -- what do anesthesiologists do? What's the primary thing that they do, and that is to anesthetize people, all right. And you would think, well, you must have a monitor for that. Well, for many years we didn't have a monitor for that. So obviously if there was a monitor out there where it was clear-cut that it could be used to detect memory, it could be used to detect awareness and so forth, it would be present in every hospital in the United States.

But, in fact, the BIS monitor has some problems with it in terms of -- I shouldn't say the monitor. But the interpretation of the data, the data are not always accurate. And I can point that out in just a moment in both the Glass paper and then the other paper that I cited, the Lui paper. It's not always accurate depending on the circumstances. There are artifacts with the BIS monitor and so forth. And there are drug differences. For example, halothane affects the BIS differently than isoflurane. But just to make the point even further, I'm not -- don't have a

copy of the Lui paper in front of me, but maybe it's in the exhibit somewhere.

But I can, as you are looking for that -- I think the Lui paper would probably be best for me to make my point.

THE COURT: Rather than wait on that -- I guess Mr. Wille's found it.

What are you handing the witness, sir?

MR. MADDEN: This is not an exhibit. It's DX 76.

Your Honor, I would like to add this as an exhibit.

THE COURT: What's the number?

MS. WOOD: What is it?

THE COURT: I don't know yet. I am just trying to get a number on it.

MR. MADDEN: 105.

THE COURT: All right.

MS. LOWE: Your Honor, it's already actually an exhibit. It's Defendants' Exhibit 76, page 1159. Bates stamped 1159. I'm sorry. I might have said 69. It's 59.

THE COURT: So if it easier, Mr. Madden, please feel free to hand Dr. Antognini the extracted matter, but I have it in front of me as "Electroencephalogram Bispectral Analysis Predicts the Effects of Midazolam Induced Sedation."

THE WITNESS: Yes, I have it in front of me. Thank you.

BY MR. MADDEN:

Q. Why is that document -- why is that article particularly relevant?

A. Again, just to illustrate some of the complexities and the abilities around the BIS. If you turn to the Figure Number 1 of that paper, it shows the BIS values relative to sedation scores. So in this particular example, the -- if you look at the number 1. So what's happening here is that they are giving the drug and the drug is starting to wear off so you got this overall decrease in the BIS and then you get this overall sedation score. So you got a sedation score of 1, which is the lowest that they had. And then you get this increase in the overall BIS, average BIS, until you get back to a score of 4.

So it's basically their way -- they are getting the drug, the BIS is going down and then their sedation is getting more and more, and then they are beginning to emerge from it.

So I would just focus on the sedation score of 1, which is about in the middle of that figure. So these were patients or volunteers -- I can't remember off the top of my head -- that from a clinical perspective all had a sedation score of 1. So clinically they all had the same level of sedation. Or in this particular case, it might be -- they might have defined that as being unconscious.

Well, in any case, the point that I am trying to make here is that at that same clinical level, it looks like the BIS was as high as 95 in one patient and as low as 40 in another if I look at the top score and the -- the top dot and the bottom dot, although this reproduction is not particularly good. At that level, you had that same type of -- you had that spread.

So now there could be methodology reasons why there is lag periods and all of that, but, nevertheless, that would happen in a clinical setting as well. So the BIS monitor, it is a step forward in terms of monitoring depth of anesthesia, but it's not completely accurate.

And there are -- there's a lot of literature out there about drugs having different effects on the BIS that I already pointed out, and that even within that certain drug, you can have differing BIS values, even at the same sedation level. That was just the point I was trying to make about the BIS score.

I have used it. It's a step forward. I have used it clinically; I have used it experimentally. It's good in terms of any, you know, using an average score to figure out what's going on but it doesn't -- it's not 100 percent sensitive and 100 percent specific.

Q. What are the other exceptions to the BIS score?

A. I do want to -- I know we have sort of used the word

"exceptions," and if I have used that as well, I am not sure it's exactly the right word, but what are other circumstances which the BIS might be not as -- not accurate or might be a little bit misleading or whatever term you want to use. Again, you have drugs that are administered, anesthetic drugs that are administered that don't affect the BIS as much as -- so ketamine, nitrous oxide. You give those drugs in addition to some other drugs they have on board and you may not change the BIS very much, even though you get a deeper level of anesthesia.

MR. MADDEN: Thank you, Your Honor. I have no further questions.

THE COURT: Recross.

MS. WOOD: Very briefly.

THE COURT: Yes, ma'am. Do you need us to break and recess?

MS. WOOD: No.

THE COURT: All right. Good.

Mr. Madden, can you help Dr. Antognini get those --

THE WITNESS: I think I have got it.

MR. MADDEN: Thank you, Doctor.

THE WITNESS: Sure.

RECROSS-EXAMINATION

BY MS. WOOD:

Q. We talked about a BIS monitor just now, right?

A. Yes.
Q. And you said that's not -- it's a good indicator but it's not the only indicator that you would use in the operating room?
A. That is correct. It's the only -- there are other EEG monitors out there besides the BIS monitor. So I want to say -- when you say indicator, obviously there are clinical signs, but there are other monitors out there. I have never used the other monitors.
Q. You could also use heart rate monitor; is that right?
A. Heart rate monitor is one thing you could use.
Q. Blood pressure cuff?
A. Yes.
Q. What else would you use?
A. To?
Q. Monitor the patient at a depth of anesthesia.
A. The heart rate monitor, the blood pressure monitor, those are used for a variety of different reasons, including the depth of anesthesia. Obviously you have a response to surgery. You are measuring the heart rate in treating that. But you also are measuring the blood pressure and heart rate for other reasons primarily because these drugs can decrease the blood pressure, so you could have blood loss and so forth. So you are looking for the -- what's going on in those regards.

But one of the things you could use those monitors for would be to measure the response to noxious stimulation.

Other monitors, the pulse oximeter is used primarily for measuring oxygen concentration or oxygen saturation, but it also picks up the pulse. So you can use that to monitor the pulse but you already have the EKG, so it's just sort of supplementary.

There are other, as I said, other monitors. The EEG monitors that could be used. People look at pupil dilation. They can look at movement, as I discussed. They can look at perspiration or sweating. These are autonomic signs of stress or that the individual's responding to the noxious stimulation.

Q. So taking together those monitors, those tools and that equipment and watching for signs of movement, that would provide you a better picture of whether patient is reacting to a noxious stimuli; is that right?

THE COURT: Better picture than what?

MS. WOOD: Than using nothing.

THE WITNESS: Yes, in the clinical setting, it would. The only caveat, I would say, is that sometimes monitors can throw you off, but in general, the more you monitor, the more data you collect, the more able you are to manage the patient.

BY MS. WOOD:

Q. Would you ever monitor the depth of anesthesia by doing a reflex check alone?

A. A reflex check alone. By itself. I would not. Not in the operating room, I would not.

Q. You mentioned movement, and you said that's not always indicative of a patient emerging, correct?

A. That's correct, yes.

Q. I believe in your earlier testimony hours ago you used the word "arbitrary," some of these signs could be arbitrary.

A. I used that -- it's not that the signs are arbitrary. I'm not sure if I have said -- if I said that correctly or I understand you correctly. Where you decide whether somebody is conscious or not is arbitrary.

So let's take an example of -- and I am not going to -- and this is just a hypothetical example. Let's say there's five things that you look for in terms of consciousness. And you are going to say, you know, arbitrarily you have two of those, two or more of those -- two or more of those signs, I am going to label the person as being conscious. So if they have only one of those five, you will say they are unconscious. And you may have some reason -- reasons to do that. There may be methodological reasons you want to do that. There may be neurophysiological reasons to do that. But it really is in my mind because consciousness is a

spectrum. The way some of these scales are used, it really is an arbitrary decision about whether they are unconscious or not. And likewise, with reflexes, there's reflex movement to signify that the patient is awake or otherwise responsive.

As was pointed out yesterday by Dr. Stevens, he referenced that table from ASA that looked at general anesthesia, and the American Society of Anesthesiologists in that table, it clearly states that reflexive withdrawal is not considered purposeful movement. So if you have somebody who was anesthetized based on that table, and they -- you apply a noxious stimulus and they have a reflex withdrawal, which doesn't necessarily mean just a reflex withdrawal from the extremity that you are stimulating, but in general that's what it does mean. The presence of a reflex withdrawal is not considered purposeful movement in that table. And, therefore, by that definition of that table, the American Society of Anesthesiologists, as I interpret that, says they are -- that patient is under general anesthesia.

So, again, a patient under general -- under anesthesia, general anesthesia who has a reflex withdrawal to a noxious stimulus is considered to be under general anesthesia as I interpret that table. Because they have a very clear, a reflex withdrawal is not considered purposeful movement.

Q. But you said some of these parameters are arbitrary, correct?
A. They are.
Q. So one study may use a certain definition of consciousness, the other study can use a different definition, and they will arrive at different results; is that right?
A. That is correct, yes.
Q. So it's possible that this criteria is arbitrary; different team members checking reflexes during the execution would arrive at different conclusions?
A. I don't want to get into the issue about --

MR. MADDEN: Objection. It calls for speculation.

THE COURT: Hang on.

THE WITNESS: Should I answer?

THE COURT: No, you should not answer. The objection's sustained. But not on the basis that you raised, Mr. Madden, but rather on the basis that it's outside the scope.

MR. MADDEN: Yes, sir.

BY MS. WOOD:
Q. You were asked about the Crawford study.
A. Yes.
Q. Just to confirm, the Crawford study used more than just midazolam; is that right?

A. For the extent of a study period for an individual patient, that is from the induction of anesthesia to the completion of anesthesia at the end of the case, they used, as I recall, mid -- either midazolam or thiopental, depending on the group, nitrous oxide, and then I believe it was meperidine, I believe is what was used, is my recollection, after the umbilical cord was tied off.

Q. And midazolam and nitrous oxide were administered simultaneously?

A. No, they were not.

Q. The nitrous oxide was administered first?

A. The nitrous oxide was administered after the midazolam.

Q. And then the study, the patients in the study were given nitrous oxide, which you testified you don't know the rate of the flow, right?

A. I do not. It was not described in the paper.

Q. So your estimate of it took as long as a minute for midazolam to be the only drug, that's an estimate?

A. That is correct.

Q. It could have been as little as a few seconds?

A. I don't think it could be as little as a few seconds. Again, it depends -- you know, I wasn't there collecting the data, doing the studies. But just based on my experience in terms of doing cesarean sections, once you intubate the patient and you tell the surgeon to go, then you actually

will hook up. You've taken the -- you have got to take the mask off the circuit. You put the circuit onto the tube. Depending on the practitioner, they may or may not tape the tube at that point, and then they will turn to turn on the anesthetic, or turn on the nitrous oxide in that case, and that takes time for that to be flushed through.

Now, we don't know the flow of the nitrous oxide. We don't know the volume of the circuit. Those issues come into play. But my -- again, my estimate is somewhere around 30 to 60 seconds. But it's an estimate, and it's -- I'm willing to accept the criticism that it's only an estimate.

Q. And just to confirm that the graph that's on the poster and that was also in *Miller's Anesthesia*, that refers to inhaled anesthetics; is that correct?

MR. MADDEN: Objection, Your Honor. It goes beyond the scope.

THE COURT: Of the redirect? Sustained.

BY MS. WOOD:

Q. Going back to *Miller's Anesthesia*, page 842, you were asked about the Yegin study that used, again, more than one drug with another anesthetic, and you said the analgesic effect was prolonged. *Miller's Anesthesia*, on page 842, talks about synergistic interaction of midazolam and other drugs, right?

A. Where does it say other -- where does it say that?

Q. "When midazolam is combined with other anesthetic drugs, coinduction, often a synergistic interaction occurs similar to what is seen with propofol."

A. Okay. I agree with that. I mean, that's what it says.

Q. Would you agree that this may explain the result you were seeing in the Yegin study when midazolam was used with another drug that has analgesic properties?

A. So another drug as what, the nitrous oxide or the meperidine or both?

Q. We are talking about the Yegin study where the bupivacaine was injected.

A. Oh, I'm sorry. I apologize. I am confusing my studies here. There absolutely could be synergy there. I mean, that was bupivacaine, as I recall. That was just a local anesthetic. So there could be a synergistic interaction there.

Q. So --

A. Have I -- have I provided the best spin on that paper? I suppose you could criticize me for that. But it's difficult to, I think, reconcile the statement that benzodiazepines lack analgesic properties when there is the -- this evidence and other evidence and the evidence that I cited that it's been used only by itself in noxious procedures.

And this, again, provides some evidence that maybe the

action might be at the spinal cord level, which is what I cited in my original report that it might be at the spinal cord level.

MS. WOOD: Can I take a moment to confer?

No more questions, Your Honor.

THE COURT: Thank you, ma'am.

Mr. -- Dr. Antognini, you may step down.

THE WITNESS: Thank you.

THE COURT: I said "Mr." before I said "Dr." For years I tried to enforce a distinction between medical doctors who got the title and Ph.D.s who didn't, but I gave that up some year ago. It's hopeless.

And may the witness be excused?

MR. MADDEN: Yes.

THE COURT: Very well. I hope you don't have a snow delay getting your flight.

THE WITNESS: Okay. Thank you.

THE COURT: And we're back to plaintiffs. Next witness?

MR. SWEENEY: Actually, Your Honor, the next expert that the defendants were going to call also has to catch a flight so we've agreed to put him on.

MR. MADDEN: Actually, Judge, he doesn't have a flight. I just found that out. So you guys can call your next witness.

MR. BOHNERT: Your Honor, plaintiffs call Sonya Rudenstine. She's by phone. We were thinking that we were going to go ahead with -- do you want me to call her?

THE COURT: We will take our afternoon recess. It's 3:30, so we will take our afternoon recess at this point for ten minutes, and we can get that set up.

MR. BOHNERT: Thank you.

THE COURTROOM DEPUTY: All rise. This Court stands in recess.

(Recess from 3:32 p.m. until 3:43 p.m.)

THE COURT: Your next witness, Mr. Bohnert.

MR. BOHNERT: Plaintiffs would call Sonya Rudenstine by telephone.

THE COURT: Ma'am, this is Judge Michael Merz in Dayton, Ohio. I understand that you are prepared to be called as a witness to testify in the plaintiffs' case in chief in the Ohio Protocol -- execution protocol case. Is that consistent with your understanding?

THE WITNESS: Yes, Your Honor.

THE COURT: And do you solemnly swear under the pain and penalty of perjury that the testimony you give in the matter now in hearing will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: I do, sir.

THE COURT: And are you willing to submit to the

jurisdiction of this court despite the fact that you are testifying at a distance? I don't know where you are. Would you first of all tell me where you are?

THE WITNESS: Yes. I'm in Gainesville, Florida. Do you need the address?

THE COURT: No, ma'am, I do not.

THE WITNESS: Okay.

THE COURT: Are you willing to submit to the personal jurisdiction of this court for purposes of any potential witness sanctions that might be imposed?

THE WITNESS: I am, Your Honor.

SONYA MARGARET RUDENSTINE, PLAINTIFFS' WITNESS

THE COURT: Very well. Would you state your name and spell your last name for the record.

THE WITNESS: Sure. It's Sonya Margaret Rudenstine, R-U-D, as in "David," -E-N-S-T-I-N-E.

THE COURT: And your current employment, ma'am?

THE WITNESS: I am self-employed as a solo practitioner.

THE COURT: Of law?

THE WITNESS: Indeed, yes, sir.

THE COURT: Your witness, Mr. Bohnert.

MR. BOHNERT: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. BOHNERT:

Q. Sonya, good afternoon. Did you witness the execution of Paul Howell in Florida?

A. Yes, I did.

Q. And do you know what protocol, what execution protocol was used to execute Mr. Howell?

A. Yes, I do. It was the September --

MS. LOWE: Objection.

THE COURT: Grounds?

MS. LOWE: Hearsay.

MR. BOHNERT: Just one second. There was an objection.

THE COURT: There was an objection, ma'am.

THE WITNESS: Oh, sorry, Judge.

THE COURT: And the objection is that it's hearsay, and so Mr. Bohnert will need to lay a foundation to show that it might not be.

BY MR. BOHNERT:

Q. Right. The question was just, do you know what protocol was used? Yes or no.

A. Oh, yes, I do.

Q. And I sent you some documents. If you could look at the document that is Plaintiffs' Exhibit 71, please?

A. Yes, I have it.

Q. Okay. And do you recognize this particular document?

A. Yes, I do.

Q. What is it?

A. This is the execution protocol, the injection protocol put in place by the Florida Department of Corrections under which Paul Howell was executed.

THE COURT: Could you hang on a second, please?

MR. BOHNERT: Sure. I'm sorry, Your Honor. This is, again, Plaintiffs' Exhibit 71, on the bottom of the Plaintiffs' Exhibits Volume II.

THE COURT: I have the document in front of me.

MR. BOHNERT: Okay.

THE COURT: And what this appears to be is -- you said 71 or 72?

MR. BOHNERT: Tab 71, here at the bottom, page 770 all the way through 782, Your Honor.

THE COURT: I am looking at the wrong volume again.

MR. BOHNERT: I see you have got the black-covered binders there, Your Honor.

THE COURT: Correct. I don't think I have been furnished a copy of the white binders.

Ms. Rudenstine, I apologize for being as disorganized as I appear to be.

THE WITNESS: No problem, Your Honor.

THE COURT: I have the exhibit.

BY MR. BOHNERT:

Q. Ms. Rudenstine, if you could turn to page 782 at the bottom at the page that's marked with that.

THE COURT: Your copy doesn't have 782 in it, Mr. Bohnert.

MR. BOHNERT: At the bottom, Your Honor.

THE COURT: Go ahead.

BY MR. BOHNERT:

Q. Is there a date there on this page, the last page of this particular protocol, Ms. Rudenstine?

A. Yes, there is, September 9, 2013.

Q. And it's signed by the secretary, Michael Crews; is that correct?

A. That's correct.

Q. And who is Mr. Crews?

A. He is the head of the department, secretary of the department.

Q. The department -- the Florida Department of Corrections?

A. At the time. Yes, the Florida Department of Corrections.

Q. And if you could turn to page -- well, it's page 6 of -- 6 and 7 of the protocol. It's Exhibit page 775 and 776, please.

A. Just give me one minute. Okay.

Q. And from those pages of this particular document, does

it -- does it state what the drug protocol would be for implementing this particular execution protocol?

A. Yes, it does.

Q. And what would be the drugs and the doses that would be used for this protocol?

A. The first injection is midazolam-hydrochloride injection, and the total amount to be given is 500 milligrams, but it is to be administered in two separate injections of 250 milligrams each. The second drug is vecuronium bromide, and a total of 200 milligrams are administered in two separate injections of 100 milligrams each. And the third is potassium chloride. The total administered is 240 milliequivalents. Again, to be administered in two separate doses of 120 milliequivalents each.

And there is a saline solution that is administered in between the injections.

Q. So in between each of the different drugs, there is a --

A. Correct.

Q. -- saline injection, okay. So, for instance, if there were three injections -- if -- to inject the first set of drugs, would there be records saying three different injections?

THE COURT: I don't think --

THE WITNESS: There would -- sorry, Judge. Did you have --

THE COURT: I am not sure that a foundation's been laid about how this witness knows this.

MR. BOHNERT: Okay. I will get there.

THE COURT: All right.

MR. BOHNERT: Sorry. Just trying to expedite things. My fault.

BY MR. BOHNERT:

Q. Now, Ms. Rudenstine, also while you are looking at this particular document, if you could go ahead and turn to page -- turn to the previous page, page 4 and 5 of the protocol that is labeled here in exhibit page 773 and 774. Do you see that?

A. I do.

Q. And do you see a paragraph down there at the bottom that says paragraph 7, FDLE monitors?

A. I do.

Q. And could you explain what those particular paragraphs require under this protocol?

MS. LOWE: Objection. Foundation.

THE WITNESS: Yes, there are two --

THE COURT: Hang on.

MR. BOHNERT: Just one second.

THE COURT: Foundation. Sustained.

BY MR. BOHNERT:

Q. Do you know whether there are any records that are required in the performance of an execution in Florida under this particular protocol that we are looking at here?

MS. LOWE: Same objection, Your Honor. I don't believe that there's been any foundation laid that this witness is --

THE WITNESS: Do you want me to answer? I heard some noise in the background.

THE COURT: Go ahead and finish, Ms. Lowe.

THE WITNESS: I'm sorry, Your Honor.

MS. LOWE: I don't believe that there's been any foundation laid as to how this witness has knowledge or any personal knowledge of the department's practices and procedures. She's stated she's a private attorney in Florida and not a member of the Department of Corrections.

THE COURT: Sustained.

MR. BOHNERT: I will correct that, Your Honor.

BY MR. BOHNERT:

Q. Ms. Rudenstine, what kind of practice of law do you engage in?

A. Post-conviction and appellate law with a specialty in capital post-conviction work.

Q. Okay. So you represent individuals who are on death row in Ohio -- excuse me -- in Florida, correct?

A. I do, yes.

Q. And in the course of your practice in that area, have you had to become familiar with the execution protocols that Florida has in place?

A. Yes, I have. And, specifically, I have become intimately familiar with -- in representing Mr. Howell in warrant proceedings.

Q. So you have knowledge and -- you have personal knowledge from your work, litigating on behalf of Mr. Howell, of the details of this particular protocol, particularly at paragraph 7 at the bottom there, would that be accurate?

MS. LOWE: Objection.

THE WITNESS: Yes, it is.

THE COURT: Grounds, Ms. Lowe?

MS. LOWE: She still -- she has knowledge -- it's still hearsay. She is gaining knowledge through her litigation -- it's not personal knowledge -- that member of the Department of Corrections in Florida and implementing these policies and procedures or keeping the records.

THE COURT: Overruled.

MS. LOWE: Thank you, Your Honor.

THE COURT: You may answer the question, ma'am.

THE WITNESS: Could you repeat the question?

THE COURT: Yes. That is, do you have knowledge,

personal knowledge from your work litigating on behalf of Mr. Howell of the details of this particular protocol, particularly at paragraph 7 on the bottom there, would that be accurate?

THE WITNESS: Yes, it is, Your Honor. I engaged in several different evidentiary hearings challenging this protocol, and among them, there was testimony presented by DOC officials concerning what is in the protocol. But, additionally, and specifically with regard to the FDLE monitors, I observed the monitors in the lethal injection, or one of the monitors in the lethal injection chamber when Mr. Howell was executed.

BY MR. BOHNERT:

Q. Okay. And so can you just explain for us what the FDLE monitors requires under this protocol?

A. Yes. There is requirement that there be independent Florida Department of Law enforcement agency -- agents, two of them, to monitor the execution, one from inside the execution chamber and one with the team member who is actually performing the execution in a separate room where the drugs are administered. And those individuals are required to keep logs at two-minute intervals or no more than two-minute intervals detailing what they see throughout the execution.

Q. So that is something that is required by law, a record

that is required by law to be kept; is that correct?

MS. LOWE: Objection. It's required under the policy. There's been no testimony about the laws of Florida regarding executions.

THE COURT: Sustained.

BY MR. BOHNERT:

Q. Is this protocol, this execution protocol, considered any kind of law in Florida?

MS. LOWE: Objection.

BY MR. BOHNERT:

Q. To your knowledge?

MS. LOWE: Calls for a legal conclusion.

THE COURT: She's a lawyer. Overruled.

THE WITNESS: So the Florida statutes provide that the Department of Corrections is to establish procedures for implementing the execution. And so it is not technically -- procedures are not technically law; they are implemented pursuant to Florida statute.

BY MR. BOHNERT:

Q. Okay. So the contents of the protocol are implemented in accordance or pursuant to what Florida law actually requires. Is that an accurate --

A. That is correct.

Q. Now, if you could turn to page -- or to Index Tab 72, please, of the same binder.

A. Okay.

Q. It starts at page 784. The hearing exhibit's page 784 and continues on from there. If you could --

THE COURT: 783 is the beginning.

MR. BOHNERT: I am sorry. Your Honor, that's correct.

BY MR. BOHNERT:

Q. It starts at 783 and then continues on until hearing exhibit page 786.

A. Okay.

Q. Ms. Rudenstine, do you recognize this particular set of documents?

A. In a generic sense, I do. They are consistent with what I have seen to be logs taken by FCLE monitors --

MS. LOWE: Same objection.

THE WITNESS: -- during the course of executions. As to each specific document, I only have personal knowledge as to the ones regarding Paul Howell.

MS. LOWE: Your Honor, I have the same objection to these documents. She is not the witness who prepared these documents, and she's testified that she doesn't have knowledge as to any of them except she stated there is a subset of them she's seen before. But she didn't prepare any of these documents and isn't a records custodian for the Florida Department of Corrections.

THE COURT: The witness is only testifying that these are the usual forms, not for the content of the forms or the accuracy of the content of the forms, and so your objection is overruled.

MR. BOHNERT: Thank you, Your Honor.

BY MR. BOHNERT:

Q. If you would turn to page -- well, yeah, turn to page 799 if you would, please.

A. Okay.

Q. Do you recognize this particular document and also the document on page -- hearing exhibit page 800?

A. Yes. These are the logs that were presented to me as the -- as having been prepared by the FCLE monitoring in the course of Paul Howell's execution.

Q. Now, and we'll get back to the contents of that in a moment, but when you were at -- well, let me back up. When you witnessed the execution of Paul Howell, how close to the death chamber or -- how close to Mr. Howell himself would you say that you were?

A. I would say approximately 15 to 20 feet, although I am not great with distances so that's an approximation. But I was in the front row, and so there was nobody impeding my vision. So as close as one can be in the witness observation room.

Q. Okay. And if you could just kind of just very briefly

explain to us how the death chamber is set up as opposed to where the witness rooms are. You will paint the picture for the Judge as far as what the scene was where you were sitting.

A. The death chamber is a sort of rectangular room with a large window through which the witnesses can view the execution. There is a gurney in the middle with the end on which the condemned's feet -- condemned's feet face forward. And their head is in the back of the chamber from the witnesses' perspective. And there are a couple of other windows that are blacked out so it's impossible for me to know what they are. I would assume one of them's going into where the drugs are administered but I don't know.

There's a clock on the right-hand side wall from where the witnesses are observing that is visible through the window. And -- well, so I will leave it there. That's basically how the room is set up.

Q. Okay. And tell us what you saw during the course of the execution of Mr. Howell, please.

A. I'm assuming you want me to start from when the drugs were administered or not.

Q. From the point where Mr. Howell -- I don't know as far as when Mr. Howell was brought in. Explain to us, I guess, the scene of Mr. Howell on the gurney and go from there.

A. He was already -- had already been brought in when the

curtain was raised to the witness room, so he -- and he was at a slight angle so that his -- he wasn't directly perpendicular to us. He was slightly -- his head was slightly to the left, so I would call it a slightly diagonal view that we had. And he was able to raise his head and look around and see us. And he gave a statement. First, the warden called to make sure there were no stays of execution in place, and then Mr. Howell gave a brief statement, and he had already been strapped in. He had arm or wrist, I wouldn't call them shackles because they are leather, but he was bound at the wrists, and then his chest and stomach and legs were also bound with large straps across him.

And the lines were placed into his arm. And I -- he had his head slightly cocked to his right so that he could look at me as the execution went forward. And so I was able to see his face completely. I saw all of the rest of his body with the exception of a small part of his upper left side just because of the way that the gurney was set up.

And when it became clear to me that a drug was -- the midazolam was administered --

MS. LOWE: Objection.

THE COURT: Hold on a second, please.

MS. LOWE: Objection to her testifying as to when the drugs were administered. She doesn't have firsthand

knowledge or personal knowledge of that time.

THE COURT: Well, she may or may not.

How do you mark -- how do you come by your ability to testify as to when the drugs began to be administered?

THE WITNESS: Well, there was a signal from the team warden to begin first of all. But, secondly, because midazolam -- I knew midazolam to have a sedative effect, which, of course, was the purpose of it, I could see Mr. Howell's body change. And so I was just making the assumption that the first drug had begun to flow.

And his --

MS. LOWE: The same objection, Your Honor.

THE COURT: Hang on, Ms. Rudenstine.

Objection overruled. Inference not observation, but appropriate inference from the facts observed.

Go ahead, ma'am.

THE WITNESS: Thank you, Judge. As that happens, Mr. Howell gradually appeared to become sedated by closing his eyes, and his left arm and shoulder were visibly moving, twitching. I could see his arm slightly more than his shoulder, but you could tell that it was sort of going all the way up. And that continued for approximately 15 to 30 seconds. I couldn't tell exactly when the twitching stopped, but it was approximately that long.

And then at 6:23 p.m., he opened his eyes slightly,

both eyes, for a full minute, and then closed them.

At 6:26 p.m., I saw him open them again, and then they remained open until the end of the proceeding which was concluded when the doctor came out and declared Mr. Howell dead at 6:32 p.m.

BY MR. BOHNERT:

Q. And you just referenced some specific times there in your testimony. What is the basis for your testimony about those specific times? How do you know that those times are where you -- when you saw those particular movements?

A. I was looking at the clock on the wall, and I had my own watch but I primarily used the clock because it was rather big and obviously easier to look at that and Mr. Howell at the same time.

I then, afterwards -- I didn't have paper and pen with me in the room because it wasn't permitted, but after the execution, in my car, I jotted down the time so that I would remember them if I ever needed to.

And I previously made reference to these notes when I drew up my affidavit or my declaration in this case and refreshed my recollection.

Q. Okay. Now, if -- was there a -- any point where there was an assessment of some sort by anybody on the execution team of Mr. Howell after the first drugs -- you believe the first drugs were injected?

A. Yes. There is a consciousness check that's required, and it consisted in this case -- the protocol doesn't say specifically what's required, but I know from testimony in a lethal injection hearing that we had that --

MS. LOWE: Objection.

THE COURT: Hold on. Go ahead, Ms. Lowe.

MS. LOWE: She said she knows from testimony in the lethal injection hearing meaning that this is hearsay.

THE COURT: Sustained.

BY MR. BOHNERT:

Q. Did you see anybody from the team perform anything that you understood to be a, quote-unquote, consciousness check?

A. Yes. Well, the only thing I actually saw was that Mr. Howell's eyelids were pressed. I believe a pinch to the shoulder was also conducted, a trapezius squeeze, although I couldn't see it because of my angle, but it was clear that someone was doing something over that -- over Mr. Howell in that area.

Q. And the movements that you saw, the opening of the eyes at 6:23 and then the closing and then the opening of the eyes again at 6:26, did those occur before or after the, quote-unquote, consciousness check?

A. Those were after.

Q. If you could turn back to the execution logs, Hearing exhibits page 99, please.

A. Okay.

Q. If we look there at the entry about two-thirds of the way down the page.

MS. LOWE: Objection.

THE COURT: Grounds?

MS. LOWE: Your Honor, I believe earlier you stated that these are not being offered for their content. It appears that they are now being offered for their content.

THE COURT: Well, this one's a little different because she observed. But in addition, she identified this as a government record. So it's admissible under 803(e).

BY MR. BOHNERT:

Q. Thank you, Your Honor. Do you see the line where it says "Warden authorized. Execution phase one initiated"?

A. Yes, I do.

Q. And based on your understanding of the Florida protocol, what does that mean?

A. That the first drug will be administered.

Q. And then there is a time written directly to the left of that, and then another time directly below that. Do you see that?

A. I do.

Q. Okay. And then there is another time yet still under that, next to a box that says "execution phase one

complete." Do you see that?
A. I do.
Q. Can you tell us what your understanding of those time entries means?
A. Yes. The first entry would be the first syringe of midazolam at 6:18. The second one would be for the second syringe of midazolam, and then the "6:22, execution phase one complete" would be when all of the midazolam has been administered.
Q. Okay. And then there is another entry below that, it's also marked at 6:22. Do you see that?
A. I do.
Q. Actually there is two of them. What's the one there that is in bold? Do you see that?
A. My copy is unclear, but I think -- I think it's checked for a consciousness by warden. I am not sure, that looks bolded to me.
Q. Let me clarify, there are three entries that appear to be 6:22. Do you see that?
A. Yes.
Q. And you already talked about the first one, "execution stage complete," which is the end of the midazolam -- all the midazolam is on board there and that's the point at which -- and you have the second line there which is what?
A. A consciousness check.

Q. Okay. And then do you see the box below that?
A. Yes.
Q. And can you explain what that next box and the three times related to that box mean?
A. Yes. Then you would have the pancuronium bromide administered in phase two, and, again, there's going to be two syringes of that, so you have two different times for that, the 6:22 and the 6:24. And then when phase two is complete, you have 6:26.
Q. And below that, if you could continue with that and just explain what the following three lines' entries mean?
A. Yes. Execution -- execution phase three was the administration of the potassium chloride. Again, in two different syringes with two different times and then a time for a completion.
Q. So just to make sure, we are reiterating for the record, the first injection of midazolam is done at 6:18; is that correct?
A. That's correct.
Q. And then the second syringe of midazolam was pushed at 6:20?
A. Right.
Q. And so all of phase one is on board at 6:22; is that right?
A. That's correct.

Q. And then they do the consciousness check at 6:22 as well, right?
A. Correct.
Q. And then starting also at 6:22, so literally within the same minute that the midazolam has been finished being put on board, they start the injection of the paralytic; is that right?
A. That's right.
Q. And then at 6 -- two minutes later, at 6:24, is the second syringe of the paralytic; is that right?

MS. LOWE: Objection. Leading.

THE WITNESS: That's right.

THE COURT: Overruled.

BY MR. BOHNERT:
Q. And then we have got two further injections of potassium at 6:26 and 6:28; is that right?
A. That's correct.
Q. Do the times that are on this log here match up with the times that you recall -- well, let me ask you this: The time that you recalled seeing Mr. Howell's eyes open the first time, after the consciousness check, does that time coincide with any of the data here as far as when anything was injected?
A. Yes. It would have been while the paralytic was being injected. So at 6:23, shortly after the first syringe or in

the process of the first syringe being injected.

Q. The first syringe of the paralytic?

A. Correct.

Q. And what about for the second time that you recalled seeing Mr. Howell's eyes open at 6:26.

A. At 6:26, so looking at this, it would have been in the first minute of the administration of the potassium chloride. So at the same time or within the first minute of that administration.

Q. Okay.

MR. BOHNERT: Give me one moment, Your Honor.

THE COURT: Of course, sir.

BY MR. BOHNERT:

Q. Ms. Rudenstine, are you aware of whether Florida has changed its execution protocol?

MS. LOWE: Objection. Relevance.

THE COURT: Grounds?

MS. LOWE: Relevance, Your Honor. I don't see how any changes to Florida's protocol are relevant to Ms. Rudenstine's testimony about witnessing the execution of Mr. Howell.

THE COURT: Overruled.

THE WITNESS: Yes, I am.

BY MR. BOHNERT:

Q. Let me finish the question just for the record. Do you

know whether Florida's execution protocol has changed from the one that was used to execute Mr. Howell using a three-drug method with midazolam as the first of the three drugs?

A. Yes, I am aware that a new protocol was issued just today.

Q. Okay.

THE COURT: Today or yesterday?

THE WITNESS: Maybe it was yesterday. I received it today. Let me check the date, Your Honor.

Yes, it's yesterday, the 4th of January.

BY MR. BOHNERT:

Q. And do you have in front of you a document, a letter and other document -- well, the front page is a letter dated January 4th, 2017, to the Honorable Rick Scott from a Julie L. Jones, secretary?

A. Yes, I do.

Q. And do you recognize that particular document?

A. I do only as having obtained it from the Department of Corrections' website as the new -- a letter indicating the new lethal injection procedures released by the department.

THE COURT: Hang on just a second, ma'am.

Ms. Lowe, an objection?

MS. LOWE: Yes. The same objection, Your Honor.

THE COURT: All right. Mr. Bohnert, what have we

labeled this in terms of number?

MR. BOHNERT: I don't know that we have. Now I will say that to try to address their, the State's objections, we are in the process of trying to get a copy of this with the URL attached to it that has the website for the Department of Corrections if Your Honor thinks it's necessary to show that this is a government document.

THE COURT: Sorry, ma'am.

MS. LOWE: I am sorry. I didn't want to interrupt Mr. Bohnert if he was still speaking. My objection was to the relevance of any changes to Florida's protocol to this current litigation.

THE COURT: Thank you. The relevance objection will be taken under advisement.

MS. LOWE: Thank you.

THE COURT: And I am going to ask, ma'am, whether you have any objection to the authenticity of this document?

MS. LOWE: I do, Your Honor, because it's not -- I don't believe it is qualified under the exception for public records. I don't think it bears a seal and signature, at least not the copy that I have seen. It has a signature, but it doesn't appear to contain a seal from the Florida Department of Corrections making it fall into the business records exception. And it doesn't -- I don't see that it's been provided.

MR. BOHNERT: It's the same basis under Rule 803(8), Your Honor, as we have done with the others.

MR. SWEENEY: Your Honor, if I may, please? Can I address this briefly just to explain?

THE COURT: If I need it.

MR. SWEENEY: I wasn't going to address the legal issue but was just going to direct you to the website where you can actually pull it up and look at it.

THE COURT: Read that out, would you, please? Someone who's got their computer set to the Internet will get that for me.

MR. BOHNERT: Okay. Thank you, Your Honor.

www.dc.state.fl.us\oth\deathrow\electrocution-procedures-as-of_01-04-17.pdf.

MS. LOWE: Could you repeat the -- I am sorry -- the last part of that beginning with "01"?

MR. BOHNERT: 01-04-17.pdf.

MS. LOWE: Thank you.

THE COURT: I don't see anything in 803(8) that requires a seal.

MR. SWEENEY: Your Honor, just for the record, earlier this afternoon, at 3 o'clock, we emailed this information to Tom and Joslyn. I just don't think they have seen the emails yet, but the emails do link directly to these DRC or Florida DC websites.

MS. LOWE: We'll withdraw our authenticity objection, but we would like to preserve the objection to relevance at this time.

THE COURT: Of course.

MS. LOWE: Thank you, Your Honor.

MR. BOHNERT: What's the problem, Kelly?

THE COURTROOM DEPUTY: The document's last page is 14 and not 13.

THE WITNESS: I am sorry, Judge, was there a question on the table? I am having trouble hearing.

THE COURT: No, ma'am, there is no question on the table. We are just talking about the document that we've been talking about. As my courtroom deputy has pulled it up on the web, it has a total of 15 pages, with Ms. Jones' signatures being on pages 1 and 14, 1 on the letter, 14 on the protocol. Whereas the document that was presented here in court has a total of 14 pages, with her signatures on page 1 and page 13. So we don't know --

THE WITNESS: Yes, Your Honor.

THE COURT: -- for sure what we've got.

THE WITNESS: I have an alternative web location for what I believe was presented, that 14-page document, if you would like that.

THE COURT: Thank you.

THE WITNESS: Okay. It's www.dc.state.fl.us/oth/

deathrow/lethal-injection-procedures-as-of_01-04-17.pdf.

THE COURT: So my law clerk suggests that what's been omitted from the longer document in the shorter document is "Procedures For Electrocution."

THE WITNESS: Well, let me see what I have here. I have -- let's see. On page 9 I have "Administration of Execution." Because I don't have the longer document in front of me, I don't know what would be missing.

THE COURT: Understood. So we are able to find the longer document, right?

MR. BOHNERT: It looks like the longer one is just electrocution. It has to be that there is another one for lethal injection. I am sorry. We will find that.

THE COURT: So, Ms. Lowe, you will be permitted to reinstate your objection.

MS. LOWE: Thank you, Your Honor.

THE COURT: It was electrocution that you read out, Mr. Bohnert.

MS. LOWE: It seems to point to the problem with not having someone from the Florida Department of Corrections to testify.

MR. BOHNERT: We e-mailed them the correct one.

MR. MADDEN: I'll email it back.

MR. SWEENEY: Why don't we email it to Judge Merz. Why don't we do that.

THE COURT: Kelly can print it. She will do that right now. Four copies.

MR. SWEENEY: The email link is -- we are going to email it to you, Your Honor.

THE COURTROOM DEPUTY: I am printing it.

MR. SWEENEY: The link had been e-mailed to the defendants. It was the correct link and there were two different links that you had to click on, one for electrocution, the other for lethal injection, and I think what we did, we read you the wrong link.

MR. MADDEN: I am turning my phone back on to check my emails.

MR. SWEENEY: The printed copy that we gave them, though, is the correct copy.

THE COURT: We need to confirm that.

MR. SWEENEY: And we will, of course.

THE COURT: While we are waiting, I will share some of my email. The President of the United States has published an article in the *Harvard Law Review*, which is a presidential first.

MS. LOWE: I assume you mean the current president, Your Honor?

THE COURT: The current. There are only two presidents of the United States who have attended the Harvard Law School. Who's the other one?

MR. BOHNERT: Was Kennedy?

MR. MADDEN: Adams, the younger Adams?

THE COURT: No.

MS. LOWE: Kennedy went to UVA.

MR. SWEENEY: Kennedy is not a lawyer.

THE COURT: One of those real greats. Aside from James Buchanan, Rutherford B. Hayes. His portrait is not in a very prominent place of display.

MR. MADDEN: The director has a bit of information about President Hayes.

MR. MOHR: Your Honor, Rutherford B. Hayes was the first President of the American Correctional Association founded in 1870 in Cincinnati, and I have the great honor of being president elect of that.

THE COURT: Good. Off the record.

(Discussion of the record.)

MR. BOHNERT: Your Honor, this is the -- I have just been handed the policy for electrocution. What we are talking about is the policy for lethal injection. I read you the address for the electrocution policy. If you go to the --

THE COURTROOM DEPUTY: I printed out the one of -- what you gave me.

MR. BOHNERT: That's what I am saying. I misspoke. The information I was given leads you directly to

the electrocution policy.

If you can go to the --

MR. SWEENEY: www.dc.

THE COURT: So we can now confirm, and the Court's prepared to take judicial notice of the fact, that two different execution policies were adopted by the State of Florida yesterday. One of them relates to electrocution, and Ms. Lowe's implicit relevance objection to that is sustained. The other one, which has only a total of 14 pages, with Ms. Jones' signature on page 1 and page 13.

Ms. Rudenstine, I think that's the document you are referring to. Is that right?

THE WITNESS: Yes, Your Honor.

THE COURT: All right. Back to you, Mr. Bohnert.

MR. BOHNERT: Thank you, Your Honor.

BY MR. BOHNERT:

Q. Now, Ms. Rudenstine, do you know, have you had a chance to review this new lethal injection protocol for Florida?

A. I have reviewed parts of it.

Q. Okay. And do you know whether it makes any changes -- well, let me ask you this way. Does it continue to use a three-drug protocol with a paralytic and potassium as the second and third drugs?

A. Yes. Slightly different third drug, potassium acetate, but, yes, the same three-drug protocol, at least in form if

not in exact type.
Q. And does this protocol remove -- well, let me ask you this: What change -- does midazolam continue to appear in this particular new Florida execution protocol?
A. No, midazolam appears to have been taken out and replaced with a drug called etomidate.
Q. I just need to have her identify also -- have her identify page 800 of the exhibits --
MR. BOHNERT: Your Honor, is this protocol -- I don't know that we have marked it, the new protocol. Can we mark it 81, please. And I assume we are not going to mark as an exhibit the electrocution protocol.
THE COURT: No. I declared that to be irrelevant.
BY MR. BOHNERT:
Q. Now, just very quickly to make sure that we have covered with page 800 of the exhibits binder, Ms. Rudenstine.
A. Yes.
Q. Is that -- what is that document that is distinguished from the earlier document at page 799?
A. That appears to be the log of the second FDLE monitor for Mr. Howell's execution.
Q. And are the times that are listed there for the different activities that we saw from the first person's log in Mr. Howell's execution consistent?

A. They are with one exception. At 6:21 it looks like the second monitor declared execution phase one complete, whereas it was 6:22 in the first log. And then the flat line at the end is off by a minute, 6:30 in the second log and 6:31 in the first.

But as to the time that I indicated Mr. Howell opened his eyes, they would have been consistent, the first time being during the beginning of the initiation of execution phase two and the second time being during the administration of the third drug.

Q. Okay. And those are also consistent with the start of the injection of the first drug, the midazolam, under phase one; is that correct?

A. That's correct.

MR. BOHNERT: No further questions, Your Honor.

THE COURT: Cross.

MS. LOWE: Thank you, Your Honor.

THE COURT: The cross-examination, Ms. Rudenstine, is being conducted by Ms. Joslyn Lowe who is an Assistant Attorney General of the -- Associate Attorney General of the State of Ohio.

THE WITNESS: Thank you, Your Honor.

CROSS-EXAMINATION

BY MS. LOWE:

Q. Good evening, Ms. Rudenstine.

A. Good evening.
Q. Thank you for the time to appear at least by telephone with us today.
A. No problem at all.
Q. You stated earlier that you were basing your conclusions about when the first drug was administered on your observations. You didn't personally witness that drug being administered, correct?
A. Correct.
Q. And your view of what you believe was the second part of the consciousness check was obstructed, correct?
A. That's right.
Q. So you didn't witness what consciousness check was actually performed, correct?
A. That's right.
Q. Or what the results of that consciousness check were, correct?
A. Well, I don't know -- I didn't see Mr. Howell move if that's what you are asking, but, no, I guess I wouldn't know exactly whether that was a result of the consciousness check.
Q. But you didn't see movement after what you believe was the second consciousness check, correct?
A. Not until Mr. Howell opened his eyes, no.
Q. And you were an attorney on a suit challenging

Florida's use of midazolam in a three-drug protocol, correct?

A. I was at the time, until we lost that suit. So I was observing so that I could intervene if necessary. But the lawsuits had already been lost at that point.

Q. You were representing Mr. Howell in that suit, correct?

A. Correct.

Q. Had you met with Mr. Howell pursuant to your representation of him in that suit?

A. Yes.

Q. You met with him -- did you meet with him multiple times?

A. Yes.

Q. Have you witnessed any other executions in Florida?

A. No, I have not.

MS. LOWE: Can I have one moment, Your Honor?

THE COURT: Of course.

MS. LOWE: Thank you, sir.

THE COURT: While Ms. Lowe is checking, let me ask you, Ms. Rudenstine -- is it Rudensteen or Rudenstine? I don't want to mispronounce your name.

THE WITNESS: It's Rudenstine, Your Honor.

THE COURT: Thank you. People all call me Mert.

Do you know if there are -- you mentioned having lost the suit. Are there any reported opinions?

THE WITNESS: Yes, Your Honor, there are. This is a 1983 lawsuit, as well as eight lawsuits, both of which went up to the appellate courts. And I don't have those citations --

THE COURT: Citations I don't need. If you can give me names, we will be able to find them.

THE WITNESS: Well, it would be *Howell versus Secretary of Department of Corrections*, and then *Howell versus State*. And you will find a lot of cases that come up for that because there were several different cases about litigation, but there is -- one of those cases is a lethal injection challenge. I'd be more than happy to forward the citations to Mr. Bohnert when I have a moment later tonight.

THE COURT: If you have got those citations and you could forward them to Mr. Bohnert, Mr. Madden, and the Court, we'd be appreciative.

She may not have your email address, Tom.

MR. MADDEN: Yes. I will give it to her.

THE WITNESS: Yes, Your Honor.

MR. BOHNERT: Allen's got it.

THE COURT: Just send it to Mr. Bohnert, and he will send it to me and Madden.

THE WITNESS: Okay. Sure.

THE COURT: That's good. Just as a matter of curiosity, does the State of Florida -- the state courts of

Florida entertain 1983 actions, or do they maintain the fiction that they don't have jurisdiction?

THE WITNESS: They do entertain them, but our 1983 action was brought in the district court, federal district court.

THE COURT: Good. Okay.

Ms. Lowe, go ahead.

MS. LOWE: Thank you, Your Honor.

BY MS. LOWE:

Q. Ms. Rudenstine, I have one question for you. Do you know if the Florida Department of Corrections has midazolam in their possession at this time?

A. I do not know.

MS. LOWE: Nothing further. Thank you, Your Honor.

THE COURT: Any redirect, Mr. Bohnert?

MR. BOHNERT: No, Your Honor.

THE COURT: Ms. Rudenstine, we hope that you are having more pleasant weather where you are than we are here with snowfall, and we thank you for your appearance, and you are excused.

THE WITNESS: Thank you, Your Honor.

THE COURT: Back to you again, Mr. Bohnert, Mr. Sweeney.

MR. SWEENEY: Your Honor, given the lateness of

the day, how long were you planning to go today?

THE COURT: 5 o'clock.

MR. SWEENEY: Till 5 o'clock. There is really no witness to call at this point.

THE COURT: All right.

MR. SWEENEY: And it may be the case that we will be done subject to the witnesses that we have on Monday.

THE COURT: Right.

MR. SWEENEY: That we have already spoken about. And there is one issue we wanted to raise. We think -- maybe I will just do if now if you don't mind.

THE COURT: Sure.

MR. SWEENEY: Since we have the time. We understand, Your Honor, respectfully, the decision you made with respect to the issue of whether we could call the reporter concerning the Lockett execution. That's the reporter from Oklahoma.

MR. BOHNERT: He addressed the guy from Alabama. We haven't raised the one in Oklahoma.

MR. SWEENEY: I'm screwing this up, Your Honor. There are two additional witnesses we would like to call. Now, I think you have said with respect to rebuttal you don't believe we should be permitted to call them as rebuttal witnesses, and I don't anticipate Your Honor is in a position to want to reconsider that decision.

With respect to these two witnesses, though -- and one of them is a reporter who witnessed the Lockett execution and the other is a reporter who witnessed an execution in Alabama -- we think they are important witnesses that this Court should hear. Now, whether they are rebuttal or whether they are in our case in chief really doesn't matter too much from our perspective. We would like you to hear them, though.

And here is our proposal, that you permit us to call them in our case in chief. We have plenty of time left in our case in chief based on our calculation of time. We would do it this week by phone. It would give Tom and his team plenty of time to know that it's coming. It's really not that difficult testimony to get ready for. It's going to be nothing more than: I saw this. Here's what I saw. And so that was -- that's our request, that we be permitted to call those two witnesses in our case in chief and/or in rebuttal if Your Honor is willing to reconsider his previous ruling this afternoon on the rebuttal issue.

THE COURT: Mr. Madden?

MR. MADDEN: Your Honor, we had a witness list. We saw the witness list. We saw -- these are all obviously biased individuals. And so we made the decision strategic to what we received that, you know, it's -- you know, we could ask for a continuance of the hearing and try to find

folks in Alabama and across the country in reaction to this, and that would have been extremely difficult. And, you know, they knew that they were going to call eyewitnesses to these executions long before I knew that they were going to. And, you know, especially the execution in Alabama, you know. We made the decision because we looked at that list and saw that all the witnesses were obviously biased that we were not going to try to contact witnesses in Alabama that may or may not be able -- we may or may not be able to obtain.

And at this late in the day, it really puts us in a bind. And we wouldn't be able to try to track down witnesses to respond to their allegations. That is really unfair.

THE COURT: Mr. Sweeney, do you need time to consult? I don't want to rush you.

MR. SWEENEY: No, I don't think so, Your Honor. I think with respect to the issue of fairness, that argument might hold some water if we were calling somebody about an execution that they hadn't anticipated we would be calling a witness about. But these are executions they knew we would be calling people to testify about. For example, Mr. Baich is going to be testifying about the Lockett execution as well -- or which one is he? Mr. Sanderford is going to be testifying about the Lockett execution as well. So they

know that there is going to be testimony about those executions, so there is no real surprise whatsoever here.

This is really -- this is an important hearing. This really isn't a significant, prejudicial to them, and we can call them, Your Honor. We can do it on Monday if necessary. We will have plenty of time on Monday to do this if need be. We have time left on our bank in terms of the time for our hearing, our side of the hearing. These witnesses will not take a lot of time. They're important. These are important issues in terms of our theory of the case. We would like you to hear from them. We think in the interest of justice our clients ought to be given the opportunity to call these two additional witnesses.

And just so the record's clear, it's these two reporters plus we have these two other, and I guess there is three other people that are on our witness list that still need to be called: Dale Baich, Mr. Sanderford, and then a Terri Deep -- what's her last name? Alang.

THE COURT: Formerly known as Deep, I guess.

MR. SWEENEY: Correct, formerly known as Deep.

MR. MADDEN: Your Honor, this is two additional witnesses already on top, moving this hearing into Monday. We don't have time to get rebuttal witnesses because, you know, they knew or should have known that if they were going to call the attorneys to these executions, that they might

want to get what might be reasonably -- be a reasonable observer. They did not do that. We cannot get witnesses at this short notice, and, you know, they've already gotten all of these depositions' testimony that I didn't anticipate to be put into this. They have already gotten an advantage on how much time they got. They got more time than we do in presenting their case in chief and now they want to add more. And I strenuously object to this.

THE COURT: I am going to allow either Ms. Barnhart or Ms. Lowe to be heard independently of Mr. Madden and Mr. Sweeney.

MR. SWEENEY: That is the best idea I've heard today.

THE COURT: Ms. Barnhart, do you have anything to add?

MS. BARNHART: I have two points to add, Your Honor. As you know, this litigation has taken place on an expedited schedule. To deal with getting journalists requires a lot of procedural hoops, dealing with objections from their employer, dealing with subpoenas, and that type of things.

I can't speak for everyone. I don't consider the witnesses that we have been calling to be biased. I believe the things that they are testifying about are observable, not really in dispute. If we want to talk about the McGuire

execution, the defendants' own witnesses we've called about things that happened there and that confirms things that our witnesses to the McGuire execution have said concerning the Joseph Wood execution. I'm not sure how the defendants could dispute that it took over two hours. There is a court hearing, a telephonic emergency hearing that took place during the execution that confirms this information.

Speaking for myself, I was surprised at the allegations of bias at this hearing, at the extent of them. Personally, as an officer of the court, as an attorney, I think all of us feel that we would not -- just would not manipulate or create facts that are not true in speaking to the Court.

Because the defendants have pressed this point so strongly, because Your Honor also raised it with our witness, it was my idea to say in rebuttal let's show that these accounts are consistent; the accounts of the witnesses that we have offered are consistent with other objective witnesses that have been reported in the newspapers. I mean, everyone we are calling, journalists, have published articles about what they saw. This is in the public record. The defendants are well aware of that information.

So, you know, I believe the defendants raised these allegations of bias in their findings of fact which were filed, I can't even remember when, but less than a week ago, I think.

THE COURT: Right. December the 31st at noon was the deadline.

MS. BARNHART: Thank you. Which was pushed back many times I know. So, right, on New Year's Eve. We are on January 5th right now. And we had designated our expert -- or we had designated our witnesses well before that. And so I don't believe that there is any surprise or unfairness or prejudice to the defendants. And if there is, the Court can accommodate that in other ways. As we mentioned, we could wait until Monday if they wanted to have a chance over the weekend to investigate these witnesses or if they want to find their own witnesses. We can reconvene telephonically to continue the hearing just if they want to present a witness or two in a week or something like that.

But as Mr. Sweeney articulated, because this issue seems to be of paramount importance in their theory of the case and to the Court, we don't want to risk having the valid observations that we presented to this Court and upon which our expert, Dr. Bergese, relied being undermined by something that I think is fixable and workable without prejudice to the parties.

THE COURT: Thank you.

Ms. Lowe.

MS. LOWE: Thank you, Your Honor. First of all, I note that the witness lists in this case were filed, I

believe, three weeks ago. They did include witnesses from their side who are, as we noted in opening statement and have elicited during examination, are attorneys for these individuals. So it's certainly not or shouldn't be surprising that we would note that inherent bias in cross-examining them.

And they could have called for additional witnesses. As she said, they have published reports that they were witnesses to this execution. It is not surprising that they are out there, but that means that it is not surprising to them that there may have been additional people who could have been put on their witness list to testify about these executions.

At this late point in the game, it would be unfair to add additional days, particularly to call witnesses on Monday after the defendants have completed their case in chief, when -- to continue their case in chief after we have completed our case in chief is certainly an unusual procedure. You know, we have noted it for the two witnesses who they were unable to gain -- unable to appear by telephone during this procedure, but to add additional witnesses after the defendants have closed their case would be prejudicial.

And I'd also note as to calling them in rebuttal, the defendants haven't called any lay witnesses, although we

have not yet put on our case, and there is no lay witnesses disclosed on our witness list. We have called Dr. Antognini. Obviously we anticipate calling Dr. Buffington tomorrow. The rest of our witnesses are DRC witness, so there is no allegations to rebut.

The fact that we cross-examined their witnesses to elicit inherit bias in their testimony does not mean that you then need to put on more and more people who have their own inherent bias to try and rebut those allegations, although reporters may be perhaps less biased than attorneys, or more biased for attorneys. I think that's a debate for maybe someone else to have. Journalists also have an inherent bias and perhaps additional motivation in how they spin their story, and so we object to adding any more witnesses either in the case in chief or rebuttal.

THE COURT: First of all, the proposed additional witnesses by the plaintiffs are not properly rebuttal witnesses. If the plaintiffs had witnesses who were prepared to say, well, no, the cross-examination, whatever bias was revealed on cross-examination isn't true because -- because this witness, who was cross-examined about that bias, has always been -- you know, has a reputation for truthfulness. I don't know. Something like that. That would be true rebuttal on the points of the witnesses' examination about -- cross-examination about bias.

Secondly, Ms. Barnhart, I believe there is case law -- I can't cite it off the top of my head -- to the effect that bias or examination for bias is expectable with respect to any witness. It's not somehow -- it shouldn't be surprising that the defendants would have questions on -- what the weight of the answers is, is another question. But it shouldn't be surprising to plaintiffs that in a trial the other side is going to look for bias. I mean, I am reminded of Ms. Wood's examination of Dr. Antognini, about whether he is ethical or not. That's the kind of thing that's good cross. It's to be expected.

So these are not true rebuttal witnesses. There is nothing inappropriate in examining any witness for possible bias. What we're talking about here is adding new witnesses on the plaintiffs' side to corroborate either persons who have already testified about their observations of particular executions or to offer new corroborative testimony -- or not -- I don't want to call it corroborative. I don't want to call it cumulative -- but new testimony, lay eyewitness testimony about other executions. And I'm not exactly certain which category these two proposed witnesses fall into, but it doesn't matter.

These are people who, per Ms. Barnhart's representation, have published accounts. Their names have

been known for some time by the general public. They are not disclosed in the witness disclosure list. The purpose of having folks file witness disclosure lists is so that the Court and the other side will know who it is that is intended to be called.

Now, when I go down the list -- this is ECF number 822 -- of the folks who were listed as witnesses, at a time when the time allocation was based upon our dealing with both the sealed claims that have now been dismissed and the claims on which I heard testimony -- there are 29 names listed. Of those 29 people, Director Mohr has not been called, Mr. Gray has not been called, Mr. Voorhies was called, Mr. Erdos has not been called, Warden Morgan hasn't been called, Mr. Theodore hasn't been called, Ms. Jenkins hasn't been called. The records custodian from ODRC has not been called. Of the five execution team members listed, only -- only two have been called. Mr. Hahn has been called. Ms. Rudenstine has been called. Mr. Johnson has been called. We have yet scheduled Mr. Baich and Mr. Sanderford. But the other eyewitness -- and Ms. Deep. But the other eyewitnesses to the McGuire execution have not been called.

So the purpose, at least in this court as I have learned it from the district judges for whom I work, the purpose of witness disclosure is to disclose, not to hide

the ball. The names of these witnesses were available to the plaintiffs well before the -- well before the witness list was required to be filed, and I find that it would be unfair to the defendants to now add these folks, who they have not had notice of and who are not surprises to the plaintiffs, to add them to the witness list. Therefore, the motion to add those two folks to the witness list is denied.

And it's 5 o'clock, and we are in recess.

MS. BARNHART: Your Honor.

THE COURT: Oh, I am sorry, Kelly. I shouldn't have done that.

Ms. Barnhart first.

MS. BARNHART: Your Honor, just to clarify the record, in regards to listing those witnesses you said who haven't been called, we are intending to submit under your ruling under Rule 32 the designations of their depositions.

THE COURT: Ah. And Ms. Wood?

MS. WOOD: I had two questions regarding the exhibits that I used for the slides. My question one is I used one slide from -- regarding BIS monitoring. The manual is 132 pages long. Would you like the full thing or just --

THE COURT: No. Just the pages that you used. And if there is -- if there is a scope note at the beginning that says, you know, this manual should never be used in court or things like that.

MS. WOOD: I will check.

THE COURT: I want to see the scope note. Anything else?

MS. WOOD: Do you want the whole thing merged as one document?

THE COURT: No, no, no. I want them separately, separately.

MS. WOOD: The slides as well?

THE COURT: Say again?

MS. WOOD: The slides as well?

THE COURT: Just print the slides out, yes.

We are in recess.

MR. SWEENEY: Your Honor, we had two more things. If you don't mind. I know the hour is late.

THE COURT: We needed the same cup of coffee.

MR. SWEENEY: With respect to the addition of the depositions, we are going to do that. We will have those. I would just like to get a sense of how you would like that to be handled. Here is what we were going to do. We intend to get the depositions we intend to introduce under Rule 32, which will include Director Mohr, Mr. Theodore, Mr. Gray, Mr. Voorhies, Mr. Morgan, Team Member 17, and Mr. Erdos, and we will have those highlighted. We will do that electronically.

THE COURT: How do you mean, highlighted?

MR. SWEENEY: Highlighted in yellow, the designations.

THE COURT: The designations, very well.

MR. SWEENEY: Highlighted. We will have those electronically. We can email those to you and provide those tomorrow to the other parties, or we can provide it in hard copy, or both. And we wanted to make sure we did it the way you would find it most useful to you.

THE COURT: Highlighted electronic on a flash drive so we can mark the flash drive as a cumulative exhibit. It seems that would be the easiest, most compact way to deal with it.

And I can see, Ms. Lowe, that you are not ready to give up for the day either. Go ahead.

MS. LOWE: Well, actually two things. One, we would like to move under Rule 32, subsection 6, to admit the entirety of those depositions rather than parts. I think it states that if any party only -- I am sorry. Will it be the entirety of the deposition? Oh, I am sorry, it sounded like it was just going to be portions.

MR. SWEENEY: What we were going to do is highlight the parts we wanted to be designated, but it would be the entire deposition.

MR. MADDEN: You want highlights from just the other side and not --

THE COURT: No, I didn't say that. So if you want to counter-designate, you are entitled to do that, and the best way to do that -- any of you ever practice before Herman Weber? Judge Weber had a rule about like four different colors that you were supposed to use. So give us -- give us the flash drive as you are giving it to Mr. Madden or Ms. Lowe. They will make the counter-designations on the same --

MS. LOWE: We didn't file --

THE COURT: I understand.

MS. LOWE: That's fine. I will work it out with Lisa.

THE COURT: Right.

MS. LOWE: And we will make sure someone --

THE COURT: One flash drive. I think that will be most convenient for the Court and ultimately for the law clerks in the Court of Appeals.

MS. LOWE: Can we get a time allocation?

THE COURT: Yes, a time allocation for today is plaintiffs used 189 minutes and the defendants used 146.

And now we are in recess.

THE COURTROOM DEPUTY: All rise. This court stands in recess.

(Proceedings concluded at 5:02 p.m.)

CERTIFICATE OF REPORTER

I, Mary A. Schweinhagen, Federal Official Realtime Court Reporter, in and for the United States District Court for the Southern District of Ohio, do hereby certify that pursuant to Section 753, Title 28, United States Code that the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

s/Mary A. Schweinhagen

_____ January 12, 2017

MARY A. SCHWEINHAGEN, RDR, CRR
FEDERAL OFFICIAL COURT REPORTER

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Article
Deborah W. **Denno** [a1]

LETHALINJECTIONCHAOSPOST-BAZE

In 2008, with Baze v. Rees*, the Supreme Court broke decades of silence regarding state execution methods to declare Kentucky's* ***lethalinjection*** *protocol constitutional, yet the opinion itself did not offer much guidance. In the six years after* Baze*, legal challenges to* ***lethalinjection*** *soared as states scrambled to quell litigation by modifying their* ***lethalinjection*** *protocols. My unprecedented study of over 300 cases citing* Baze *reveals that such modifications have occurred with alarming frequency. Moreover, even as states purportedly rely on the* Baze *opinion, they have changed their* ***lethalinjection*** *protocols in inconsistent ways that bear little resemblance to the original protocol evaluated in* Baze *and even differ from one execution to the next within the same state. States' continuous tinkering often affects already-troubled aspects of their* ***lethalinjection*** *procedures. The compendium of these deficiencies has led to some of the most glaring failures in* ***lethalinjection*** *history.*

An even more disturbing revelation relates to the ***lethalinjection*** *drugs used in these rapidly changing protocols. Recent drug shortages threaten many states' abilities to carry out executions, and this Article presents evidence of the unfettered substitutions states have made in their desperate attempts to adhere to their execution schedules. These attempts include frequent drug switches that take place quickly, without oversight, and based purely on convenience and* ***1332** *availability. The resulting unreliability and randomness heighten the risk that the execution process will violate the Eighth Amendment's Cruel and Unusual Punishment Clause. As that risk increases, so does the tendency for states to retreat into secrecy regarding their* ***lethalinjection*** *protocols.*

For a growing number of states, alternative protocols also incorporate the use of compounding pharmacies to produce ***lethalinjection*** *drugs. Traditionally, compounding pharmacies are non-FDA regulated, small-scale pharmacies that make customized drugs on an as-needed basis in response to individualized prescriptions. This trend toward using compounding pharmacies is highly problematic. For example, state regulations are paltry. They also tend to differ from one state to the next, making it difficult to ensure that compounded drugs are held to consistently high standards of quality, safety, and effectiveness. Evidence shows, however, that proposed and newly adopted federal legislation regulating these pharmacies may create major obstacles for the use of compounded drugs in executions, leaving states without even this risky recourse.*

Death-penalty opponents and medical professionals have long objected to ***lethalinjection*** *on the basis that the use of drugs to carry out executions links death to the practice of medicine. Ironically, that reliance on drugs may end up accomplishing what countless legal challenges could not: drug shortages have devastated this country's execution process to an unparalleled degree. Rather than masking the "machinery of death," the mimicry of medicine may end up dismantling it.*

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***1333 INTRODUCTION**

Lethalinjection has been a controversial method of execution since its inception in 1977, with many critics focusing on problems with the three-drug protocol traditionally used by most death-penalty states. [1] By 2007, the growing number of legal challenges and the variance among state responses resulted in a sufficient number of circuit splits for the Supreme Court to grant certiorari to review the issue. [2] The Court chose *Baze v. Rees*, a Kentucky case, to determine the future direction of **lethalinjection**. [3] In *Baze*, a 7-2 decision with a plurality opinion, [4] the Court upheld the constitutionality of Kentucky's **lethalinjection** protocol under the Eighth Amendment's Cruel and Unusual Punishment Clause. [5] The Court found that the defendants had failed to show that Kentucky's three-drug combination posed a "substantial" or "objectively intolerable" risk of "serious harm" [6] compared to "known and available alternatives." [7] The typical formula, which Kentucky was then using, consists of a serial sequence of three drugs: sodium thiopental, a barbiturate anesthetic that brings about deep unconsciousness; pancuronium bromide, a total muscle relaxant that paralyzes all voluntary muscles and causes suffocation; and potassium chloride, a toxin ***1334** that induces irreversible cardiac arrest. [8]

A primary concern in *Baze*, and **lethalinjection** challenges generally, rested with the second drug, pancuronium bromide. Without adequate anesthesia, pancuronium can cause an inmate excruciating pain and suffering because the inmate slowly suffocates from the drug's effects while paralyzed and unable to cry out. The inmate's agony increases dramatically when executioners **inject** the third drug, potassium chloride, which creates an intense and unbearable burning. [9] The *Baze* Court agreed that if the sodium thiopental is ineffective, it would be reprehensible to **inject** the second and third drugs into a conscious person. [10] A key issue in litigation was whether prison officials and executioners can determine if an inmate is aware and in torment because pancuronium is such a powerful mask of emotions. [11] Starting in 2006, this litigation so successfully prompted death-penalty moratoria and execution stalemates across the country that a Supreme Court case like *Baze* appeared inevitable. [12]

Yet in many ways, *Baze* was a puzzling choice. Kentucky had conducted only one execution by **lethalinjection** and thus offered an extremely limited record on which to base a **lethalinjection** challenge. Other states had far better evidentiary and execution data. [13] Moreover, the suit that petitioners brought had not been scrutinized by the federal hearings being carried out in similar kinds of cases. Rather, Kentucky's hearings took place only in state court and concerned only Kentucky's procedures and short execution history. [14] Some death-penalty opponents came to believe that the Justices who voted to hear *Baze* did so only because they "regarded the challenge as insubstantial and wanted to dispose of it before many more state and federal courts could be tied up with similar cases." [15]

However, the *Baze* opinion had quite the opposite effect. Limits to the *Baze* Court's analysis suggest that the decision is by no means a definitive response to the issue of **lethalinjection's** constitutionality. [16] In fact, *Baze* was so splintered that

none of its seven opinions garnered more than three votes,[17] and the ***1335** Justices offered a wide range of explanations and qualifications in their reasoning.[18] In addition, the decision was confined to Kentucky and its particular protocol. Voices on both sides of the death-penalty debate have emphasized that *Baze* left doors open for future **lethalinjection** challenges.[19] Even members of the *Baze* Court itself anticipated the repercussions of the opinion's shortcomings: in separate concurrences, Justices Stevens,[20] Thomas,[21] and Alito[22] expressed concern that the *Baze* decision would only lead to additional debate and litigation. Until now, however, criticisms and concerns regarding developments in **lethalinjection** protocols after *Baze* have been largely predictive.

This Article provides facts where there has been only foresight. I present the results of a unique empirical study in which I collected and analyzed over 300 cases citing *Baze* in the first five years since the decision (2008-2013). My analysis of these cases indicates that states can--and do--modify virtually any aspect of their **lethalinjection** procedures with a frequency that is unprecedented among execution methods in this country's history. There have been more changes in **lethalinjection** protocols during the past five years than there have been in the last three decades. The resulting protocols differ from state to state and even from one execution to the next within the same state. As a result, many states' **lethalinjection** issues and procedures scarcely resemble those evaluated by the *Baze* Court. Furthermore, this continuous tinkering often affects already-troubled aspects of states' **lethalinjection** procedures, such as the paltry qualifications of executioners, the absence of medical experts, and the failure to account for the difficulties with **injecting** inmates whose drug-use histories diminish the availability of usable veins.[23] Despite states' efforts to improve their procedures, such deficiencies have led to some of the most glaring and gruesome failures ever documented in the history of **lethalinjection**.[24]

Baze ushered in a perfect storm for litigation. Although the Supreme Court's grant of certiorari in *Baze* was remarkable given the Court's long history of silence regarding the constitutionality of execution methods, *Baze* did little to resolve the problems that plagued **lethalinjection** prior to 2008. The *Baze* Court's vague and diffuse Eighth Amendment analysis engendered greater coverage of **lethalinjection** research and litigation in medical journals, as well ***1336** as controversy over physician involvement. Combined with widely publicized botched executions, the **lethalinjection** debate after *Baze* encompassed problems even worse and more varied than those that existed before the Court's intervention.[25] Yet no one--not even the more prescient Justices of the *Baze* Court--could have foreseen the more pragmatic threats to the continuation of executions that were to come with rampant drug shortages that started after *Baze* was decided.[26]

As death-penalty states face the daunting reality of diminishing or depleted drug supplies and ever-increasing restrictions on drug importation, they are struggling to match their protocols to drug availability.[27] Some states have put **lethalinjection** executions on hold until the drug situation is resolved,[28] while others have turned to the U.S. Department of Justice for help.[29] Many continue to search for manufacturers that will agree to produce drugs for **lethalinjections**. As states' desperation increases, so does their tolerance for risk.[30] Most recently, death-penalty states have pinned their hopes on "compounded" drugs, individualized prescription medications created in facilities referred to as ""compounding pharmacies." Unlike commercial pharmaceutical manufacturers, which are regulated by the Food and Drug Administration (FDA) and subject to intense oversight,[31] compounding pharmacies (and pharmacies generally) are regulated relatively permissively by the states.[32]

Over the past few decades, however, the FDA has discovered a disturbing trend in which compounding pharmacies capitalize on their ability to produce ***1337** and sell large batches of medications to a broad market without meeting the stringent safety and efficacy standards required of commercial drug manufacturers. Essentially, these facilities act like large-scale pharmaceutical companies while hiding behind small-scale pharmacy licenses.[33] This practice has had, at times, disastrous results.

For example, in early October 2012, a contaminated steroid produced by a compounding pharmacy in Massachusetts led to a fungal meningitis outbreak that has killed a total of sixty-four people and sickened hundreds more. [34] This tragedy led the FDA to inspect thirty-one compounding pharmacies over the next six months, whereby the FDA made a series of disturbing discoveries concerning the pharmacies' lack of safeguards. [35] Moreover, an April 2013 study released by the U.S. House of Representatives revealed that almost all states provide overall ineffective oversight and regulation of the compounding pharmacies within their borders. In response to these findings, legislation has been proposed that would require FDA approval of not only pharmacies engaged in interstate commerce, but also those involved in high-risk compounding. [36]

As the FDA continues to explore ways to increase oversight of compounding pharmacies, state pharmacy boards have also been working on their own to increase their regulatory oversight in response to the negative focus on compounding pharmacies after the meningitis outbreak. Proposed state regulations include stricter requirements for both local compounding pharmacies and out-of-state pharmacies that cross state lines, clearer definitions of compounding, additional inspection protocols, and the installment or improvement of prescription-monitoring programs. [37]

***1338** If any compounded **lethalinjection** drugs are considered high risk--and they possibly could be--then the compounding pharmacies that produce them will be subject to FDA oversight. The new regulations may require public disclosure of all the drugs the pharmacies produce, to whom they intend to sell them, and advance evidence of individual prescriptions. The FDA, in turn, may be required to share information on inspected compounding pharmacies with relevant state agencies. Finally, and perhaps most significantly, several of the proposed restrictions may effectively negate altogether the ability of compounding pharmacies to produce **lethalinjection** drugs.

Thus, death-penalty states could be confronted with an ironic outcome in which their quest for **lethalinjection** drugs is thwarted both by the problems and the proposed solutions associated with the regulation of compounding pharmacies. The historically dismal safety standards and haphazard daily practices of many compounding pharmacies all but invite **lethalinjection** challenges, while public-health calamities such as the meningitis outbreak make increased regulation inevitable. Death-penalty states have an unsettling tendency to retreat into secrecy with respect to execution protocols and source materials when legal challenges appear threatening, yet currently proposed regulations may hinder such retreat.

In sum, *Baze v. Rees*--the Supreme Court's only opinion on the constitutionality of **lethalinjection**--failed to answer significant questions, and many of the issues that the Court did consider have been subsumed by new legal and practical challenges. The future of **lethalinjection** remains unclear. This Article is intended to be a point-in-time snapshot of the rapidly changing factors affecting the use of **lethalinjection** in the United States. Part I of this Article briefly describes the history of **lethalinjection** methods and provides a foundation for the current debate regarding **lethalinjection** drugs. Part II discusses the role of *Baze* as precedent, supporting the remarkable assertion that *Baze* has been rendered mostly irrelevant merely five years after its issuance. Part II also discusses legal challenges after *Baze* as well as states' attempts to quell litigation by switching their **lethalinjection** protocols from three-drug to one-drug procedures. Part III explains how these legal challenges have been overshadowed by an even bigger obstacle to **lethalinjection**: unanticipated national shortages in **lethalinjection** drugs, which have resulted in a new wave of litigation and protocol changes. Part IV reveals the dangers associated with states' attempts to address those shortages by seeking compounded drugs from pharmacies that lack federal oversight and explains how new regulations may impede states' increasingly frantic efforts to procure **lethalinjection** drugs. Part V explores the trend toward secrecy that has accompanied these efforts as states attempt to protect the identities and conceal the dangers of their drug sources, even as the risks associated with compounding pharmacies seem to demand increased transparency. Part V also emphasizes the likelihood that new compounding pharmacy regulations will promote such transparency. This Article concludes by condemning states' efforts to retreat into secrecy regarding execution ***1339** practices. Such efforts thwart any attempt to address problems with **lethalinjection** and only further contribute to the **chaos**. Transparency regarding **lethalinjection** procedures is a

desirable and constitutionally sound outcome for the public, if not for the states that will have to begin yet again the search for drugs to dole out death.

I. A BRIEF HISTORY OF LETHALINJECTION

This country's adoption of **lethalinjection** follows more than a century of searching for humane methods of execution, [38] starting with hanging and the firing squad and then replaced by seemingly more acceptable techniques. The increasingly modern quest for an execution method began with electrocution in 1890, then **lethal** gas in 1921, and, in an evolving pattern, ended in 1977 with **lethalinjection**. [39] An analysis of **lethalinjection's** history, however, shows little excuse for its adoption or its perpetuation. **Lethalinjection's** deficiencies persisted over the decades yet were simply ignored. [40] The State of New York considered using one form of **lethalinjection** (cyanide **injection**) as early as 1888, [41] yet a state commission rejected that choice because the medical profession believed that the public would begin to link the practice of medicine to death. [42] Of course, this concern about **lethalinjection** remains today. [43]

In 1953, Great Britain's Royal Commission on Capital Punishment also dismissed a form of **lethalinjection**, concluding after a five-year study that **injection** was no better than Great Britain's long-standing method of execution by hanging. [44] The host of problems the Royal Commission detected with **lethalinjection** still exists, ranging from the physical limitations presented by individuals with inaccessible veins to the recognition that **lethalinjection** requires medical skill because of the technique's complexity. [45] In 1976, the United States started to examine the **lethalinjection** issue more intently after the ***1340** Supreme Court reinstated the death penalty in *Gregg v. Georgia*, [46] a case that marked the end of a nine-year pause in this country's executions. [47] Remarkably, no state legislature addressed the evidence gathered and conclusions reached on **injection** procedures either from the New York or British commissions. [48]

Such disregard for past medical investigations was clear in May 1977, when Oklahoma became the first state to adopt **lethalinjection**. [49] An Oklahoma legislator asked Jay Chapman, M.D., the state's medical examiner, to create a **lethalinjection** protocol that the state could implement even though Dr. Chapman was clear about his lack of expertise in fulfilling such a request. [50] According to Dr. Chapman, when lawmakers initially contacted him, his "first response was that [he] was an expert in dead bodies but not an expert in getting them that way." [51]

With virtually no scientific study or relevant medical background, Dr. Chapman quickly concocted the three-drug formula formerly used by Kentucky. [52] Yet, within days of the Oklahoma legislature adopting his method, Chapman warned the public of **lethalinjection's** hazards. [53] In the *Daily Oklahoman*, for example, he noted that "if the death-dealing drug is not administered properly, the convict may not die and could be subjected to severe muscle pain." [54] Other news articles at the time stressed the tentative status of Oklahoma's protocol. A 1979 article in the *Daily Oklahoman* emphasized that "[o]fficials with the State Department of Corrections say it may be years--if ever--before they are required to carry out mandates of the 1977 Legislature." [55] The article also noted that "[o]fficials feel that if and when they have to use the **injection** law, *new and better drugs may be available.*" [56] Such statements suggest that officials had minimal confidence in the effectiveness of the chemicals that Dr. Chapman introduced and even anticipated that they might never be applied.

Initial concerns over the lack of medical testing were sufficient to stall Oklahoma's **lethalinjection** bill prior to state senate approval. [57] At one point, the Oklahoma legislature considered requiring that **injection** could not supplant electrocution without being "ruled legal by the U.S. Supreme Court." [58] Legislative ***1341** history indicates that **lethalinjection** was not to be used quickly or confidently, if at all.

Despite the benefits of hindsight, states did not medically improve upon the **lethalinjection** method that consistently had resulted in documented debacles. [59] As the trial court in *Baze v. Rees* concluded in 2005, "there is scant evidence that ensuing States' adoption of **lethalinjection** was supported by any additional medical or scientific studies .... Rather, it is this Court's impression that the various States simply fell in line relying solely on Oklahoma's protocol." [60] Indeed, after Oklahoma adopted the method, state after state followed suit. As Chart 1 of this Article shows, thirty-nine states joined this movement between ***1342** 1977 and 2009, switching to **lethalinjection** like falling dominos. Many of these states simply copied the language of Oklahoma's **lethalinjection** statute. [61]

CHART 1

STATES ADOPTING LETHALINJECTION BY YEAR: 1977-2014 [A1]

1977	Oklahoma • Texas
1978	Idaho
1979	New Mexico
1981	Washington
1982	Massachusetts
1983	Arkansas • Illinois • Montana • Nevada • New Jersey • North Carolina • Utah
1984	Mississippi • Oregon • South Dakota • Wyoming
1986	Delaware • New Hampshire
1988	Colorado • Missouri
1990	Louisiana • Pennsylvania
1992	Arizona • California
1993	Ohio [1]
1994	Kansas • Maryland • Virginia
1995	Connecticut • Indiana • New York • South Carolina
1998	Kentucky • Tennessee
2000	Florida • Georgia
2002	Alabama
2009	Nebraska

Footnotes

1 In 2001, Ohio changed from a choice state to a single-method state.

a1 Information for this chart comes from the following sources: NEB. REV. STAT. § 83-964 (2010); **Deborah** W. **Denno**, *For Execution Methods Challenges, the Road to Abolition Is Paved with Paradox, in*THE ROAD TO ABOLITION? THE FUTURE OF CAPITAL PUNISHMENT IN THE UNITED STATES 183, 188 (Charles J. Ogletree, Jr. & Austin Sarat eds., 2009).

The thirty-nine-state figure alone is remarkable. Even more extraordinary is that six states, including Oklahoma, made the switch by 1982, [62] the year this country's first **lethalinjection** execution took place. [63] Another seven states changed in 1983 alone. [64] Therefore, within a year of the country's first **lethalinjection** execution, thirteen states--over one-third of all death-penalty states at that time--had decided to engage in executions with the new method. [65] In addition, twelve states enacted **lethalinjection** in the nine-year stretch from 1994, when Kansas, Maryland, and Virginia adopted the method, to 2002, when Alabama did. [66] Nebraska was a lone wolf, switching to **lethalinjection** in 2009, a year after the Nebraska Supreme Court finally declared electrocution unconstitutional. [67] By 2009, then, all death-penalty states in this country had switched to **lethalinjection**, either entirely or as an option, [68] and nearly all states used a protocol consisting of the same three drugs. [69]

Of the thirty-two death-penalty states that exist in mid-2014, **lethalinjection** is the sole method of execution in twenty-one states, as shown in Chart 2 of this Article. [70] Three states--Utah, Kentucky, and Tennessee--have also adopted ***1343 lethalinjection** as their sole execution method but have done so with provisions that are not retroactive. [71] **Lethalinjection** is one of two possible methods of execution in eleven states, including Utah (which allows some inmates the choice of firing squad) as well as Kentucky and Tennessee (which allow some inmates the choice of electrocution). [72] A growing number of states, eighteen in total, no longer have the death penalty, a figure that includes New Mexico, New Jersey, and Maryland, the most recent state to join this list. [73]

CHART 2
EXECUTION METHODS BY STATE: 2014 [A1]
Single-Method States (24)

Arizona • Arkansas • Colorado • Delaware • Georgia • Idaho • Indiana • Kansas • Kentucky • Louisiana • Mississippi • Montana • Nebraska • Nevada • North Carolina • Ohio • Oklahoma • Oregon • Pennsylvania • South Dakota • Tennessee • Texas • Utah • Wyoming
Choice States (11)
LethalInjection or Hanging (2): New Hampshire • Washington
LethalInjection or Firing Squad (1): Utah
LethalInjection or Electrocution (6): Alabama • Florida • Kentucky • South Carolina • Tennessee • Virginia
LethalInjection or **Lethal** Gas (2): California • Missouri
States Without the Death Penalty (18)
Alaska • Connecticut • Hawaii • Illinois • Iowa • Maine • Maryland • Massachusetts • Michigan • Minnesota • New Jersey • New Mexico • New York • North Dakota • Rhode Island • Vermont • West Virginia • Wisconsin Also--District of Columbia

Footnotes

a1 Kentucky, Tennessee, and Utah have provisions that are not retroactive and therefore allow choices for some inmates. These three states are listed in both the Single-Method States and Choice States categories.

***1344** Statistics demonstrating **lethalinjection's** dominance, however, ignore the effect that **lethalinjection** challenges can have on capital punishment. Indeed, it was the dominance of **lethalinjection** that imperiled all capital punishment when **lethalinjection** faced legal challenges. The events leading up to *Baze* illustrated this effect. In 2006, for example, executions plunged to about half their 1999 numbers, a trend that continued in 2007 and 2008. [74] Numerous states and the federal government ceased executions entirely, often at least partly due to problems and legal challenges related to **lethalinjection**. [75] Beginning on ***1345** September 26, 2007, the day the Court granted certiorari in *Baze*, no additional executions were conducted until May 6, 2008. [76] Although the Court did not declare a general moratorium on executions during this seven-month period, a de facto moratorium evolved when the Court granted stays of execution for individual cases that came before it. [77] Historically, such a lengthy hiatus is rare. [78] After *Baze* was decided, those stays ended when the Justices denied the underlying appeals. Executions began again, but so did **lethalinjection** litigation, and with a vengeance.

When the Supreme Court affirmed Kentucky's three-drug protocol in *Baze*, some commentators predicted that there would be a surge of executions because the de facto moratorium had created a backlog of death-row inmates. [79] That prediction was never realized; apart from a slight rise in 2009, executions have continued their downward trend. [80] The number of executions by year is as follows: thirty-seven in 2008, fifty-two in 2009, forty-six in 2010, forty-three in 2011, forty-three in 2012, and thirty-nine in 2013. [81] One reason for this decline may be that the death penalty's popularity has weakened in recent years. [82] Whether because of discoveries of innocence among death-row inmates, a reduction in the number of individuals eligible for execution, racial disparities, botched executions, or other reasons, the courts and the public have shown more skepticism of the capital punishment process in the twenty-first century than they have since the early 1970s. [83] Yet, **lethalinjection** challenges may have contributed to this skepticism. According to one death-penalty commentator, **lethalinjection** challenges "have already held up more executions, and for a ***1346** longer time than appeals involving such ... issues as race, innocence, and mental competency." [84]

II. *BAZE* AS PRECEDENT

Given the narrowness and ineffectiveness of the *Baze* opinion, the Court's decision has had minimal effect in the way that the *Baze* plurality intended.[85] Rather than offering guidance on the future direction of **lethalinjection**, the legal issues and procedures evaluated by the *Baze* Court have been overshadowed by far more pragmatic threats to the continuation of executions by **lethalinjection**. Considered together with the ongoing mass of **lethalinjection** challenges and protocol changes that have ensued since 2008, it can be argued that *Baze* has rendered itself moot.[86] Strikingly, even Kentucky itself--the "model" state at the heart of *Baze*--has switched to a single-drug protocol, such that it is no longer "substantially similar" to the procedure the *Baze* Court hailed as the standard for other states to follow.[87]

Yet this is a remarkable conclusion to reach regarding a Supreme Court opinion merely six years after its issuance, particularly in a case that marks the Court's first foray into the constitutionality of an execution method in over six decades.[88] I base this assertion on two grounds. First, although *Baze* has not been entirely void of precedential force, my analysis of all cases that have cited *Baze*, which I discuss in section II.A, indicates that the case's value as precedent has been limited. My study demonstrates that number of citations is not always indicative of an opinion's efficacy. Second, citations to *Baze* have decreased substantially in the last three years.[89] As I explain in section II.B, this decline is most likely because the nature of **lethalinjection** challenges now bear on issues that have only remote or nonexistent parallels to those that prompted *Baze* in the first place.[90] In addition, recent developments have shown that some of the purposes for which *Baze* may have been used in the past are no longer viable, ***1347** the use of foreign-sourced drugs being a particularly striking example.[91] Indeed, **lethalinjection** litigation after *Baze* is so prolific and variable that it seemingly dwarfs the extent to which *Baze* has been used to dismiss challenges. I conclude that *Baze*'s already constrained precedential force is barely applicable to recent litigation spurred by this country's unanticipated drug shortages.

A. *BAZE*'S LIMITED PRECEDENTIAL FORCE

Three hundred thirty-three cases have cited the *Baze* Court's plurality opinion (as well as the concurrences and dissent) from the time *Baze* was decided until May 30, 2013.[92] I reviewed the nature of each case's citation and reference to *Baze* and then grouped the cases along several dimensions into one or more of the following categories: the substantial-risk standard; concurring and dissenting opinions; and the Eighth Amendment standard.[93] In the next three subsections, I will discuss each group in turn.

***1348** 1. Substantial-Risk Standard

The substantial-risk standard in *Baze* was the most encompassing category in my study. Although *Baze* alludes to a number of risk standards,[94] the cases in this study tended to favor a particularly high hurdle for the petitioner: in order to constitute an Eighth Amendment violation, a risk must be *"'sure or very likely* to cause serious illness and needless suffering,' and give rise to 'sufficiently *imminent* dangers.'"[95] Altogether, 248 cases cited this standard in response to four potential Eighth Amendment challenges related to state protocols: (1) execution team training, (2) drug type and protocol procedure, (3) use of foreign-sourced drugs, or (4) failure to protect inmates from alleged violent and assaultive prison conditions.[96]

a. Execution Team Training. Twenty-nine cases cited *Baze* in discussions of execution-team or supervisor training levels and protocols and reached varying results.[97] All cases, with the exception of one that was remanded,[98] relied on *Baze* to question evidence of improper training. As noted in one representative case, any risk of mistake on the execution team's

part connected to the team's lack of practice using a certain drug "is speculative and fails to rise to the level required to demonstrate a substantial risk of serious harm under Eighth Amendment jurisprudence." [99]

b. Drug Type and Protocol Implementation. Most cases (216 cases or 87%) cited *Baze*'s substantial-risk standard to refute challenges concerning a protocol's use of particular **lethalinjection** drugs or procedures. [100] Many of the cases ***1349** argued that the protocol's implementation violates the Eighth Amendment, [101] whereas others involved challenges to the type of drug being **injected**, such as the choice of pentobarbital in place of sodium thiopental, which was needed to rectify the issues presented by a shortage of the latter. [102] Almost every court relied on the *Baze* substantial-risk standard to establish that the method of **injection** and the drugs administered did not pose a risk sufficient to constitute an Eighth Amendment violation. [103]

A breakdown of these cases provides more specific insight into the kinds of issues addressed. For example, 195 of the 216 cases concern challenges to a state protocol's method or procedure. [104] These cases include challenges to the type of method used--a one-drug [105] or three-drug [106] method--and the state protocol's **lethalinjection** procedure in general. [107] As stated above, each court presented with a protocol challenge found that the plaintiffs in question could not establish that the protocol created a demonstrated risk of severe pain, as explicated in *Baze*, or that the risk was substantial compared to other known ***1350** methods. [108] In coming to this conclusion, many courts compared the challenged state protocol to Kentucky's protocol and found the two protocols to be ""substantially similar," and thus, the challenged protocol constitutional. [109]

Additionally, 27 of the 216 cases dealt with challenges to the drug being used for the procedure, [110] with 19 specific challenges to the use of pentobarbital as a replacement for sodium thiopental in a state's one-drug or three-drug method. [111] Despite the drug's limited testing and use in **lethalinjection** procedures, courts consistently upheld the implementation of pentobarbital and found that its substitution for sodium thiopental did not create a substantial risk of harm to the inmate. [112]

c. Foreign-Sourced Drugs. With the increasing scarcity of **lethalinjection** drugs in this country, especially sodium thiopental, departments of corrections started purchasing drugs from other countries. [113] Some drug-protocol challenges attacked the use of foreign-sourced drugs, and thirteen cases cite *Baze* for support. [114] Strikingly, almost every court presented with a foreign-drug challenge found that the plaintiff did not have sufficient evidence to show that the use of a foreign-produced drug would be likely to create a substantial risk of ***1351** unconstitutional harm. [115] By July 23, 2013, such determinations would no longer be viable. On that date, the D.C. Circuit held that the FDA violated the Food, Drug and Cosmetic Act and the Administrative Procedure Act by allowing the importation of unapproved or misbranded sodium thiopental for use in **lethalinjection** procedures. [116]

d. Failure to Protect. Not surprisingly, courts have relied on *Baze* for challenges apart from problems associated with **lethalinjection**. Altogether, thirty-three cases cited *Baze* in the context of "failure to protect" claims under the Eighth Amendment, most typically raised against a prison official for failing to protect an inmate from harm or for a violation of a duty to protect from future harm. [117] *Baze* was most often cited to affirm that in order to establish such a claim, the plaintiff must "allege facts from which a court could conclude that he faces a substantial risk of serious harm, and that the defendants knew of and disregarded that risk." [118] The finding in *Baze* that an "isolated mishap" or "an accident, with no suggestion of malevolence," [119] would not give rise to an Eighth Amendment violation is often used to support the rejection of the failure to protect claims brought about in these cases. [120] Most of the failure to protect cases are in reference to prison violence, assault, or abuse; however, some cases discuss different settings in which a substantial

risk first must be established. [121] Although such a use of *Baze* is unsurprising given the dearth of Eighth Amendment precedent, it seems a stretch in light of more relevant doctrine specifically dealing with prison violence in a way *Baze* does not. [122]

***1352 2. Concurring and Dissenting Opinions**

Over one-fifth of the 333 cases cited opinions other than the *Baze* plurality. [123] These seventy-two cases primarily included references to Justice Thomas's and Justice Stevens's concurrences as well as Justice Ginsburg's dissent, nearly in equal number. [124] In total, thirty-four cases cited to Justice Thomas's concurrence, [125] which argued that inmates should be required to show that a **lethalinjection** protocol is ""deliberately designed to inflict pain" to establish an Eighth Amendment violation. [126] These cases concluded that if there was sufficient evidence to uphold a **lethalinjection** procedure under the Eighth Amendment standard set by the *Baze* plurality, there was also sufficient evidence to uphold the procedure under Justice Thomas's more rigorous intent-based standard. [127] A disproportionate number of these cases (sixteen in total) originated in Florida and frequently cited the following quote from the Florida Supreme Court: [128] "Florida's current **lethal-injection** protocol passes muster under *any* of the risk-based standards considered by the *Baze* Court (and would also easily satisfy the intent-based standard advocated by Justices Thomas and Scalia)." [129] Although seemingly dicta, the repeated use of this particular quote by the Florida Supreme Court in its holdings was noticeable and unique among those courts approving **lethalinjection** protocols.

In turn, a comparable number of cases (thirty-three in total) cited Justice Stevens's concurrence, [130] a particularly noteworthy opinion because it was the first time he voiced his general opposition to the death penalty. [131] Justice Stevens explained that he concurred in *Baze* because he felt obligated under the Court's precedents; however, like Justices before him, he had gradually changed his mind about the death penalty for a range of reasons that he articulated in great detail. [132] In my study, some cases cited Justice Stevens's commentary ***1353** regarding the risk of error in capital cases, [133] whereas other cases cited his reservations regarding the value of the death penalty. [134]

Justice Ginsburg's dissent, which Justice Souter joined, focused more narrowly on the perils of **lethalinjection**, emphasizing that a number of other states had instituted far more adequate procedures than Kentucky to ensure that an inmate is anesthetized before execution. [135] "[I]f readily available measures can materially increase the likelihood that the protocol will cause no pain, a State fails to adhere to contemporary standards of decency if it declines to employ those measures." [136] The thirty-six cases in my study that cited to Justice Ginsburg's dissent stressed the safeguards that states had implemented in their **lethalinjection** protocols. [137] The majority of states went even further, comparing a specific state's **lethalinjection** safeguards to Kentucky's lack of safeguards as a way to further affirm the constitutionality of the specific state's **lethalinjection** protocol. [138]

3. Eighth Amendment Standard

Altogether, fifty-four cases cited *Baze* in reference to the Eighth Amendment or to affirm the constitutionality of **lethalinjection** by the Court's holding that **injection** does not constitute cruel and unusual punishment. [139] Some cases, ***1354** for example, referenced the *Baze* plurality's characterization of the Eighth Amendment merely to affirm that citizens are privy to the rights listed within the Amendment. [140] Other cases focused more specifically on **lethalinjection**. *Broom v. Strickland*, for instance, cited the *Baze* Court's determination that Kentucky's **lethalinjection** protocol is constitutional in order to compare a situation in which a **lethalinjection** attempt may be considered unconstitutional. [141]

B. POST-*BAZE* LITIGATION AND RISK

On June 10, 2008, less than two months after *Baze* was decided, an Ohio state court ruled in *State v. Rivera* that Ohio could no longer employ the standard three-drug protocol (used in Kentucky) for executing inmates because the drug combination contravened Ohio's own **lethalinjection** statute and therefore violated due process. [142] In making this determination, the court heard testimony from two of the key medical experts who also testified for the defense and the state respectively in *Baze*. [143] Yet the *Rivera* court reached different conclusions from *Baze*, holding specifically that "the use of two drugs in the **lethalinjection** protocol (pancuronium bromide and potassium chloride) creates an unnecessary and arbitrary risk that the condemned will experience an agonizing and painful death." [144] This recognition prompted the court to hold that the state's **lethalinjection** protocol should use only "a **lethalinjection** of a single, anesthetic drug." [145]

By way of affirming these dangers, the *Rivera* court listed as a finding of fact nearly every criticism made of the three-drug combination, ranging from the difficulties in assessing the condemned person's depth of anesthesia before administering the second and third drugs, to the heightened risk from physicians' refusal to participate in the process, to the number of mistakes made in the delivery of anesthesia even in a clinical setting. [146] The *Rivera* court also recognized "[c]ircumstantial evidence ... that some condemned prisoners have ***1355** suffered a painful death, due to a flawed **lethalinjection**." [147]

One reason for the seeming divergence of *Rivera*'s holding from that of *Baze* is Ohio's **lethalinjection** statute. That statute requires "a **lethalinjection** of a drug or combination of drugs of sufficient dosage to quickly and painlessly cause death." [148] In contrast, "the Kentucky **lethalinjection** statute has no mandate that an execution be painless." [149] Therefore, an interpretation of Kentucky's statute "is not applicable" in *Rivera* because unlike Ohio's statute, "the [U.S.] Constitution does not demand the avoidance of all risk of pain in carrying out executions." [150]

Rivera was the first case in which a court ordered a state to employ only a single anesthetic drug, thus reflecting the momentum created by other judges and commissions that had long criticized the three-drug combination. [151] The *Baze* Court emphasized the uniqueness of this very situation by noting that the petitioners' proposed alternative protocol (the use of a single barbiturate) was "one that ... has not been adopted by any State and has never been tried." [152] With *Rivera*, the "uniqueness" claim from *Baze* would no longer be accurate. By breaking away from the three-drug-formula pact, *Rivera* started to weaken the safety-in-numbers argument states had embraced in determining that a shared **lethalinjection** formula provides a humane death.

Like *Morales v. Hickman* [153] and earlier cases, [154] *Rivera* also cut through much of the paradox in *Baze* that even the Supreme Court was unable to avoid. For example, with the single-barbiturate **injection**, *Rivera* provided a potential solution to the absence of a medical professional in the execution chamber because a one-drug formula was considered so much easier to administer. [155] This solution was aided by the *Rivera* court's focus on the constitutional ***1356** viability of the execution method itself and not on the larger topic of the death penalty generally. After all, medical professionals have recommended abolition as a solution for avoiding the potential hazard of physician involvement in executions. [156] Without the distraction of having to grapple with death-penalty debates more broadly, the *Rivera* court was better able to evaluate different types of **lethalinjection** procedures.

As it would turn out, however, Ohio's breaking from the pack, even to satisfy legislative requirements, would garner substantial notice. This switch was a huge development in the death-penalty world and the first such inroad with **lethalinjection**, especially coming on the heels of *Baze*. [157] *Baze* was supposed to be the Supreme Court's effort to end the **lethalinjection** story, not push it full throttle.

The next chapter after *Baze* would be even more critical because it would involve all three administrative layers in the execution process: the legislature, the courts, and the department of corrections. No matter what **lethalinjection** statute a legislature has in place or how a court interprets that statute, both legislatures and courts delegate the actual business of executions to a department of corrections. [158] Until Ohio's change to a single-drug protocol, the Southern Ohio Correctional Facility (Ohio Facility) in Lucasville held a striking record of ineptitude in the execution or attempted execution of inmates, the Romell Broom case being the most egregious example. [159]

Although the Ohio Facility was stung by its experiences with the three-drug ***1357** procedure, officials were concerned about implementing a one-drug procedure that had yet to be used on anyone, anywhere. [160] Wanting to ensure that history did not repeat itself in the upcoming execution of Kenneth Biros, in November 2009, the Ohio Facility issued a two-part **lethalinjection** protocol. [161] In the first part (Plan A), executioners would **inject** only sodium thiopental. If the execution team failed at Plan A, Plan B directed the team to **inject** directly into the inmate's arm or leg muscles an overdose of two drugs never before used in any execution in the world. [162]

Plan B's potential problems are vast. According to expert commentary, the two Plan B drugs, hydromorphone and midazolam, could produce a slow, lingering death with the inmate in a state of confusion, disorientation, and intense psychological anguish and torment. The nausea-evoking effect of hydromorphone could cause the prisoner to vomit, before or after drifting into unconsciousness. [163] Ohio officials warned journalists witnessing the execution that Biros could end up vomiting and convulsing if in fact the backup plan went into effect. [164] Although Ohio's own **lethalinjection** statute requires that death be quick and painless, expert testimony suggests that Plan B is probably the slowest **lethalinjection** method yet proposed in the United States. [165] Likewise, Plan B directly contravenes Ohio's veterinary euthanasia laws because the particular drugs and intramuscular method are all prohibited for animals (the Ohio statute forbids any euthanasia for animals by intravenous drugs other than pentobarbital). [166]

Plan B still remains in effect in Ohio. Regardless, Kenneth Biros's Plan A execution on December 8, 2009, was fraught with problems. Executioners required a half-hour and nine unsuccessful attempts to finally find a vein in which to put an IV catheter. [167]

Ohio's move to a single-drug protocol served as an impetus for other states to also make the switch, irrespective of Ohio's difficulties with Biros's execution and the state's unique statute. For over a century, states have closely followed ***1358** the execution strategies of other states, [168] and Ohio's change would be no exception. The key switch from the past was the greater rapidity and extent to ***1359** which states would follow Ohio's decision to use only sodium thiopental. As Charts 3 and 4 of this Article show, eleven states--or over one-third of all the death-penalty states--have moved from three drugs to one drug in less than five years (2009-2013). [169] Ohio's decision to move at the end of 2009 would be quickly followed, respectively, over the next two years by Washington in 2010 and South Dakota in 2011 and then by five states in 2012 (Arizona, Georgia, ***1360** Idaho, Missouri, and Texas). [170] So far, three states have switched from three drugs to one in 2013 (Arkansas, Kentucky, and Louisiana). [171]

CHART 3

CHANGES IN STATE LETHALINJECTION PROTOCOLS: 2009-2013 [A1]

YEAR	THREE DRUGS TO ONE DRUG	SODIUM THIOPENTAL TO PENTOBARBITAL	SODIUM THIOPENTAL TO PROPOFOL
2009	Ohio [5]		
2010	Washington [1]	Oklahoma	
2011	South Dakota [1 2 3 7]	Alabama	
		Arizona [1 2]	
		Delaware	
		Florida	
		Georgia	
		Idaho [1]	
		Mississippi	
		Montana [2 4]	
		Ohio [5]	
		South Carolina	
		South Dakota [1 2 3 7]	
		Texas	
		Virginia	
2012	Arizona [1 2]		Missouri
	Georgia		
	Idaho [1]		
	Missouri		

	Texas		
2013	Arkansas[4] [8]	Kentucky[2] [3] [4] [5]	
	Kentucky[2] [3] [4] [5]	Louisiana[6]	
	Louisiana[6]		

Footnotes

1 Allows for either one or three drugs.

2 Allows either sodium thiopental or pentobarbital.

3 Allows for either one or two drugs.

4 Executions are on hold due to court challenges.

5 Backup protocol uses two drugs.

6 Execution stayed so judge can evaluate protocol.

7 Allows for one, two, or three drugs.

8 Considering other drugs.

a1 Information for this chart reflects trends up to August 1, 2013, and comes from the following sources: *State by State* ***LethalInjection***, DEATH PENALTY INFO. CENTER, http://www.deathpenalty.org/state-**lethal**-**injection** (last visited Jan. 31, 2014); Death Penalty Clinic, Univ. of Cal., Berkeley, Sch. of Law, *Execution Protocol Information*, LETHALINJECTION.ORG, https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html (last visited Aug 1, 2013).

Chart 4

Types of Anesthetic Used in LethalInjection Protocols: 2013 [a1]

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

Like other states' changes, Kentucky's was prompted by efforts to quell continuing litigation over the state's three-drug protocol despite the outcome of *Baze*. [172] For example, from a resource standpoint, obtaining one drug is simpler than three drugs; in addition, the process is presumably less risky because there is just one **injection** and no controversial paralytic agent (pancuronium bromide). [173] At the same time, death by sodium thiopental alone typically takes longer, and the procedure is less predictable because it is far less known. [174] Regardless, perhaps the primary source of the one-drug method's popularity with states is that it was at least a move away from a three-drug process with its long and documented record of trouble. In 2013, two-thirds of the **lethalinjection** executions used a one-drug protocol compared to one-half of the **lethalinjection** executions in 2012. [175] Yet death-penalty states would soon encounter an obstacle that the switch from three drugs to one drug would not alleviate: a nationwide dearth of **lethalinjection** drugs. More than any legal argument, this practical challenge--one that the *Baze* Court could not have anticipated--would threaten the continued use of **lethalinjection** as this country's primary method of execution.

III. POST-*BAZE* DRUG SHORTAGES

In 2009, the United States confronted a national shortage of sodium thiopental when Hospira, Inc., the sole U.S. manufacturer of the drug, ceased production due to difficulties procuring its active ingredient from another company. [176] In late 2010, the British government announced plans to create an export restriction that would ban the export of sodium thiopental to the United States after learning that the drug would be solely used for executions. [177] Hospira originally intended to resume production of the drug at its plant in Italy, but Italian authorities threatened legal action if Hospira could not successfully ***1361** prevent the drug from "being diverted to departments of corrections for use in capital punishment procedures." [178] Unwilling to risk potential liability, in January 2011, Hospira stopped manufacturing sodium thiopental entirely. [179] Europe's prohibition of the death penalty had become an American problem. [180]

Hospira's exit from the sodium thiopental market created the most serious challenge yet to the continuation of **lethalinjection**. The shortage of sodium thiopental led prison officials to seek out questionable alternative sources of the drug throughout the world, ranging from England to Pakistan. [181] Until recently, for example, the London wholesaler Dream Pharma Ltd. purchased sodium thiopental manufactured in Austria and then shipped it to various states in the United States for use in **lethalinjections**. [182] Such practices raised concerns that prisoners may be **injected** with drugs that are impure, expired, unsafe, or ineffective. [183] It bears reminding that if sodium thiopental is ineffective and does not render the inmate unconscious, that inmate is tortured by the **injection** of the second and third drugs. [184]

Many death-penalty states experienced an onslaught of litigation challenging the use of foreign-sourced sodium thiopental in **lethalinjection** proceedings. [185] Then in 2011, the Drug Enforcement Administration (DEA) began to seize some states' supplies of foreign-sourced sodium thiopental on grounds that the seized drugs did not meet importation standards. Other states voluntarily relinquished their supplies. [186] But the most striking legal development occurred in ***1362** March 2012. In *Beaty v. FDA*, the U.S. District Court for the District of Columbia ultimately banned the importation of sodium thiopental, finding that the drug did not follow FDA regulations and exposed plaintiffs "to the risk that the drug will not function as intended"; therefore, plaintiffs were able to show "at least a 'modest' increment of risk that the use of foreign thiopental in their executions would result in conscious suffocation, pain, and cardiac arrest." [187] On July 23, 2013, the D.C. Circuit affirmed *Beaty* with an unambiguous holding in *Cook v. FDA*:

> The FDA acted in derogation of [its] duties by permitting the importation of thiopental, a concededly misbranded and unapproved new drug, and by declaring that it would not in the future sample and examine foreign shipments of the drug despite knowing they may have been prepared in an unregistered establishment. [188]

As a consequence of *Beaty*, *Cook*, and the events leading up to both cases, many death-penalty states amended their **lethalinjection** protocols to either replace sodium thiopental with pentobarbital or to allow a choice between the two drugs. [189] Indeed, in 2012 and 2013, pentobarbital was the primary drug employed in executions by **lethalinjection**. [190] Pentobarbital, a drug most commonly used as a sedative or to control convulsions, was first used in a three-drug **lethalinjection** execution in Oklahoma in 2010 [191] and in a one-drug execution in Ohio the following year. [192] As Charts 3 and 4 of this Article show, an unprecedented number of states--thirteen in total, including Ohio--switched from sodium thiopental to pentobarbital in 2011 alone. [193] Only Kentucky and Louisiana changed thereafter--both in 2013. [194]

The quick switch to pentobarbital has done little, if anything, to address the issues surrounding **lethalinjection**. In fact, states' inclusion of the drug in their protocols has engendered a new wave of legal challenges. [195] Much of the ***1363** litigation involves Eighth Amendment Cruel and Unusual Punishment challenges [196] and is based in part on the sparse

data available regarding the drug's effects on humans. [197] Of the first eight documented pentobarbital challenges, seven focused on the lack of substantial data concerning the efficacy of pentobarbital as an execution drug--that is, whether or not it is actually successful in anesthetizing the prisoner. [198] In fact, it appears that the drug is not always successful for that purpose; as some of the litigation notes, even the drug's manufacturers have cautioned against its use in **lethalinjection** proceedings for reasons related to politics, if not efficacy. [199]

Eighth Amendment challenges are not the only issue facing states with pentobarbital protocols. As with sodium thiopental, states that have included pentobarbital in their protocols have had great difficulty obtaining it. The ***1364** Danish manufacturer H. Lundbeck A/S (Lundbeck) worked vehemently to prevent the use of its pentobarbital--which it sold for treatment of seizures-- in executions. [200] Lundbeck announced in July 2011 that it "would require customers to buy [pentobarbital] through a single wholesaler and to sign a form confirming they won't resell it, aren't a prison, and know Lundbeck opposes executions." [201] In December 2011, Lundbeck sold its pentobarbital rights to the Illinois pharmaceutical company Akorn, Inc. but first insisted upon an agreement that the drug would not be sold for the purpose of executing inmates. [202] Although it is not entirely clear how much pentobarbital is still available, ultimately it will either run out or expire. [203]

Like sodium thiopental, pentobarbital's effects are most difficult to measure when a state uses a three-drug protocol because the subsequent paralytic agent (pancuronium bromide) can mask the first drug's effects. [204] Regardless, the first three-drug execution using pentobarbital in Georgia--that of Roy Blankenship--was so seriously botched [205] that the next pentobarbital execution in Georgia--that of Andrew Grant DeYoung--was videotaped as a safeguard. [206] Notably, the only other videotaped execution in this country's history was the 1992 gas-chamber execution of Robert Alton Harris in California due to that state's horrific problems with **lethal** gas. [207]

These events make clear that the use of pentobarbital in **lethalinjection** proceedings is not a lasting solution. Most likely, death-penalty states soon will have to switch to yet a different drug, which will bring with it a host of new ***1365** problems. In May 2012, for example, Missouri amended its **lethalinjection** protocol to permit the use of propofol in one-drug executions. [208] Less than a month after the drug's adoption, concerns were raised about its implementation [209] and on July 11, 2012, the United Kingdom announced its ban on the exportation of propofol for execution purposes. [210] In September 2012, the German healthcare company Fresenius Kabi USA, a main supplier of propofol, announced it would not sell the drug to corrections departments, [211] thereby following in the footsteps of restrictions on the sale of thiopental and pentobarbital. [212] Despite the drug's unavailability, Missouri's **lethalinjection** protocol included the use of propofol until October 2013, although it was never used in a **lethalinjection** procedure. [213] No state other than Missouri has indicated plans to adopt the drug.

Meanwhile, in May 2013, yet another drug company withdrew from the **lethalinjection** market. Hikma, a British pharmaceutical company that produces phenobarbital, announced a plan to limit distribution of the drug in an effort to prevent it from being considered as a potential new drug for executions. This announcement came shortly after Arkansas declared its intent to be the first state to employ phenobarbital for **lethalinjections** [214] in lieu of the other two execution drugs, pentobarbital or sodium thiopental, which most states currently use.

Phenobarbital has been prescribed to treat seizures but presumably has never been used for executions in the United States, and some experts have expressed their concern that it could have dire and unpredictable effects on inmates. [215] According to the Arkansas Department of Corrections, it selected phenobarbital after attorneys for several death-row inmates mentioned in a lawsuit that it ***1366** might be an available drug. [216] The Department has revealed little other

information about the drug selection process apart from explaining that the agency also consulted other medical sources, which it did not identify.[217] In July 2013, Arkansas still did not have a valid execution statute,[218] and the Department of Corrections had changed its mind about incorporating phenobarbital because it could no longer acquire sufficient quantities of the drug.[219] Indeed, death-penalty states are becoming increasingly desperate in their efforts to procure **lethalinjection** drugs, and this practical challenge has subsumed many of the issues addressed by the *Baze* Court.[220]

IV. THE HIGH-RISK ROLE OF COMPOUNDING PHARMACIES

Given the impact of drug shortages on **lethalinjection** procedures,[221] it should come as no surprise that states are seeking help internally from local compounding pharmacies for the production of **lethalinjection** drugs.[222] Yet recent discoveries of subpar conditions and contaminated drugs demonstrate the risk posed by compounding pharmacies. This risk provides states with an incentive to keep their **lethalinjection** protocols secret because of the foreseeable challenges that they will face should it become known that the drugs are coming from pharmacies of this kind. However, the nondisclosure of a **lethalinjection** protocol renders *Baze* moot because it becomes impossible to subject that protocol to all of the requirements of *Baze*. Further, compounding pharmacies by their very nature run counter to the requirements of *Baze* because the practices they engage in already pose a substantial risk.

Because of the heightened risk posed by compounding pharmacies, states face a quandary: states use compounded drugs because they could not carry out executions otherwise; yet they also recognize the risks associated with these drugs, as well as the potential for legal challenges. As a result, states default to secrecy regarding their protocols.

Yet there are also a number of reasons why states may view compounding pharmacies as better suited than large-scale drug manufacturers for the job of executing inmates. Most apparent is the reason discussed in Part III: large-scale ***1367** companies that are based in Europe but have subsidiaries in the United States have been strictly prohibited from facilitating the death penalty in the United States in any way.[223] Even if they were permitted to do so, big pharmaceutical companies would have a much larger reputation at stake when they considered associating themselves with **lethalinjection**.

Another key reason that states are turning to compounding pharmacies is the lack of regulation compared to large-scale manufacturers.[224] The latter are governed by strict FDA regulations, whereas compounding pharmacies fall under the relatively lax authority of the states. In addition, state regulations tend to differ from one state to the next, making it difficult to ensure that compounded drugs are held to consistently high standards of quality, safety, and effectiveness. These seemingly permissive regulations stem from the traditional view of compounding pharmacies as small-scale productions that lend themselves to easy quality control and present a low risk of public-health concerns.[225] Yet recent events suggest that this perspective may be outdated. The remainder of Part IV provides a brief history of compounding pharmacies as well as a discussion of current legislation aimed at improving oversight of these facilities.

A. A BRIEF OVERVIEW OF COMPOUNDING PHARMACIES

Traditionally, all compounded drugs were custom-made in small batches for individual patients pursuant to a medical prescription.[226] Physicians usually prescribe compounded medications when commercial drugs are unavailable or if the use of existing commercial alternatives is inhibited by allergies.[227] When compounding pharmacies were first conceived in the 1800s, they typically served as the only source of prescription medication.[228] Their prevalence was somewhat diminished during the Industrial Revolution when mass drug-manufacturing companies emerged with a superior capacity to produce generic drugs,[229] but those companies did not dominate the market until around 1950.[230] Today,

there are about 56,000 compounding pharmacies in the United States.[231] Recent estimates show that approximately "3,000 facilities practice sterile compounding and supply most of the **injectable** drugs in the United States."[232]

Compounded drugs are prepared by licensed pharmacists who practice in a licensed compounding pharmacy.[233] Pharmacist licensure requirements are regulated ***1368** by state pharmacy boards[234] and therefore vary by state.[235] However, all pharmacists are required to pass a national, standardized licensure exam, and all states require pharmacists to pass an examination on compounding.[236]

Compounded drugs must be prescribed to a patient by a licensed physician. Providing such a prescription carries some risk. According to a recent article published by the American Medical Association, many patients have successfully sued their doctors based on negligence and failure-to-warn claims with respect to defective or dangerous compounded medications.[237] Indeed, when considering use of a compounding facility, doctors are often advised to weigh the risk of liability, which is exacerbated by the fact that medical malpractice insurance typically excludes coverage for claims involving medications and procedures not approved by the FDA.[238] The lack of FDA regulation is in fact the very root of physician liability. Because compounding pharmacies are not regulated by the FDA,[239] they are "less legally secure than alternatives," such as regular pharmacies and regulated medications.[240] Doctors are required to know whether a given compounding pharmacy meets applicable safety standards.[241]

B. REGULATORY OVERSIGHT OF COMPOUNDING PHARMACIES

In the early 1990s, the FDA became aware of compounding pharmacies whose practices did not align with the traditional individualized, prescription-based schema.[242] In response to this discovery, the FDA issued a compliance ***1369** guide in 1992,[243] which effectively alerted compounding pharmacies that they were not unconditionally exempt from FDA regulation: if a compounding pharmacy's actions exceeded its traditional scope, the FDA had the authority to intervene.[244] Five years later, however, the FDA acknowledged continued confusion regarding the actual scope of that authority and worked with the Senate Committee on Labor and Human Resources to design legislation to clarify the matter.[245]

In 1997, section 127 of the Federal Food and Drug Administration Modernization Act (FDAMA)[246] represented the first time that specific federal law governed the practices of compounding pharmacies. With unprecedented clarity, the FDAMA distinguished drug manufacturers from compounding pharmacies and listed nine requirements for classification as a true compounding pharmacy.[247] These requirements stipulated the need to produce compounded drugs for identified individual patients pursuant to a prescription from a licensed physician and prohibited the production of drugs that were effectively identical to "commercially available drug product[s]."[248] Pharmacies that met these requirements fell within the scope of regulatory exemptions that the FDA had created for true compounding pharmacies[249] and would not be required to register with the FDA, obtain its approval, or comply with any manufacturing practices or safety and efficacy standards.[250] The FDA's goal was to create a framework that would enable true compounding pharmacies to continue to produce customized drugs but prevent large-scale manufacturers from operating under the guise of compounders.[251]

Since the passage of the FDAMA, several lawsuits and FDA actions have triggered reexamination of the legislation but, rather remarkably, no substantial changes have been made.[252] Beginning in the early 2000s, however, the FDA sent seventy-five publicly available warning letters to compounding pharmacies in twenty-eight states as well as Puerto Rico, Canada, and Brazil, noting a series of problems: failed inspections, the discovery of problematic compounded

drugs, potential and actual violations of the FDA regulations, failed safety and efficacy standards, false or misleading statements, and other disturbing ***1370** issues.[253] As concern grew that some pharmacies were exceeding the scope of traditional compounding practices,[254] the FDA issued reports in 2003[255] and 2006[256] revealing the discovery of compounded drugs that failed safety and efficacy tests, as well as serious illnesses and deaths that had occurred in association with compounded drugs.[257] Yet in 2007, legislation aimed at reassessing and increasing the FDA's limited authority over compounding pharmacies was met with criticism and disregard. The prevailing notion remained that state pharmacy boards were better equipped to regulate compounding pharmacies than the FDA.[258]

By October 2012, however, sentiments had shifted. A contaminated steroid produced by the New England Compounding Center (NECC) in Massachusetts led to a fungal meningitis outbreak that has killed a current total of 64 people and sickened 751 others across the nation.[259] The facility that had compounded the contaminated drug was alleged to be a prime example of a compounding pharmacy operating like a drug-manufacturing company on a larger-than-permissible scale, and the tragic public-health consequences triggered a new receptiveness to increased oversight of compounding pharmacies.[260]

The FDA inspected thirty-one compounding pharmacies over the next six months and made a series of disquieting discoveries:[261] "unidentified black particles floating in vials of supposedly sterile medicine; rust and mold in "clean rooms' where sterile **injectable** medications were produced; technicians handling supposedly sterile products with bare hands; and employees wearing ***1371** non-sterile lab coats."[262] Furthermore, a study released in April 2013 by the U.S. House of Representatives revealed that almost all states provide grossly inadequate and often altogether ineffective oversight and regulation of the compounding pharmacies within their borders. Issues include poor record keeping, a lack of uniformity among states, ignorance of dangerous processes and products from other states, and minimal preventative and safety assurance measures.[263] In response to these findings, legislation has been proposed that would require FDA approval of not only pharmacies engaged in interstate commerce but also those involved in high-risk compounding.

As the FDA continues to explore methods of increasing its authority over compounding pharmacies,[264] state pharmacy boards are working hastily to improve their regulatory systems in response to the negative attention. Proposed state regulations include the following: stricter licensure requirements for local compounding pharmacies and out-of-state pharmacies that deliver in state; clearer definitions of compounding; additional inspection programs and requirements; and the installment or improvement of prescription monitoring programs.[265]

C. PROPOSED BILLS AND NEWLY ADOPTED LEGISLATION

Following the October 2012 fungal meningitis outbreak in Massachusetts, several bills were proposed regarding the regulation of compounding pharmacies.[266] In large part, these bills address the question of which government body should enforce regulations and penalize violations. Other features of the bills include the need to clearly and consistently distinguish between the terms "compounding" and "manufacturing"; the definitions of ""compounding," "sterile," and "non-sterile" practices; guidelines for the frequency, funding, and performance of inspections; and the scope of transparency.[267] The bills also create three separate categories of pharmacies, distinguishing among those that ***1372** engage in basic compounding and those that engage in high-risk sterile compounding.[268]

In May 2013, the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP Committee) unanimously approved the Pharmaceutical Compounding Quality and Accountability Act, clarifying which kinds of compounding pharmacies are regulated by the state and which are regulated by the FDA.[269] The legislation distinguishes FDA-regulated drug manufacturers from state-regulated small-scale traditional compounding pharmacies and separately

identifies large-scale compounding manufacturers who operate more like mass drug producers.[270] The bill then categorizes these large-scale businesses as manufacturers, eliminating their pharmacy status altogether and removing their ability to be licensed as such.[271] If passed, the legislation would grant the FDA full authority to be the sole regulator of these compounding manufacturers through measures such as conducting regular inspections and ensuring that all products manufactured are reported to the FDA.[272] Under this bill, however, compounding manufacturers still would not be subject to the same kinds of regulations as traditional drug manufacturers under FDA authority because, for example, drugs produced by these kinds of manufacturers are by their very nature compounded rather than approved by the FDA.[273] The HELP Committee continues to urge the Senate to bring this legislation to the floor for a vote in order to "prevent further tragedies."[274]

On May 23, 2013, a House bill was proposed that also appears to close the gap in FDA authority.[275] The Verifying Authority and Legality in Drug Compounding ***1373** Act of 2013 (VALID Compounding Act) also separates pharmacies into three categories and recognizes that small traditional compounding pharmacies that produce drugs for an "identified individual patient" should remain under the authority of the state.[276] However, the VALID Compounding Act still acknowledges large-scale compounders as pharmacies, in contrast to the Senate bill.[277] The legislation seeks to give the FDA exclusive authority over compounding pharmacies that ship products across state lines or engage in "high-risk sterile compounding,"[278] whereas other compounding pharmacies must follow different FDA regulations in addition to state regulations.[279] Compounding pharmacies would be subject to inspections, reporting, and labeling requirements.[280] The VALID Compounding Act does create exceptions for compounding manufacturers to produce non-patient-specific drugs and commercially available drugs under certain circumstances, including the ability to compound drugs listed on the drug shortage list or drugs that are "necessary to protect public health or wellbeing."[281]

The House also proposed a second bill, the Compounding Clarity Act of 2013 (Clarity Act), which is a discussion draft authored by Representative Morgan Griffith.[282] Like both the Senate bill and the VALID Compounding Act, this legislation recognizes that traditional pharmacy compounding is a separate practice that should remain subject to only state regulation and exempt from various FDA regulations.[283] Similar to the other bills, the Clarity Act creates a new category for nontraditional compounding pharmacies that do not operate like a traditional, small-scale compounding pharmacy.[284]

The Clarity Act, however, differs from the other bills regarding what kind of pharmacy is considered a "traditional compounding pharmacy" and what regulations those pharmacies must follow. For example, the Clarity Act creates a broad exception allowing traditional compounding pharmacies to compound both limited and unlimited quantities of drugs in advance of a prescription, subject to a variety of specific terms, whereas the Senate bill has a similar but much more limited provision, particularly with respect to the unlimited- ***1374** quantities portion.[285] In even sharper contrast, the VALID Compounding Act strictly requires that a drug only be compounded pursuant to a valid and existent prescription, without exception.[286] Finally, the Clarity Act has not yet provided much detail on what kind of pharmacy would be identified as a large-scale-manufacturing compounding pharmacy or what regulations manufacturing compounders must follow.[287]

On July 16, 2013, the Subcommittee on Health of the U.S. House Energy and Commerce Committee held a hearing to discuss all three proposed bills and examine their differences as well as the general need for stricter compounding regulation.[288] At the hearing, a representative from the National Association of Boards of Pharmacy (NABP) testified regarding the proposed compounding regulatory bills.[289] The representative's statements provided a great deal of support for the Senate bill, specifically with respect to the distinction between a compounding pharmacy and a

compounding manufacturer and the clarity afforded by the provision to prohibit compounding manufacturers from becoming licensed as pharmacies.[290] Additionally, the NABP representative stated that the House bills seemed too permissive and left open several gaps for businesses to potentially operate as licensed compounding pharmacies despite being engaged in large-scale compounded-drug manufacturing.[291]

Irrespective of these efforts, it was not until November 2013 that the final piece of proposed legislation--the "Drug Quality and Security Act"--was passed by both the House and the Senate.[292] Introduced at the end of September, the Act clarifies current federal law about pharmacy compounding so that a uniform, nationwide standard may be applied to compounding pharmacies.[293] Although other bills had proposed it, the Drug Quality and Security Act marks the first piece of passed legislation that separates regulation of traditional small-scale compounding pharmacies from large-scale compounders that operate more like pharmaceutical manufacturers. The Act leaves regulation over traditional compounding pharmacies in the hands of the states, subject to the same FDA Compliance Policy guidance that they have adhered to since 2002. The Act refers to these large-scale compounding manufacturers as outsourcing facilities and provides voluntary federal registration for outsourcing facilities, set to begin in fiscal year 2015. These facilities will be permitted to compound ***1375** bulk quantities of drugs on the FDA's drug shortage list, in addition to other drugs that are on a "'clinical need' list to be established by the FDA, without a prescription, as well as distribute these formulations out of state without limitation."[294] Registered outsourcing facilities will be subject to FDA oversight similar to that of regular pharmaceutical manufacturers in the United States.[295] Under the Act, outsourcing facilities will have to identify themselves for the FDA, enabling the FDA to know what kinds of pharmaceuticals each outsourcing facility is making and to receive event reports about all of the compounded drugs.[296] The FDA's regulation powers will also grant them the authority to conduct risk-based inspections.[297] Further, certain drugs will be listed as prohibited from being compounded at these facilities.[298] The Act has been widely endorsed by many national health organizations[299] and by President Obama.[300]

D. IMPLICATIONS FOR DEATH-PENALTY STATES

Heightened regulation of compounding pharmacies seems inevitable under both state and federal law. This regulation is unlikely to further the goals of death-penalty states for a number of reasons. For example, the proposed VALID Compounding Act prohibits even small, state-regulated pharmacies from producing copies or effective copies of commercial drugs, no matter the quantity and with few exceptions.[301] This limitation would be problematic for states seeking **lethalinjection** drugs, given that many such drugs are simply high doses of commercially available medication.[302] Another notable aspect of general compounding regulation is its strict prescription requirements, which should prohibit a compounding pharmacy from issuing a supply of **lethalinjection** drugs.[303] Instead, a physician must specifically order a prescription for an identified, individual patient in advance of the drug being compounded, which would raise the issue of finding a licensed physician willing to write a prescription for an execution drug.[304] As previously discussed, physicians who write compounded ***1376** drug prescriptions are already placing themselves at considerable risk for liability.[305] Physicians who participate in executions also face a broad range of potential repercussions, a topic discussed in depth elsewhere.[306] Presumably, writing a prescription would qualify as participation.

Whether under state or federal oversight, compounding pharmacies may soon also face an unprecedented barrage of regulations and requirements that will complicate every aspect of their operations, ranging from systems of communication, to sterilization procedures, to the need for lengthy and strict memorandums with each individualized prescription.[307] Additional complications associated with producing **lethalinjection** drugs, such as the Drug Quality and Security Act's extensive requirements for tracking and tracing drug products, may be too great a burden. Perhaps most significantly, however, these regulations would require an unprecedented degree of transparency from death-penalty

states regarding their execution methods. Although the exact specifications are yet to be established by the Secretary of Health and Human Services, it seems that it would be challenging for a correctional facility to maintain the secrecy of its pharmaceutical supplier because it would be up to the pharmacy itself to disclose all of its transaction history. Death-penalty states have a history of gravitating toward secrecy when their execution methods are questioned, [308] yet these regulations may hinder them from doing so.

V. POST-*BAZE* SECRECY

As states hone in on local compounding pharmacies as potential sources of **lethalinjection** drugs, they are becoming increasingly less willing to share information about executions with the public, which raises the disturbing possibility that states are knowingly trying to hide the risks associated with compounded drugs. South Dakota, after switching to a one-drug protocol and carrying out an execution in October 2012, was said to have obtained its order of pentobarbital from a local compounding pharmacy. [309] Alarmingly, the compounded drug was contaminated with fungus [310] --a discovery that was made only because the drug was analyzed after the inmate began snoring and then ***1377** remained open-eyed as he was executed. [311] Shortly after the South Dakota execution, Pennsylvania also announced that it would be using compounded drugs in its **lethalinjection** protocol for an execution the following month. [312] That announcement came only after enormous judicial pressure, including two federal court orders to disclose the drug source in a ruling pursuant to a class action lawsuit challenging the constitutionality of the state's protocol. [313] The Pennsylvania Department of Corrections initially refused to reveal the identity of their drug supplier because they feared disclosure would lead to public pressure on the pharmacy to withdraw its agreement to provide the drugs. [314] Indeed, it seems that states are keenly aware that their difficulties in obtaining **lethalinjection** drugs stem largely from transparency issues and thus seek to block that transparency at every turn.

This secrecy regarding **lethalinjection** practices and risk is particularly troublesome given that the number of states reaching out to compounding pharmacies is only increasing. In March 2013, the Colorado Department of Corrections sent a letter to almost one hundred local compounding pharmacies seeking to "acquire sodium thiopental or other equally or more effective substance to cause death" in accordance with state law. [315] In July 2013, Georgia became the fourth state to join the effort, acknowledging the increasing difficulty of obtaining **lethalinjection** drugs after its existing supply of pentobarbital expired in March. [316] When the Georgia Department of Corrections revealed in July 2013 that it would use a compounding pharmacy to obtain its supply of pentobarbital for an upcoming execution, that information was only acquired from an email received through an open-records request. [317] In March 2013, Georgia passed the **LethalInjection** Secrecy Act, enabling the identities of **lethalinjection** suppliers to be shielded from disclosure to the public and the media--and possibly even the judiciary. [318] According to the Act's provisions, this information is considered a ""state secret." [319] Several states have proposed or passed new regulations that exclude the death-penalty protocol from required ***1378** disclosure, thereby keeping both the method itself as well as the source pharmacy, compounding or otherwise, completely confidential. [320]

Certain states have addressed this issue more candidly than others. An Arkansas bill that was approved in February 2013 simply addresses all matters of **lethalinjection** administration and provides that all execution procedures are not subject to disclosure under the state's Freedom of Information Act. [321] Similarly, a Tennessee bill passed in April 2013 expanded the existing law that broadly protects the identity of individuals who have been or may be involved in an execution to include protecting the identity of entities as well. [322] A South Dakota bill passed in February 2013 is a bit more explicit, openly stating that the Act's specific purpose is to "protect the identity of the person or entity supplying" the **lethalinjection** drug. [323]

In spite of compelling public interest in ensuring that **lethalinjection** protocols are acceptable, legal, and constitutional (not to mention the First Amendment right of access to certain information, including the viewing of executions), custom and in some cases state regulation dictate that the identities of execution teams are concealed. [324] States profess crucial reasons to shield the identities of all parties who are involved in the **lethalinjection** process, including doctors, pharmacists, drug providers, wholesalers, retailers, or manufacturers. [325] Currently the American Medical Association, American Nurses' Association, American Society of Anesthesiologists, and National Commission on Correctional Health Care all have ethical rules and guidelines opposing participation in **lethalinjections**. [326] Without guaranteed anonymity, states argue, companies and medical professionals would be disinclined to assist the state with its execution duties for fear of a blight on their personal or professional reputations, while executioners and correctional facilities might face threats from death-penalty opponents. [327] Yet these fears are carryovers from past methods of execution, which employed a substantially smaller execution team. In contrast, **lethalinjections** involve multiple participants, [328] none of whom presumably is wholly responsible for the execution, including the producer of the **lethalinjection** ***1379** drugs. [329]

Given states' current desperation to obtain such drugs, the need for states to ensure safe and constitutional practices with regard to procurement and protocol far outweighs antiquated notions regarding the perceived risk to a lone executioner. Greater transparency of the entire **lethalinjection** process is a feasible solution. Indeed, my own research indicates that in modern times, death-penalty states' aversion to transparency is far more rooted in the desire to conceal inconsistencies and incompetence. [330]

In 2001, I conducted a nationwide study of **lethalinjection** protocols for all thirty-six states that used the method at that time (Study One). Study One focused on a number of key criteria common to many **lethalinjection** protocols, including the types and amounts of chemicals that are **injected**; the selection, training, and qualifications of the **lethalinjection** team; and the involvement of medical personnel. One of Study One's most problematic findings, however, was that the criteria set out in many of the protocols were far too vague to allow for adequate assessment. When the protocols did offer details, such as the amount and type of chemicals that executioners **inject**, they often revealed striking errors and a shocking level of ignorance about the procedure. [331] Four years later, in 2005, I conducted a second nationwide study (Study Two). One of the goals of Study Two was to determine if states had changed their protocols during the years in which **lethalinjection** litigation gained traction. In other words, Study Two provides a snapshot of **lethalinjection** protocols at a key point in time--at the cusp of the increased scrutiny of protocols but prior to the onslaught of **lethalinjection** challenges starting in 2006. [332]

For the most part, I found that over the four-year period between Study One and Study Two, states typically withheld more information than in the past. For example, one aspect of Study Two showed that the number of states with complete protocols fell to less than one-third of the Study One numbers. In addition, in Study Two, the number of states claiming confidentiality about their protocols increased nearly fourfold. Likewise, in Study Two, two states said protocols did not exist and one state provided no information whatsoever. In total, one-half of the states that applied **lethalinjection** did not allow any ***1380** evaluation of their protocols, either because the information is confidential or nonexistent. [333]

In 2008, death-penalty states had safety in numbers because, at least superficially, they appeared to follow essentially the same kind of protocol in terms of **lethalinjection** drug usage. [334] By 2013, however, there is a hodgepodge of protocols among states that has no parallel prior to *Baze*, whether that comparison is being made relative to 2008 or 1977 or as far back as 1890. [335] The **lethalinjection** procedure is more dangerous and inconsistent than ever, and the result is a perpetual effort by states to maintain secrecy at a time when transparency is most paramount.

Recognizing this need for transparency, state justice departments have started to intervene. In 2011, the Chief Deputy Attorney General of Delaware ordered that the state Department of Corrections violated the Freedom of Information

Act [336] by denying a request from a reporter for access to all information regarding its purchase and inventory of pentobarbital and sodium thiopental. [337] A year later in Texas, Assistant Attorney General Sean Opperman ordered the Department of Criminal Justice to respond to requests for public access to information regarding the amount of a specific **lethalinjection** drug in the Department's possession as well as information about the **lethalinjection** protocol. [338] He acknowledged that such information is not considered confidential under the state code in conjunction with a physical safety exception recognized by the Texas Supreme Court one year earlier [339] and concluded that the information is not exempt from public disclosure. Opperman further stated that safeguarding the identity of the Department's suppliers of **lethalinjection** drugs so that they are free from harassment and harm by certain interest groups is not a compelling enough reason to inhibit access. In June 2013, a federal judge ruled that the Louisiana Department of Corrections is required to publicly disclose details of its intended death-penalty protocol, including inventory records, the drugs to be used, and expiration dates issued by the supplying pharmacy. [340] Most recently, an Atlanta circuit judge granted injunctive relief to a death-row inmate who challenged Georgia's **LethalInjection** Secrecy Act as a violation of ***1381** his due process rights in a potential Eighth Amendment claim. [341] As a result, the court found unacceptable the potential for the death-row inmate to be barred from any knowledge about the drugs, including whether they would facilitate an execution that is cruel and unusual. [342]

In May 2013, the American Civil Liberties Union (ACLU) of Colorado sued the Colorado Department of Corrections over the secrecy of its death-penalty procedures and asked the court to compel the Department to make publicly available information pertaining to agreements with **lethalinjection** drug pharmacies as well as details of its execution protocol. [343] On August 1, 2013, a district court judge ordered the Department to release a redacted version of its execution protocol, reasoning that it would facilitate a necessary public discussion of the death penalty in Colorado. [344] However, the judge decided that details about the drug supplier should be part of the redacted information. [345] The judge rejected the ACLU request for the Department to release the identity of the source of the drugs, specifically reasoning that exposing the pharmacy could negatively impact their business or employees, "which far outweighs" the need for public disclosure. [346] Yet the judge's decision contrasts sharply with developments in other states which allow scrutiny of the drug supplier *and* the drug protocol, not just the protocol alone. Providing cover solely to compounding pharmacies--now such a key component of the **lethalinjection** process--fails to recognize the complex interdependency among the many different participants in the machinery of death. No participant should be holding secrets.

CONCLUSION

Lethalinjection is this country's primary method of execution, yet its implementation is **chaotic** and its future is unclear. This Article's point-in-time snapshot provides an overview of the multiple factors that have contributed to the prevailing state of confusion. The Supreme Court has done little to clarify matters--the *Baze* Court left key questions regarding **lethalinjection** unanswered, and the issues that the Court did address have been rendered moot by ***1382** unanticipated obstacles such as the shortage of **lethalinjection** drugs. More than any legal argument, this practical impediment jeopardizes the use of **lethalinjection** as a method of execution. As death-penalty states turn to increasingly nontraditional sources of drugs, such as compounding pharmacies, they face overwhelming criticism and legal challenges. In response, they have intensified their efforts to obscure information regarding the development and implementation of their **lethalinjection** protocols.

Indeed, as risk and confusion surround **lethalinjection** procedures, the only overarching constant appears to be states' desire for secrecy regarding execution practices. Amidst the **chaos** of drug shortages, changing protocols, legal challenges, and botched executions, states are unwavering in their desire to conceal this disturbing reality from the public. In fact, the current **chaos** may be viewed at least in part as a repercussion of that reticence: any efforts to fix the system via legal challenges and legislation are hindered by the difficulty in gathering enough information to even understand its

problems. Until death-penalty states are willing to focus more on solutions than secrecy, **lethalinjection** as a method of execution will remain mired in an endless cycle of difficulty and disorder.

Footnotes

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1 Baze v. Rees, 553 U.S. 35, 40-63 (2008) (plurality opinion) (examining the issues concerning the three-drug protocol). For a detailed discussion of these problems and developments over the decades, see **Deborah** W. **Denno**, *Getting to Death: Are Executions Constitutional?*, 82 IOWA L. REV. 319, 373-400 (1997) [hereinafter **Denno**, *Getting to Death*]; **Deborah** W. **Denno**, *The **LethalInjection** Quandary: How Medicine Has Dismantled the Death Penalty*, 76 FORDHAM L. REV. 49, 51-101 (2007) [hereinafter **Denno**, ***LethalInjection** Quandary*]; **Deborah** W. **Denno**, *When Legislatures Delegate Death: The Troubling Paradox Behind State Uses of Electrocution and **LethalInjection** and What It Says About Us*, 63 OHIO ST. L.J. 63, 90-141 (2002) [hereinafter **Denno**, *When Legislatures Delegate*].

2 Richard C. Dieter, *Methods of Execution and Their Effect on the Use of the Death Penalty in the United States*, 35 FORDHAM URB. L.J. 789, 802-03 (2008).

3 553 U.S. at 40-41.

4 Chief Justice John Roberts announced the judgment of the Court and delivered an opinion in which Justices Anthony Kennedy and Samuel Alito joined, *id.* at 40-63; Justice Alito filed a concurring opinion, *id.* at 63-71; Justice John Paul Stevens filed an opinion concurring in the judgment, *id.* at 71-87; Justice Antonin Scalia filed an opinion concurring in the judgment, which Justice Clarence Thomas joined, *id.* at 87-93; Justice Thomas filed an opinion concurring in the judgment, which Justice Scalia joined, *id.* at 94-107; Justice Stephen Breyer filed an opinion concurring in the judgment, *id.* at 107-13; and Justice Ruth Bader Ginsburg filed a dissenting opinion in which Justice David Souter joined, *id.* at 113-23.

5 *Id.* at 41 (plurality opinion). The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. CONST. amend. VIII.

6 *Baze*, 553 U.S. at 50 (plurality opinion) (internal quotation marks omitted).

7 *Id.* at 61.

8 **Deborah** W. **Denno**, *The **LethalInjection** Debate: Law and Science*, 35 FORDHAM URB. L.J. 701, 702 (2008).

9 *Baze*, 553 U.S. at 53-54 (plurality opinion); **Denno**, ***LethalInjection** Quandary*, *supra* note 1, at 55-56.

10 *Baze*, 553 U.S. at 53 (plurality opinion) ("It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the **injection** of potassium chloride.").

11 *Id.* at 53-61.

12 Dieter, *supra* note 2, at 800-08.

13 Adam Liptak, *Challenges Remain for **LethalInjection***, N.Y. TIMES, Apr. 17, 2008, http://www.nytimes.com/2008/04/17/washington/17*l*ethal.html.

14 Dieter, *supra* note 2, at 803-04.

15 Linda Greenhouse, *Justices Chilly to Bid to Alter Death Penalty*, N.Y. TIMES, Jan. 8, 2008, http://www.nytimes.com/2008/01/08/us/08scotus.html.

16 *See infra* Part II.

17 *See supra* note 4 and accompanying text.

18 For an analysis of the different opinions in *Baze*, see generally **Deborah** W. **Denno**, *For Execution Methods Challenges, the Road to Abolition Is Paved with Paradox*, *in*THE ROAD TO ABOLITION? THE FUTURE OF CAPITAL PUNISHMENT IN THE UNITED STATES 183 (Charles J. Ogletree, Jr. & Austin Sarat eds., 2009).

19 Liptak, *supra* note 13 (citing commentators' responses to *Baze*).

20 Baze v. Rees, 553 U.S. 35, 71 (2008) (Stevens, J., concurring) ("When we granted certiorari in this case, I assumed that our decision would bring the debate about **lethalinjection** as a method of execution to a close. It now seems clear that it will not.").

21 *Id.* at 105 (Thomas, J., concurring) (emphasizing that the weaknesses and vagueness of the *Baze* Court's decision would be "sure to engender more litigation").

22 *Id.* at 71 (Alito, J., concurring) (warning that "[t]he Court should not produce a *de facto* ban on capital punishment by adopting method-of-execution rules that lead to litigation gridlock").

23 *See infra* Part II.

24 *See infra* notes 159, 205, 311-12 and accompanying text.

25 *See infra* section II.B.

26 *See*U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-14-194, DRUG SHORTAGES: PUBLIC HEALTH THREAT CONTINUES, DESPITE EFFORTS TO HELP ENSURE PRODUCT AVAILABILITY 14 fig.4, 21 (2014) (charting the number of active drug shortages from January 2007 through June 2013 and finding that the immediate cause of drug shortages is traceable to slow or halted production of drugs). Hospira, Inc. was among the manufacturers interviewed for the GAO report. *Id.* at 65.

27 *See infra* Parts III, IV.

28 *See* Kimberly Leonard, ***LethalInjection** Drug Access Could Put Executions on Hold*, CENTER FOR PUB. INTEGRITY (July 11, 2012, 4:23 PM), http:// www.publicintegrity.org/2012/04/04/8589/**lethal**-injectiondrugaccess-could-put-executions-hold.

29 *See* Bill Mears, *States Urge Feds to Help Import **LethalInjection** Drugs*, CNN (May 21, 2012, 7:40 PM), http://www.cnn.com/2012/05/21/politics/states-**lethal**-**injection**-drugs (citing a statement released by the state attorneys general from fifteen states asking for help, noting that "[a]t the very core of the states' police powers are their powers to enact laws to protect their citizens against violent crimes" and "[a]s state attorneys general, we are tasked with enforcing those laws, including in instances where capital punishment is authorized for the most heinous of crimes").

30 *See* Meredith Clark, *US Execution Strategy Threatened by Drug Shortfall*, MSNBC (May 3, 2013, 11:20 AM), http://www.msnbc.com/melissa-harris-perry/us-execution-strategy-threatened-drugshor.

31 *See*STAFF OF REP. EDWARD J. MARKEY, U.S. HOUSE OF REPRESENTATIVES, STATE OF DISARRAY: HOW STATES' INABILITY TO OVERSEE COMPOUNDING PHARMACIES PUTS PUBLIC HEALTH AT RISK 6 (2013), *available at* http://www.hsdl.org/? view&did=735130 (reporting the responses to an investigation which examined the state oversight of compounding pharmacies).

32 *See* Jesse M. Boodoo, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36 AM. J.L. & MED. 220, 232-34 (2010).

33 *See*OFFICE OF REP. EDWARD J. MARKEY, U.S. HOUSE OF REPRESENTATIVES, COMPOUNDING PHARMACIES: COMPOUNDING RISK 5 (2012), *available at* http:// www.snmmi.org/files/docs/Compounding %20Pharmacies%20-%20Compounding%20Risk% 20FINAL_0_1382017898361_1.pdf (addressing current regulatory oversight and gaps in legal authority over compounding pharmacies in response to the fungal meningitis outbreak in Boston); Editorial, *Fix 'Compounding Pharmacy' Oversight: Our View*, USA TODAY (Apr. 28, 2013, 6:27 PM), http://www.usatoday.com/story/opinion/2013/04/28/compounding-pharmacy-fda-editorials-debates/2119621.

34 *See Multi-State Meningitis Outbreak--Current Case Count*, CENTERS FOR DISEASE CONTROL & PREVENTION (Oct. 23, 2013, 5:30 PM), http:// www.cdc.gov/hai/outbreaks/meningitis-map-large.html. For more information on the meningitis outbreak and the continually developing outcomes, see Scott Gottlieb, *Compounding a Crisis at FDA*, FORBES (May 24, 2013, 8:59 AM), http:// www.forbes.com/sites/scottgottlieb/2013/05/24/compounding-a-crisis-at-fda/.

35 *See* Margaret A. Hamburg, *Proactive Inspections Further Highlight Need for New Authorities for Pharmacy Compounding*, FDA VOICE (Apr. 11, 2013), http://blogs.fda.gov/fdavoice/index.php/2013/04/proactive-inspections-further-highlight-need-for-new-authorities-for-pharmacy-compounding/; *Summary: 2013 FDA Pharmacy Inspection Assignment*, FDA, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm347722.htm (last updated Jan. 9, 2014); *see also infra* notes 261-62 and accompanying text (listing the extent of the problems).

36 *See*STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 2-3.

37 *See* Andrew Pollack, *Checks Find Unsafe Practices at Compounding Pharmacies*, N.Y. TIMES, Apr. 12, 2013, at A12; *see also* Kara Nett Hinkley, *Compounding Interest*, ST. LEGISLATURES, June 2013, at 22, 23, *available at* http://www.ncsl.org/Portals/1/Documents/magazine/articles/2013/SL_0613-Compounding.pdf; *State Regulation of Compounding Pharmacies*, NAT'L CONF. OF ST. LEGISLATURES, http://www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx (last updated Jan. 2014).

38 *See*AUSTIN SARAT, WHEN THE STATE KILLS: CAPITAL PUNISHMENT AND THE AMERICAN CONDITION 84 (2001) (referring to the "unending search for technologies that in their capacity to kill with a pretense of humanity allow those who kill both to end life and, at the same time, to believe themselves to be the guardians of a moral order that, in part, bases its claims to superiority in its condemnation of killing").

39 For discussions of legislative changes in execution methods over time, see **Deborah** W. **Denno**, *Is Electrocution an Unconstitutional Method of Execution? The Engineering of Death over the Century*, 35 WM. & MARY L. REV. 551, 559-77 (1994) [hereinafter **Denno**, *Engineering of Death*]; **Denno**, *Getting to Death*, *supra* note 1, at 375-79; **Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 59-75; **Denno**, *When Legislatures Delegate*, *supra* note 1, at 82-85, 90-92, 130-31, 188-206.

40 *See generally***Denno**, ***LethalInjection*** *Quandary*, *supra* note 1 (documenting the history and perpetuation of **lethalinjection**).

41 *See*REPORT OF THE COMMISSION TO INVESTIGATE AND REPORT THE MOST HUMANE AND PRACTICAL METHOD OF CARRYING INTO EFFECT THE SENTENCE OF DEATH IN CAPITAL CASES 78, 85 (Albany, The Argus Co. 1888).

42 *See***Denno**, *Engineering of Death*, *supra* note 39, at 572-73.

43 *See***Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 80-81.

44 *See*ROYAL COMMISSION ON CAPITAL PUNISHMENT, REPORT, 1949-1953, [Cmd.] 8932, at 258-61 (U.K.).

45 *Id.* at 258.

46 428 U.S. 153, 207 (1976) (plurality opinion).

47 *See*Baze v. Rees, 553 U.S. 35, 42 (2008) (plurality opinion).

48 *See***Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 65.

49 *See***Denno**, *Getting to Death*, *supra* note 1, at 375.

50 *See***Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 66.

51 *Id.* (alteration in original) (quoting E-mail from A. Jay Chapman, Forensic Pathologist, Santa Rosa, Cal., to author (Jan. 18, 2006) (on file with author)).

52 *See id.* at 66-75.

53 *See* Jim Killackey, *Execution Drug Like Anesthesia*, DAILY OKLAHOMAN, May 12, 1977, at 1.

54 *Id.*

55 *See* Jim Killackey, *Officials Draw Grim Execution Scene*, DAILY OKLAHOMAN, Nov. 12, 1979, at 1.

56 *Id.* (emphasis added).

57 *See* John Greiner, *Drug Execution Plan Suffers Senate Setback*, DAILY OKLAHOMAN, Feb. 16, 1977, at 16 (explaining that one senator "apparently had drummed up enough votes to have killed the bill had it been brought to a final vote" and noting the concerns of a former assistant district attorney that "the legislature and the Senate should study [the bill] more carefully").

58 *See* Mike Hammer, *Drug Death Bill Passes*, DAILY OKLAHOMAN, Apr. 21, 1977, at 65.

59 *See***Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 64-117.

60 Baze v. Rees, No. 04-CI-01094, 2005 WL 5797977, at *2 (Ky. Cir. Ct. July 8, 2005), *aff'd*, 217 S.W.3d 207 (Ky. 2006), *aff'd*, 553 U.S. 35 (2008).

61 *See***Denno**, *Getting to Death*, *supra* note 1, at 375; **Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 78; **Denno**, *When Legislatures Delegate*, *supra* note 1, at 92, 95-100.

62 *See supra* Chart 1 (showing that Idaho, New Mexico, Washington, and Massachusetts followed the lead set by Oklahoma and Texas by adopting **lethalinjection** before an actual execution took place).

63 *See***Denno**, *Getting to Death*, *supra* note 1, at 375 (discussing the 1982 execution of Charles Brooks, Jr. in Texas).

64 *See supra* Chart 1 (showing that Arkansas, Illinois, Montana, Nevada, New Jersey, North Carolina, and Utah adopted **lethalinjection** in 1983).

65 By the end of 1983, thirty-eight states had the death penalty. *See*BUREAU OF JUSTICE STATISTICS, U.S. DEP'T OF JUSTICE, CAPITAL PUNISHMENT 1983, at 6-7 (1986).

66 *See supra* Chart 1 (showing that a series of states adopted **lethalinjection** between 1994 and 2002, starting with Kansas, Maryland, Virginia in 1994; Connecticut, Indiana, New York, and South Carolina in 1995; Kentucky and Tennessee in 1998; Florida and Georgia in 2000; and Alabama in 2002).

67 In 2008, the Nebraska Supreme Court held electrocution to be unconstitutional. State v. Mata, 745 N.W.2d 229, 278 (Neb. 2008). A year later, the Nebraska legislature adopted **lethalinjection**. NEB. REV. STAT. § 83-964 (2010).

68 *See supra* Chart 1.

69 Baze v. Rees, 553 U.S. 35, 40-63 (2008) (plurality opinion).

70 *See*ARIZ. REV. STAT. ANN. § 13-757 (2010); ARK. CODE ANN. § 5-4-617 (Supp. 2013); COLO. REV. STAT. ANN. § 18-1.3-1202 (West 2013); DEL. CODE ANN. tit. 11, § 4209 (Supp. 2012); GA. CODE ANN. § 17-10-38 (2013); IDAHO CODE ANN. § 19-2716 (Supp. 2013); IND. CODE § 35-38-6-1 (2012); KAN. STAT. ANN. § 22-4001 (2007); LA. REV. STAT. ANN. § 15:569 (2012); MISS. CODE ANN. § 99-19-51 (West 2013); MONT. CODE ANN. § 46-19-103(3) (2013); NEB. REV. STAT. § 83-964 (Supp. 2010); NEV. REV. STAT. ANN. § 176.355 (LexisNexis Supp. 2013); N.C. GEN. STAT. § 15-187 (2013); OHIO REV. CODE ANN. § 2949.22 (LexisNexis 2006); OKLA. STAT. ANN. tit. 22, § 1014 (West Supp. 2014); OR. REV. STAT. § 137.473 (2013); 61 PA. CONS. STAT. ANN. § 4304 (West 2010); S.D. CODIFIED LAWS § 23A-27A-32 (Supp. 2013); TEX. CODE CRIM. PROC. ANN. art. 43.14 (West Supp. 2013); WYO. STAT. ANN. § 7-13-904 (2013). The New York Court of Appeals held the state's death-penalty statute unconstitutional in 2004, preventing executions. *See*People v. LaValle, 817 N.E.2d 341, 367 (N.Y. 2004). However, the chosen method of execution in New York remains **lethalinjection**. N.Y. CORRECT. LAW § 658 (McKinney Supp. 2013).

71 *See*KY. REV. STAT. ANN. § 431.220 (West Supp. 2013); TENN. CODE ANN. § 40-23-114 (2012); UTAH CODE ANN. § 77-18-5.5 (LexisNexis 2012).

72 These eleven states are divided according to the alternative execution method they allow apart from **lethalinjection**. Alabama, Florida, South Carolina, and Virginia allow for electrocution. *See*ALA. CODE § 15-18-82.1 (LexisNexis 2011); FLA. STAT. ANN. § 922.105 (West Supp. 2014); S.C. CODE ANN. § 24-3-530 (2007); VA. CODE ANN. § 53.1-234 (2013). New Hampshire and Washington also have hanging as a method. *See*N.H. REV. STAT. ANN. § 630:5 (2007); WASH. REV. CODE ANN. § 10.95.180 (West 2012). California and Missouri both have **lethal** gas as an alternative. *See*CAL. PENAL CODE § 3604 (West 2011); MO. REV. STAT. § 546.720 (Supp. 2012). This footnote does not include statutes designating a choice only if an inmate was sentenced before a certain date or any of the other myriad variations in statutes that have been documented in detail elsewhere. *See***Denno**, *When Legislatures Delegate*, *supra* note 1, at 188-206.

73 The statutes for these eighteen states are listed in chronological order as follows beginning with the first state without the death penalty: Act of May 18, 1846, ch. 153, sec. 1, 1846 Mich. Pub. Acts 658 (fixing the punishment for first-degree murder at "solitary confinement at hard labor in the state prison for life"); Act of July 12, 1853, ch. 103, 1853 Wis. Sess. Laws 100; Act of Mar. 17, 1887, ch. 133, 1887 Me. Laws 104; Act of Apr. 22, 1911, ch. 387, 1911 Minn. Laws 572 (revising Minnesota's sentence for first-degree murder to "imprisonment for life"); Act of June 4, 1957, No. 282, 1957 Haw. Sess. Laws 314 (changing Hawaii's sentence for first- and second-degree murder to "imprisonment at hard labor" and repealing the law permitting capital punishment); Act of Mar. 30, 1957, ch. 132, 1957 Alaska Sess. Laws 262 (abolishing the death penalty "as punishment in Alaska for the commission of any crime," prior to Alaska gaining statehood); Act of Apr. 15, 1965, No. 30, 1965 Vt. Acts & Resolves 28 (codified as amended at VT. STAT. ANN. tit. 13, § 2303 (2009)); W. VA. CODE ANN. § 61-11-2 (LexisNexis 2013) (abolishing capital punishment in West Virginia); Act of May 14, 1965, ch. 436, sec. 3, 1965 Iowa Acts 828; Criminal Law Revision Act, ch. 116, §§ 31, 41, 1973 N.D. Laws 215, 286-88, 300 (repealing North Dakota's capital-punishment statute and creating new criminal sentencing guidelines); Act of Dec. 26, 1980, No. 3-307, 27 D.C. Reg. 5624 (repealing the death penalty and substituting it with life imprisonment instead); Commonwealth v. Colon-Cruz, 470 N.E.2d 116, 129 (Mass. 1984) (holding that Massachusetts's death-penalty statute violated the state constitution); Act of July 1, 1984, ch. 221, sec. 1, 1984 R.I. Pub. Laws 523 (removing the punishment of death from sentencing provisions for first-degree murder); People v. LaValle, 817 N.E.2d 341, 367 (N.Y. 2004) (holding the death-penalty statute in violation of the state constitution); People v. Taylor, 878 N.E.2d 969, 983-84 (N.Y. 2007) (applying the holding in *LaValle* to the last remaining person on death row in the state); Act of Dec. 17, 2007, ch. 204, 2007 N.J. Laws 1427 (eliminating the death penalty in New Jersey and allowing for life imprisonment without eligibility for parole); Act of Mar. 18, 2009, ch. 11, 2009 N.M. Laws 133 (abolishing the death penalty in New Mexico and providing for life imprisonment without possibility of release or parole); Act of Mar. 9, 2011, No. 96-1543, 2011 Ill. Laws 7778 (creating a death-penalty-abolition fund and abolishing the death penalty in Illinois); Act of Apr. 25, 2012, No. 12-5, 2012 Conn. Acts 13 (Reg. Sess.) (providing for a definite sentence of imprisonment for capital felonies); Act of May 2, 2013, ch. 156, 2013 Md. Laws 2298 (repealing the death penalty and substituting it with life without the possibility of parole). Notably, the abolishment of the death penalty was retroactive in every state except for New Mexico, Connecticut, and Maryland, therefore leaving several people on each of the three states' death rows. *See* 2009 N.M. Laws 133; 2012 Conn. Acts 13 (Reg. Sess.); 2013 Md. Laws 2298.

74 *See Executions by Year Since 1976*, DEATH PENALTY INFO. CENTER, http://deathpenaltyinfo.org/executions-year (last updated May 6, 2014).

75 *See*DEATH PENALTY INFO. CTR., THE DEATH PENALTY IN 2013: YEAR END REPORT 2-4 (2013), *available at* http:// deathpenaltyinfo.org/documents/YearEnd2013.pdf (discussing the significant decline in executions in 2013 due to states either suspending executions or repealing capital punishment because of problems such as drug availability and constitutional challenges to their protocols); Manny Fernandez, *Executions Stall as States Seek Different Drugs*, N.Y. TIMES, Nov. 9, 2013, at A1 (reporting on the inability of several states to perform executions because of the unavailability of **lethalinjection** drugs and noting that Texas, Florida, and Ohio have been scrambling to find alternative drugs); Clare Algar, *Big Pharma May Help End the Death Penalty*, NEW REPUBLIC (Oct. 22, 2013), http:// www.newrepublic.com/article/115284/big-pharma-may-end-death-penalty ("Shortages of **lethalinjection** drugs and attendant litigation have resulted in moratoria-- an official halting of executions--in Arkansas, California, Kentucky, Louisiana, Maryland, Missouri, Montana, Nebraska, North Carolina, Oregon, and Tennessee."); Dustin Volz, *Death Penalty Opponents Are Winning ... Almost Everywhere*, NAT'L J. (Dec. 19, 2013), http:// www.nationaljournal.com/technology/death-penalty-opponents-are-winningalmosteverywhere-20131219 ("The [Death Penalty Information Center's] end-year report cites an ongoing shortage of **lethal**-**injection** drugs in several states for 2013's drop in executions. California, North Carolina, Arkansas, and Maryland have not required a death sentence in more than seven years 'because of their inability to settle on a **lethal**-**injection** protocol.'" (quoting DEATH PENALTY INFO. CTR., *supra*, at 4)).

76 *See* Shaila Dewan, *Executions Resume, as Do Questions of Fairness*, N.Y. TIMES, May 7, 2008, http:// www.nytimes.com/2008/05/07/us/07execute.html (noting that an execution on May 6, 2008 "ended a seven-month national suspension").

77 *See* Linda Greenhouse, *Justices Uphold* ***LethalInjection*** *in Kentucky Case*, N.Y. TIMES, Apr. 17, 2008, http:// www.nytimes.com/2008/04/17/washington/17scotus.html.

78 *See supra* notes 44-47 and accompanying text.

79 *See* Liptak, *supra* note 13.

80 *See*DEATH PENALTY INFO. CTR., THE DEATH PENALTY IN 2012: YEAR END REPORT 1 (2012), *available at* http:// deathpenaltyinfo.org/documents/2012YearEnd.pdf (noting that the number of new death sentences in 2012 was the second lowest since the death penalty was reinstated in 1976, representing a near 75% decline since 1996 when there were 315 new death sentences).

81 *See Executions by Year Since 1976*, *supra* note 74.

82 A 2012 Gallup poll measured Americans' abstract support for the death penalty at 63%, the second-lowest level of support for capital punishment since 1978 and a significant decline from 1994, when 80% of respondents were in favor of the death penalty. Likewise, in 2011, Gallup found 61% in support of the death penalty, the lowest level in 40 years. Lydia Saad, *U.S. Death Penalty Support Stable at 63%*, GALLUP (Jan. 9, 2013), http:// www.gallup.com/poll/159770/death-penalty-support-stable.aspx?utm_source_ alert&utm_medium_email&utm_campaign_syndication&utm_content_morelink&utm_term_ All%20Gallup%C20Headlines%20-%20Politics.

83 *See* Ronald J. Tabak, *Capital Punishment*, *in*THE STATE OF CRIMINAL JUSTICE 2013, at 305, 305-24, 328-38, 343-45 (Myrna S. Raeder ed., 2013).

84 Dieter, *supra* note 2, at 789.

85 *See id.* at 806.

86 *See infra* section II.B.

87 Baze v. Rees, 553 U.S. 35, 41 (2008) (plurality opinion) (upholding Kentucky's three-drug protocol).

88 This six-decade demarcation was offered by the Court. *See id.* at 48-50 (plurality opinion) (discussing the Eighth Amendment precedents of Wilkerson v. Utah, 99 U.S. 130 (1879), *In re* Kemmler, 136 U.S. 436 (1890), and Louisiana *ex rel.* Francis

v. Resweber, 329 U.S. 459 (1947)). There is room for disagreement, however, on when the Court last reviewed evidence concerning the constitutionality of an execution method given that the cases the Court cites were decided before the Eighth Amendment's incorporation into the Due Process Clause. *See* **Denno**, *Getting to Death*, *supra* note 1, at 321-34.

89 The distributions by year are as follows: fifty-three cases in 2008; seventy-five cases in 2009; eighty-one cases in 2010; sixty-three cases in 2011; fifty-three cases in 2012; twelve cases in 2013 (as of May 13, 2013). **Deborah** W. **Denno**, Analyzing Precedent in *Baze v. Rees*: 2008-2013, at 5 (Aug. 1, 2013) (unpublished manuscript) (on file with author).

90 *See infra* section II.B.

91 For more information on the use of foreign-sourced drugs, see *infra* Part III.

92 A total of 406 cases cited *Baze*; however, 73 cases were lower-court decisions that eventually evolved into the appellate-court decisions that this Article analyzes. *See* **Denno**, *supra* note 89, at 3-4. Thus, the final 333 cases are not redundant. *Id.* All 406 cases, however, are categorized and documented in detail in a manuscript on file with the author. *Id.* at tbl.A.

93 *See* **Denno**, *supra* note 89, at 5-23. In total, fourteen cases were not included in this analysis because their use of *Baze* was not directly relevant. For example, six of these cases cited *Baze* for the purpose of declaring that states are subject to the Excessive Fines Clause of the Eighth Amendment. *See, e.g.*, Bethea v. Salazar, No. EDCV 05-1168 DOC (FFM), 2008 WL 4381545, at *13 n.24 (C.D. Cal. Sept. 23, 2008) (citing *Baze* stating that the Eighth Amendment provides that excessive bail shall not be required, and excessive fines shall not be imposed); State v. Cottrell, 271 P.3d 1243, 1250 n.4 (Idaho Ct. App. 2012) (citing *Baze* explaining that states are subject to the Excessive Fines Clause because the whole of the Eighth Amendment is applicable to the states). Eight cases cited *Baze* in ways that do not coincide with the three categories. Most of these cases mentioned *Baze* in a footnote or in combination with other cases to reinforce a briefly mentioned point. *See* Zack v. Tucker, 704 F.3d 917, 925 (11th Cir. 2013) (stating that the Supreme Court in *Baze* "observed that the purpose of the habeas statute of limitations is to end delays in criminal cases"); Walker v. Epps, 550 F.3d 407, 416 (5th Cir. 2008) (stating that *Baze* has permitted inmates to challenge the state's method of execution under 42 U.S.C. § 1983 and a constitutional standard); Schwab v. Sec'y, Dep't of Corr., 284 F. App'x 643, 644 (11th Cir. 2008) (stating that the plaintiff "has abandoned the argument he made in the district court that it had misinterpreted its November 14, 2007 order providing that unless Schwab filed a motion to re-open the case within 30 days after a final decision in *Baze v. Rees*, his case would be dismissed" (citation omitted)); Karban v. Ryan, No. CV 10-0406-TUC-DCB, 2011 WL 320559, at *3 (D. Ariz. Jan. 27, 2011) (using *Baze* as a citation for the statement: "[S]peculation cannot substitute for evidence of irreparable harm" (alteration in original) (internal quotation marks omitted)); Barrett v. United States, No. 09-CIV-105-JHP, 2010 WL 774192, at *1 (E.D. Okla. Feb. 26, 2010) (stating that "[w]hile the Court understands that 'death is different,' the issues in this particular case are not significantly more complex than any other criminal case tried in this district" (footnote omitted) (quoting Baze v. Rees, 553 U.S. 35, 84 (2008) (Stevens, J., concurring))); Wilson v. Strickland, No. 2:09-cv-271, 2009 WL 1362511, at *3 (S.D. Ohio May 13, 2009) (stating that *"%7FBaze* did not *establish* a new claim or constitutional right but simply made clear the expansive *scope* of the claim and right involved"); State v. Jackson, No. 92003717DI, 2008 WL 5048424, at *3 (Del. Super. Ct. Nov. 25, 2008) ("A trial in the District Court litigation was then postponed pending a decision of the United States Supreme Court in *Baze v. Rees*."); State v. Hartman, No. 25055, 2010 WL 4867370, at *4 (Ohio Ct. App. Nov. 24, 2010) (stating that in *Baze*, "the United States Supreme Court recognized a condemned prisoner's right to challenge the method of execution and adopted the appropriate standard to be applied in considering that challenge").

94 *Baze*, 553 U.S. at 47-50 (plurality opinion). For a discussion and criticism of these standards, see Ty Alper, *The Truth About Physician Participation in* ***LethalInjection*** *Executions*, 88 N.C. L. REV. 11, 14-16, 39-40 (2009); Eric Berger, *In Search of a Theory of Deference: The Eighth Amendment, Democratic Pedigree, and Constitutional Decision Making*, 88 WASH. U. L. REV. 1, 9-10, 24-25 (2010); **Deborah** W. **Denno**, *When Willie Francis Died: The ""Disturbing" Story Behind One of the Eighth Amendment's Most Enduring Standards of Risk*, *in* DEATH PENALTY STORIES 17, 89-93 (John H. Blume & Jordan M. Steiker eds., 2009); Nadia N. Sawicki, *"%7FThere Must Be a Means"--The Backward Jurisprudence of* Baze v. Rees, 12 U. PA. J. CONST. L. 1407, 1409-14 (2010); **Denno**, *supra* note 18, at 196-201.

95 *Baze*, 553 U.S. at 50 (quoting Helling v. McKinney, 509 U.S. 25, 33, 34-35 (1993)).

96 *See* **Denno**, *supra* note 89, at tbl.B.

97 *Id.* at 13-14.

98 *See*Morales v. Cate, 757 F. Supp. 2d 961, 969 (N.D. Cal. 2010) (noting that a prior California case found "that the execution team improperly mixed, prepared, and administered sodium thiopental during executions; that members of California's execution team were insufficiently qualified; that the IV team members were 'not adequately prepared to deal with any complications that may arise'; that the walk-throughs in which the execution team participated were incomplete, and the team did not receive meaningful training" (citations omitted) (quoting Morales v. Tilton, 465 F. Supp. 2d 972, 979-80 (N.D. Cal. 2006))).

99 Beaty v. Brewer, 791 F. Supp. 2d 678, 684-85 (D. Ariz. 2011); *see also*Campbell v. Wood, 18 F.3d 662, 687 (9th Cir. 1994) ("The risk of accident cannot and need not be eliminated from the execution process in order to survive constitutional review.").

100 *See***Denno**, *supra* note 89, at 10.

101 *See*Jackson v. Danberg, 656 F.3d 157, 163 (3d Cir. 2011) ("Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of "objectively intolerable risk of harm' that qualifies as cruel and unusual." (quoting Baze v. Rees, 553 U.S. 35, 50 (2008)) (internal quotation marks omitted)); Batiste v. State, 121 So. 3d 808, 873 (Miss. 2013) (finding that Mississippi's protocol was "substantially similar to Kentucky's protocol" and thus that an Eighth Amendment challenge was unfounded (quoting Chamberlin v. State, 55 So. 3d 1046, 1056 (Miss. 2010))).

102 *See*Pavatt v. Jones, 627 F.3d 1336, 1339-40 (10th Cir. 2010) (upholding a district court's finding that the state's use of pentobarbital in a **lethalinjection** protocol fell short of the level of risk that was needed to establish an Eighth Amendment claim); *see also Jackson*, 656 F.3d at 160 ("Delaware, along with a number of other states, revised its protocol to allow for the use of an alternative barbiturate, pentobarbital, as the first chemical to be administered."); Lucas v. Upton, No. 5:09-CV-289 (CAR), 2011 WL 4526754, at *4 n.3 (M.D. Ga. Sept. 28, 2011) ("Since confiscation of its supply of sodium thiopental, Georgia, as well as several other states, has started to use pentobarbital as the first drug in the three-step **lethalinjection** process."); State v. Santiago, 49 A.3d 566, 698 (Conn. 2012) (noting that "in light of recent developments that have seriously restricted the availability of sodium thiopental for use in executions, those death penalty jurisdictions that more actively implement death sentences have turned to pentobarbital as a substitute drug"); State v. Rizzo, 31 A.3d 1094, 1169 (Conn. 2011) (noting the shortage of thiopental sodium generally).

103 *See***Denno**, *supra* note 89, at 11.

104 *See id.* at tbl.B.

105 *See*Pardo v. Palmer, 500 F. App'x 901, 902-05 (11th Cir. 2012) (upholding a one-drug **lethalinjection** protocol); Cooey v. Strickland, 589 F.3d 210, 223-25 (6th Cir. 2009) (holding that the risk of improper implementation of Ohio's one-drug protocol did not violate the Eighth Amendment).

106 *See*Peterson v. State, 2 So. 3d 146, 156-57 (Fla. 2009) (finding that the plaintiff's argument "that Florida's **lethalinjection** process is unconstitutional because it employs a three-drug protocol that may cause undue pain" does not qualify as a substantial risk); Thomas v. State, No. W2008-01941-CCA-R3-PD, 2011 WL 675936, at *46-47 (Tenn. Crim. App. Feb. 23, 2011) (upholding a three-drug **lethalinjection** protocol).

107 *See*Grant v. Workman, No. 05-CV-0167-TCK-TLW, 2010 WL 5069853, at *39 (N.D. Okla. Dec. 2, 2010) (ruling against the plaintiff's argument that the state's **lethalinjection** protocol violates the Eighth Amendment because it creates a substantial risk of the inmate suffering intense pain due to the fact that "there is no assurance that Oklahoma's procedure will render him unconscious during the execution"); State v. Odom, No. W2008-02464-CCA-R3-DD, 2010 Tenn. Crim. App. LEXIS 223, at *103-07 (Tenn. Crim. App. Mar. 4, 2010) (ruling against the plaintiff's argument that the state's written protocol lacks safeguards and other written provisions and is thus unconstitutional).

108 *See*Harbison v. Little, 571 F.3d 531, 535-39 (6th Cir. 2009) (finding that the inmate failed to show that the protocol retained an inherent risk of severe pain, which was substantial compared to the alternatives).

109 *See, e.g.*, Batiste v. State, 121 So. 3d 808, 873 (Miss. 2013); *see also*Jackson v. Danberg, 656 F.3d 157, 163 (3d Cir. 2011) (affirming the district court's conclusion that the state's **lethalinjection** protocol was constitutional because it was found to be "substantially similar" to Kentucky's protocol); Emmett v. Johnson, 532 F.3d 291, 300 (4th Cir. 2008) (concluding that "Virginia's protocol is substantially similar to Kentucky's protocol" and that the plaintiff "failed as a matter of law to demonstrate a substantial or objectively intolerable risk that he will receive an inadequate dose of thiopental"); Brown v. Sec'y, Dep't of Corr., No. 8:01-cv-2374-T-23TGW, 2009 WL 4349320, at *21 (M.D. Fla. Nov. 25, 2009) (adopting "a trial court's analysis concluding that Florida's **lethal-injection** protocol is 'substantially similar' to that of Kentucky" (quoting Schwab v. State, 995 So. 2d 922, 924-33 (Fla. 2008))).

110 *See, e.g.*, Brewer v. Landrigan, 131 S. Ct. 445, 445 (2010) (ruling against a plaintiff who challenged the use of potentially non-FDA approved sodium thiopental); Kerr v. Thaler, 384 F. App'x 400, 405 (5th Cir. 2010) (citing *Baze* in holding that the use of pancuronium bromide in a three-drug **injection** method was not a violation of the Eighth Amendment).

111 *See***Denno**, *supra* note 89, at tbl.B.

112 *See Jackson*, 656 F.3d at 164 (noting that "each court to consider this issue has uniformly held that the use of pentobarbital in lieu of sodium thiopental is constitutional"); Creech v. Reinke, No. 1:12-cv-00173-EJL, 2012 WL 1995085, at *16-24 (D. Idaho June 4, 2012) (upholding a one-drug **lethalinjection** protocol using pentobarbital); Beaty v. Brewer, 791 F. Supp. 2d 678, 681-86 (D. Ariz. 2011) (holding that the inmate failed to establish a likelihood of success in his claim that the state's last-minute substitution of pentobarbital for sodium thiopental violated the Eighth Amendment); Valle v. State, 70 So. 3d 530, 538-53 (Fla. 2011) (upholding the use of pentobarbital in the state's three-drug **lethalinjection** method); *see also*DeYoung v. Owens, 646 F.3d 1319, 1327 (11th Cir. 2011) (holding that use of pentobarbital does not violate the Eighth Amendment); Powell v. Thomas, 641 F.3d 1255, 1257-58 (11th Cir. 2011) (approving the substitution of pentobarbital for sodium thiopental).

113 *See infra* notes 181-82 and accompanying text.

114 *See***Denno**, *supra* note 89, at 8.

115 *See*Towery v. Brewer, No. CV-12-245-PHX-NVW, 2012 WL 592749, at *15 (D. Ariz. Feb. 23, 2012) (rejecting the plaintiffs' argument that use of foreign-obtained pancuronium bromide will subject them to a risk of pain and suffering because foreign-sourced drugs do not have FDA approval); *Valle*, 70 So. 3d at 546 (finding that the use of a potentially FDA-unapproved drug did not show that the modified procedure was "sure or very likely to cause serious illness and needless suffering or ... result in a substantial risk of serious harm").

116 *See*Cook v. FDA, 733 F.3d 1, 12 (D.C. Cir. 2013) (affirming the judgment from *Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), which permanently enjoined the FDA from allowing the importation of apparently misbranded or unapproved sodium thiopental based on the finding that the use of such drugs creates an unnecessary risk of improper anesthetization).

117 *See***Denno**, *supra* note 89, at tbl.A.

118 Wilson v. Ryker, 451 F. App'x 588, 589 (7th Cir. 2011).

119 Baze v. Rees, 553 U.S. 35, 50 (2008) (quoting Louisiana *ex rel.* Francis v. Resweber, 329 U.S. 459, 463 (1947)) (internal quotation marks omitted).

120 *See, e.g.*, Porter v. Cash, No. CV 11-10308-DMG (AGR), 2012 WL 5308369, at *3 (C.D. Cal. Sept. 20, 2012); Mitchell v. Cnty. of San Bernardino, No. CV 09-5531-SJO (AGR), 2011 WL 4801890, at *5 (C.D. Cal June 13, 2011); Wallace v. Moberg, No. CV 07-6-VAP (AGR), 2009 WL 91079, at *8 (C.D. Cal. Jan. 10, 2009).

121 *See*Betts v. New Castle Youth Dev. Ctr., 621 F.3d 249, 252-61 (3d Cir. 2010) (presenting a case in which a delinquent juvenile brings an Eighth Amendment failure-to-protect challenge against a youth development center for a spinal injury that occurred during a "pick-up" football game at the center).

122 Prison-condition and violence cases have, in the past, been justifications for dismissing execution-methods claims. *See***Denno**, *Getting to Death*, *supra* note 1, at 327-48.

123 *See***Denno**, *supra* note 89, at 18.

124 *See id.* at tbl.A.

125 *See id.*

126 Baze v. Rees, 553 U.S. 35, 94 (2008) (Thomas, J., concurring).

127 *See*Jackson v. Danberg, 594 F.3d 210, 222-23 (3d Cir. 2010); *see also*Brown v. Sec'y, Dep't of Corr., No. 8:01-cv-2374-T-23TGW, 2009 WL 4349320, at *20 (M.D. Fla. 2009) (explaining that Justice Thomas "renounced any risk-based standard in favor of a rule of law that would uphold any method of execution which does not involve the *purposeful* infliction of 'pain and suffering beyond that necessary to cause death'" (emphasis added) (quoting *Baze*, 553 U.S. at 96 (Thomas, J., concurring))).

128 *See***Denno**, *supra* note 89, at 18.

129 Ventura v. State, 2 So. 3d 194, 200 (Fla. 2009) (discussing the variety of opinions in *Baze* and noting that it believes Florida's protocol would meet all the risk-based standards mentioned by the *Baze* Court).

130 *See***Denno**, *supra* note 89, at tbl.A.

131 *See Baze*, 553 U.S. at 78-86 (Stevens, J., concurring).

132 For example, Justice Stevens observed the problems with the way capital punishment is actually implemented and the paradoxical result that "more recent cases have endorsed procedures that provide less protections to capital defendants than to ordinary offenders." *Id.* at 84. In his eyes, capital punishment is the "product of habit and inattention rather than an acceptable deliberative process that weighs the costs and risks of administering that penalty against its identifiable benefits." *Id.* at 78. Therefore, the punishment "represents 'the pointless and needless extinction of life with only marginal contributions to any discernible social or public purposes.'" *Id.* at 86 (quoting Furman v. Georgia, 408 U.S. 238, 312 (1972) (White, J., concurring)).

133 *See In re* Noling, 651 F.3d 573, 576 (6th Cir. 2011) ("In *Baze v. Rees*, Justice Stevens brings to mind the fact that many innocent people are convicted of crimes they did not commit before being vindicated by the timely revelation of exculpatory facts. Some of those people are capital defendants." (citation omitted)); People v. Runge, 917 N.E.2d 940, 998 (Ill. 2009) (Burke, J., dissenting) (noting that the "risk of error in capital cases may be greater than in other cases because the facts are often so disturbing" (quoting *Baze*, 553 U.S. at 84 (Stevens, J., concurring)) (internal quotation marks omitted)).

134 *See*Jackson v. Danberg, 594 F.3d 210, 218 (3d Cir. 2010) (noting that "the imposition of the death penalty represents the pointless and needless extinction of life with only marginal contributions to any discernible social or public purposes" (quoting *Baze*, 553 U.S. at 86 (Stevens, J., concurring)) (internal quotation mark omitted)); Brown v. Sec'y, Dep't of Corr., No. 8:01-cv-2374-T-23TGW, 2009 WL 4349320, at *20 (M.D. Fla. 2009) (citing Justice Stevens's "general disagreement with ... the death penalty").

135 *See Baze*, 553 U.S. at 119-21 (Ginsburg, J., dissenting).

136 *Id.* at 117.

137 *See***Denno**, *supra* note 89, at tbl.A.

138 *See*Henyard v. Sec'y, Dep't of Corr., 543 F.3d 644, 648 (11th Cir. 2008) (citing to the finding by Justice Ginsberg that revisions to Florida's **lethalinjection** protocols provide additional safeguards in comparison to Kentucky's protocols); Chester v. Wetzel, No. 1:08-cv-1261, 2012 WL 5439054, at *11 (M.D. Penn. Nov. 6, 2012) ("Justice Ginsburg noted that Kentucky's protocol did not require anyone to call the inmate's name, shake the inmate, brush his eyelashes, or apply noxious stimulus to gauge his response .... [S]uch a consciousness check could be easily implemented and could reduce the risk of dreadful pain.").

139 *See***Denno**, *supra* note 89, at tbl.A; *see, e.g.*, Hartman v. Bobby, 319 F. App'x. 370, 372 n.1 (6th Cir. 2009) (stating that the court "cannot authorize a successive petition or grant a stay on this ground, because the Supreme Court's decision in *Baze* did not create a new constitutional right that applies retroactively"); Alba v. Quarterman, 621 F. Supp. 2d 396, 432 (E.D. Tex. 2008) (citing *Baze* to state that **lethalinjection** is a constitutionally permissible form of execution); Fields v. Commonwealth, 274 S.W.3d 375, 420 (Ky. 2008) (citing *Baze* to support the statement that "[**l**]**ethalinjection** is not cruel and unusual punishment"); *see also*Thompson v. Bell, 580 F.3d 423, 448 (6th Cir. 2009) (Suhrheinrich, J., concurring); Scott v. Houk, No. 4:07-CV-0753,

2011 WL 5838195, at *45-46 (N.D. Ohio Nov. 18, 2011); Riley v. McDaniel, No. 3:01-cv-0096-RCJ-VPC, 2010 WL 3786070, at *59 (D. Nev. Sept. 20, 2010).

140 *See*Trinidad y Garcia v. Thomas, 683 F.3d 952, 964 (9th Cir. 2012) (citing *Baze* in support of the statement that "the Constitution guarantees an individual a broad range of 'rights, privileges, and immunities' against the United States government, including the right to be free from torture" (quoting Neely v. Henkel, 180 U.S. 109, 122-23 (1901))).

141 No. 2:09-cv-823, 2010 WL 3447741, at *2 (S.D. Ohio Aug. 27, 2010) (stating that "a series of abortive execution attempts could potentially indeed present an unconstitutional violation").

142 No. 04CR065940, 2008 WL 2784679, at *1, *9 (Ohio Ct. Com. Pl. June 10, 2008).

143 *See id* at *1. The two doctors were Mark Heath, M.D., for the defense and Mark Dershwitz, M.D., for the government. *See* Susi Vassallo, *Thiopental in* ***LethalInjection***, 35 FORDHAM URB. L.J. 957, 958-59 (2008).

144 *Rivera*, 2008 WL 2784679, at *6.

145 *Id* at *9.

146 *See id* at *3-4.

147 *Id* at *4.

148 OHIO REV. CODE ANN. § 2949.22(A) (LexisNexis 2006). The *Rivera* court emphasized that the statute's purpose "is to provide the condemned person with an execution that is 'quick' and 'painless;' and the legislature's use of the word, 'shall,' when qualifying the state's duty to provide a quick and painless death signifies that the duty is mandatory." *Rivera*, 2008 WL 2784679, at *5. Because "the duty of the state to the individual is mandatory, a property interest is created in the benefit"; the statute confers on the condemned person a property interest in a painless death. *Id.* For the state to then execute the condemned person in a manner that carries an "unnecessary risk of pain, and, as well, any unnecessary expectation by the condemned person that his execution may be agonizing, or excruciatingly painful," *id.* at *7, violates the Due Process Clause of the Fifth and Fourteenth Amendments. *Id.* at *8. As a result, the *Rivera* court held that "the words, 'or combination of drugs,' may be severed" from the Ohio statute in light of the court's ruling that only one anesthetic drug be employed. *Id.* at *9.

149 *Rivera*, 2008 WL 2784679, at *7 (alteration in original).

150 *Id.* at *9 (quoting Baze v. Rees, 553 U.S. 35, 47 (2008) (plurality opinion)).

151 *See* Adam Liptak & Adam B. Ellick, *Judge Orders Ohio to Alter Its Method of Execution*, N.Y. TIMES, June 11, 2008, http://www.nytimes.com/2008/06/11/us/11death.html.

152 *Baze*, 553 U.S. at 41 (plurality opinion).

153 415 F. Supp. 2d 1037 (N.D. Cal. 2006), *aff'd per curiam*, 438 F.3d 926 (9th Cir. 2006).

154 *See***Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 102-17.

155 *See Death Penalty: States Transition to One-Drug Executions*, PBS NEWSHOUR (July 19, 2012, 6:56 PM), http://www.pbs.org/newshour/rundown/2012/07/death-penalty-states-transition-to-onedrugexecutions.html.

156 *See* Atul Gawande, *When Law and Ethics Collide--Why Physicians Participate in Executions*, 354 NEW ENG. J. MED. 1221, 1229 (2006).

157 *See***Denno**, *supra* note 18, at 202-04.

158 *See generally***Denno**, *When Legislatures Delegate*, *supra* note 1 (discussing the extent to which legislatures delegate the execution process to departments of corrections, which are typically not in a position to handle such responsibility).

159 *See*State v. Broom, No. 96747, 2012 WL 504504, at *1 (Ohio Ct. App. Feb. 16, 2012). All executions in Ohio are conducted at the Southern Ohio Correctional Facility in Lucasville, Ohio. *See id.* In 2007, a nearly two-hour execution of an Ohio prisoner

who appeared to be suffocated alive followed a comparably controversial ninety-minute execution a year earlier that had compelled the state to revise its procedures. *See id.* at *8. Yet, those revisions did not take hold. On September 15, 2009, Romell Broom would undergo one of the most egregious efforts by any department of corrections to attempt to **inject** an inmate to death, even though he would be the first inmate ever to survive a **lethalinjection** procedure. *See id.* at *1, *7. For over two hours, Broom withstood nearly twenty "puncture wounds," as the execution team made ""numerous, unsuccessful" attempts to search for a viable vein that would not collapse when drugs were **injected**. *Id.* at *1. During this time, the team took breaks, changed execution strategies, probed different access sites on Broom's body, as well as garnered the direct assistance of a staff doctor who was not part of the team. *See id.* After the first forty-five minutes of the execution process, for example, the prison director ordered the team to stop so that they could confer about what to do because nothing was working. *See id.* Ten-to-twenty minutes later, the team reconvened to try to establish an intravenous line (IV) in Broom's biceps, forearms, and hands. When this strategy failed, they called upon the staff doctor to try something else. That doctor unsuccessfully attempted to insert the IV catheters on top of Broom's foot and ankle bone, an excruciating experience for Broom who claimed that the needle entered his ankle bone. *See id.* Ultimately, the execution was halted, and Broom remains alive, awaiting the possibility of a second execution attempt. *See* Josh Sanburn, *Ohio's Grisly Execution History*, TIME (Jan. 17, 2014), http:// nation.time.com/2014/01/17/ohios-grisly-executionhistory/.

160 *See* Ariane de Vogue & Dennis Powell, *Ohio Killer Executed in First Use of Single-Drug **LethalInjection***, ABC NEWS (Dec. 8, 2009), http:// abcnews.go.com/Politics/**lethal-injection**-ohio-performexecutionsingle-drug/story?id_9277599 (describing the use of an untested, single-drug formula).

161 *See*Cooey v. Strickland, 604 F.3d 939, 942-43 (6th Cir. 2010).

162 *See* de Vogue & Powell, *supra* note 160.

163 *See Cooey*, 604 F.3d at 943.

164 *See***Deborah** W. **Denno**, *Ohio's Perverse First Place*, HUFFINGTON POST (Dec. 9, 2009), http:// www.huffingtonpost.com/**deborah**-w-**denno**/ohios-perverse-first-plac_b_385808.html; Andrew Welsh-Huggins, *States: Death-Penalty Drug Scramble, Higher Cost*, BLOOMBERG BUS. WEEK (July 9, 2011, 2:14 PM), http:// www.businessweek.com/ap/financialnews/D9OC9L100.htm.

165 *See* Cooey v. Strickland, No. 2:04-cv-1156, 2009 U.S. Dist. LEXIS 122025, at *225-26 (S.D. Ohio Dec. 7, 2009) (testimony of Mark Heath, M.D.).

166 *See*OHIO REV. CODE ANN. § 4729.532 (LexisNexis 2013).

167 *See* Aaron Marshall, *Kenneth Biros Becomes First Inmate Executed Using Single-Drug Method*, CLEVELAND.COM (Dec. 8, 2009, 6:10 PM), http:// blog.cleveland.com/metro/2009/12/biros_becomes_first_inmate_exe.html.

168 For detailed examinations of these trends, see generally **Denno**, *Getting to Death*, *supra* note 1; **Denno**, ***LethalInjection*** *Quandary*, *supra* note 1; **Denno**, *When Legislatures Delegate*, *supra* note 1.

169 *See supra* Charts 3 & 4.

a1 Information for this chart reflects trends up to August 1, 2013 and comes from the following sources: *State by State **LethalInjection***, DEATH PENALTY INFO. CENTER, http://www.deathpenalty.org/state-**lethal-injection** (last visited Jan. 31, 2014); Death Penalty Clinic. Univ of Cal., Berkeley, Sch. of Law, *Execution Protocol Information*, LETHALINJECTION.ORG, https:// www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html (last visited Aug. 1, 2013).

170 *See supra* Charts 3 & 4.

171 *See supra* Charts 3 & 4.

172 As Franklin Circuit Judge Phillip Shepherd postulated, by moving to a one-drug protocol in Kentucky, "any claims of cruel and unusual punishment by the inmates 'will be rendered moot.'" *Ky. to Change Execution Method from 3 Drugs*, FOX NEWS (June 1, 2012), http://www.foxnews.com/us/2012/05/31/ky-to-change-execution-method-from-3-drugs/.

173 *See supra* note 155.

174 *See supra* note 155.

175 *Compare Execution List 2013*, DEATH PENALTY INFO. CENTER, http:// www.deathpenaltyinfo.org/execution-list-2013 (last visited Feb. 17, 2014), *with Execution List 2012*, DEATH PENALTY INFO. CENTER, http:// www.deathpenaltyinfo.org/execution-list-2012 (last visited Feb. 17, 2014).

176 *See*Cook v. FDA, 733 F.3d 1, 4 (D.C. Cir. 2013) ("In 2009 the last domestic manufacturer of thiopental stopped making it."); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-14-194, *supra* note 26, at 14 fig.4, 21; Kevin Sack, *Shortage of Widely Used Anesthetics Is Delaying Executions in Some States*, N.Y. TIMES, Sept. 30, 2010, http://www.nytimes.com/2010/09/30/us/30drug.html.

177 *See* Dominic Casciani, *US* ***LethalInjection*** *Drug Faces UK Export Restrictions*, BBC NEWS (Nov. 29, 2010, 13:47), http:// www.bbc.co.uk/news/uk-11865881.

178 *See* Press Release, Hospira, Inc., Hospira Statement Regarding Pentothal™ (Sodium Thiopental) Market Exit (Jan. 21, 2011), *available at* http://phx.corporate-ir.net/phoenix.zhtml?c_175550&p_irol-newsArticle&ID_ 1518610&highlight.

179 *See id.*; Erik Eckholm & Katie Zezima, *States Face Shortage of Key* ***LethalInjection*** *Drug*, N.Y. TIMES, Jan. 22, 2011, www.nytimes.com/2011/01/22/us/22lethal.html.

180 *See* Makiko Kitamura & Adi Narayan, *Europe Pushes to Keep* ***LethalInjection*** *Drugs From U.S. Prisons*, BLOOMBERG BUSINESSWEEK (Feb. 7, 2013), www.businessweek.com/articles/2013-02-07/europe-pushes-to-keep-**lethal**-**injection**-drugs-from-u-dot-s-dot-prisons.

181 *See "****LethalInjection*** *Scramble" Map from ACLU of Northern California*, DEATH PENALTY INFO. CENTER, http://www.deathpenaltyinfo.org/**lethal**-**injection**-moratorium-executions-ends-after-supremecourtdecision (follow "'**LethalInjection** Scramble' map from ACLU of Northern California" hyperlink); *see also* Press Release, ACLU of N. Cal., CDCR Documents Reveal "Secret Mission" to Acquire **LethalInjection** Drug (Dec. 10, 2010), *available at* https:// www.aclunc.org/news/cdcr-documents-revealsecretmission-acquire-**lethal**-**injection**-drug (noting that documents from the California Department of Corrections and Rehabilitation revealed "a global search for [**lethalinjection**] drugs in places as far-flung as Pakistan").

182 *See "****LethalInjection*** *Scramble" Map from ACLU of Northern California*, *supra* note 181.

183 *See*Beaty v. FDA, 853 F. Supp. 2d 30, 36-37 (D.D.C. 2012).

184 *See supra* note 10 and accompanying text.

185 *See***Denno**, *supra* note 89, at tbl.B.

186 *See State by State* ***LethalInjection***, DEATH PENALTY INFO. CENTER, http://www.deathpenaltyinfo.org/state-**lethal**-**injection** (last visited Feb. 17, 2014). Arizona, Arkansas, California, Georgia, Nebraska, South Carolina, South Dakota, and Tennessee received letters from the FDA in April 2012 requesting the relinquishment of foreign-sourced sodium thiopental, in accordance with the U.S. district court's ruling in *Beaty v. FDA*. *See id.* Alabama, Georgia, Kentucky, South Carolina, and Tennessee had foreign-sourced sodium thiopental seized by the DEA in March or April 2011. *See id.* Arkansas turned over its foreign-sourced sodium thiopental to the DEA in July 2011. *See id.* Both *Beaty* and *Cook* list Arizona, Arkansas, California, Georgia, South Carolina, and Tennessee as states that received shipments of sodium thiopental from the United Kingdom pharmaceutical company, Dream Pharma Ltd. *See*Cook v. FDA, 733 F.3d 1, 4 (D.C. Cir. 2013); *Beaty*, 853 F. Supp. 2d at 34-35. For further discussion of these cases, see *infra* notes 187-88 and accompanying text.

187 853 F. Supp. 2d at 32, 37, 41-43.

188 733 F.3d at 12. The court did, however, reverse another portion of the lower court's order and enabled departments of corrections to retain the sodium thiopental that they already had in their possession. *See id.*

189 *See supra* Charts 3 & 4.

190 *See Execution List 2012*, *supra* note 175; *Execution List 2013*, *supra* note 175.

191 *See* Robert Boczkiewicz, *Appeals Court Rejects Convicted Killer's Challenge to Oklahoma Execution Method*, NEWSOK (Dec. 15, 2010), http:// newsok.com/court-rejects-convicted-killers-challengetooklahoma-execution-method/article/3523770.

192 *See* Mears, *supra* note 29; Rob Stein, *Ohio Executes Inmate Using New, Single-Drug Method for Death Penalty*, WASH. POST (March 11, 2011), http:// www.washingtonpost.com/wp-dyn/content/article/2011/03/10/AR2011031006250_ pf.html.

193 *See supra* Charts 3 & 4.

194 *See supra* Charts 3 & 4.

195 *See, e.g.*, Arthur v. Thomas, 674 F.3d 1257, 1259 (11th Cir. 2012); Jackson v. Danberg, 656 F.3d 157, 162 (3d Cir. 2011); DeYoung v. Owens, 646 F.3d 1319, 1322 (11th Cir. 2011); Powell v. Thomas, 643 F.3d 1300, 1301-02 (11th Cir. 2011); Pavatt v. Jones, 627 F.3d 1336, 1337-38 (10th Cir. 2010); Valle v. State, 70 So. 3d 530, 538 (Fla. 2011); Verified Complaint at 3, Blankenship v. Owens, No. 2011cv202236 (Ga. Super. Ct. June 20, 2011); *see also* cases cited *supra* note 112; David Beasley, *Georgia Executes Man for 1978 Rape and Murder*, REUTERS (June 23, 2011, 9:11 PM), http://www.reuters.com/article/2011/06/24/us-execution-georgia-idUSTRE75N06P20110624 ("The Georgia Supreme Court late Thursday unanimously rejected Blankenship's last-minute request for a stay, including his claim that using pentobarbital in the execution would cause undue pain and suffering.").

196 *See, e.g.*, *Arthur*, 674 F.3d at 1259 (noting plaintiff's allegations that "pentobarbital takes substantially longer to render an inmate fully insensate than sodium thiopental and, as a result of this delayed effect, there is a significant risk that Alabama administers the second and third drugs in its **lethalinjection** procedure before pentobarbital has taken effect," constituting cruel and unusual punishment).

197 *See id.* at 1266-67 (Hull, J., dissenting) (quoting anesthesiologists' declarations that pentobarbital "is not approved by the FDA as an anesthesia induction agent," that "there is no scientific literature establishing the anesthetic dose of pentobarbital," and that "[t]he switch to pentobarbital, for which there is no clinical knowledge regarding its effects on human beings when rapidly administered in high dosages to a conscious person, combined with the use of pancuronium bromide and potassium chloride, confers a substantial risk of an excruciating and agonizing death process" (alteration in original) (internal quotation marks omitted)).

198 *See Arthur*, 674 F.3d at 1259 ("Arthur alleges that pentobarbital takes substantially longer to render an inmate fully insensate than sodium thiopental and, as a result of this delayed effect, there is a significant risk that Alabama administers the second and third drugs in its **lethalinjection** procedure before pentobarbital has taken effect."); *Jackson*, 656 F.3d at 162-63 (finding that the district court "did not abuse its discretion in denying Plaintiffs' motion for a stay" based on Plaintiffs' allegations that the use of pentobarbital violates the Eighth Amendment); *DeYoung*, 646 F.3d at 1327 ("DeYoung has wholly failed to show that pentobarbital, once fully administered and allowed to act, is ineffective as an anesthetic."); *Powell*, 643 F.3d at 1304 (rejecting plaintiff's argument that the "change from sodium thiopental to pentobarbital[] is a substantial or significant change in the **lethalinjection** protocol"); *Pavatt*, 627 F.3d at 1339-40 (upholding the district court's denial of a stay of execution based on inmate's failure to "establish a substantial likelihood of success on the merits of his Eighth Amendment challenge to the ... revised protocol" calling for the use of pentobarbital); *Valle*, 70 So. 3d at 538 (rejecting plaintiff's argument that the "use [of] pentobarbital constitutes cruel and unusual punishment because as a result of the substitution, he may remain conscious after being **injected** with pentobarbital, thereby subjecting him to significant pain during the administration of the final two drugs"); Verified Complaint, *supra* note 195, at 3 ("The administration of these drugs, particularly including Pentobarbital, a drug which has not been tested for induction of anesthetic coma in humans, by unqualified and untrained individuals creates a substantial risk of a botched and inhumane execution." (footnote omitted)).

199 *See Valle*, 70 So. 3d at 542.

200 *See* Press Release, H. Lundbeck A/S, Lundbeck Overhauls Pentobarbital Distribution Program to Restrict Misuse (July 1, 2011), *available at* http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=605775; Letter from Staffan Schüberg, President, H. Lundbeck A/S, to Gary C. Mohr, Dir., Dep't of Rehab. and Corr., Columbus, Ohio (Jan. 26, 2011),

available at http:// www.deathpenaltyinfo.org/documents/LundbeckLethInj.pdf; *Activities: Human Rights*, LUNDBECK, http://www.lundbeck.com/global/corporate-responsib/report/activities/human-rights (last updated Feb. 6, 2014).

201 Kitamura & Narayan, *supra* note 180; *see* David Jolly, *Danish Company Blocks Sale of Drug for U.S. Executions*, N.Y. TIMES (July 1, 2011), http:// www.nytimes.com/2011/07/02/world/europe/02execute.html; Press Release, H. Lundbeck A/S, *supra* note 200.

202 *See* Leonard, *supra* note 28; ***LethalInjection***, DEATH PENALTY INFO. CENTER, http:// www.deathpenaltyinfo.org/**lethal**-**injection**-moratorium-executions-ends-after-supreme-court-decision (last visited Feb. 18, 2014).

203 *See* Leonard, *supra* note 28 ("[T]hough some states may soon run out [of pentobarbital,] ... the drug could expire. Like most pharmaceuticals, pentobarbital has an expiration date of about 18 months.").

204 *See supra* notes 195-99 and accompanying text.

205 *See* Rachel Quigley, *'He Suffered Greatly': Medical Expert Describes How Prisoner Thrashed Desperately During 'Botched' Execution with New Drug*, DAILY MAIL ONLINE (June 30, 2011, 10:53 EST), http:// www.dailymail.co.uk/news/article-2009873/He-suffered-greatly-Medical-expertdescribesprisoner-thrashed-desperately-botched-execution-new-drug.html.

206 *See* Rhonda Cook, *DeYoung Executed with Videographer Documenting His Death*, ATLANTA J. CONST. (July 22, 2011, 7:46 AM), http:// www.ajc.com/news/news/local/deyoung-executed-withvideographerdocumenting-his/nQJq5/; *see also***Deborah** W. **Denno**, *Should Executions Be Televised?*, ENCYCLOPAEDIA BRITANNICA BLOG (Aug. 16, 2011), http:// www.britannica.com/blogs/2011/08/shouldexecutionsbe-televised/ (discussing the history of televised executions).

207 *See* Dan Morain, *Witness to the Execution: A Macabre, Surreal Event*, L.A. TIMES (Apr. 22, 1992), http:// articles.latimes.com/1992-04-22/news/mn-509_ 1_gas-chamber.

208 *See* ***LethalInjection****: Missouri Intends to Use Propofol in One-Drug* ***LethalInjection***, DEATH PENALTY INFO. CENTER, http:// www.deathpenaltyinfo.org/**lethal**-**injection**-missouri-intends-use-propofolonedrug-**lethal**-**injection** (last visited Feb. 18, 2014).

209 *See* Jim Salter, *Missouri Opts for Untested Drug for Executions*, ASSOCIATED PRESS, May 24, 2012, *available at* http:// bigstory.ap.org/content/missouri-opts-untested-drug-executions-1 ("Litigation over Missouri's new protocol is possible. Attorneys for death row inmates told The Associated Press that they are still gathering information on the new process and no decision has been made on whether to seek an injunction.").

210 *See* Juliette Jowit, *UK to Ban Export of Drug Approved for Use in US Executions*, GUARDIAN (July 10, 2012, 15:00 EDT), http:// www.guardian.co.uk/world/2012/jul/10/uk-ban-export-drug-usexecutions.

211 *See* Letter from Scott Meacham, Exec. Vice President & Chief Commercial Officer, Fresenius Kabi USA, LLC, to Healthcare Provider (Aug. 28, 2012), *available at* http:// deathpenaltyinfo.org/documents/FreseniusPropofolStatement.pdf; *Another Manufacturer Blocks Propofol for Execution Use*, USA TODAY (Sept. 27, 2012, 3:53 PM), http://www.usatoday.com/story/money/business/2012/09/27/manufacturer-blocks-proprofol-execution-use/1598109/.

212 *See supra* notes 177-80 and accompanying text.

213 *See State by State* ***LethalInjection***, *supra* note 186.

214 *See* Press Release, Hikma Pharm. PLC, Hikma Pharmaceuticals Strongly Objects to the Use of Its Products in Capital Punishment (May 15, 2013), *available at* http://www.hikma.com/en/mediacenter/news-and-press-releases/all-news/2013/15-05-2013.aspx; Jeannie Nuss, *Arkansas Turns to Different* ***LethalInjection*** *Drug*, YAHOO NEWS (Apr. 19, 2013, 7:18 PM), http:// news.yahoo.com/arkansas-turnsdifferentlethal-**injection**-drug-214639034.html.

215 *See* Press Release, Hikma Pharm. PLC, *supra* note 214.

216 *See* Nuss, *supra* note 214.

217 *See id.*

218 *See* Death Penalty Clinic, Univ. of Cal., Berkeley, Sch. of Law, *Execution Protocol Information*, LETHALINJECTION.ORG, https:// www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html (last visited Aug. 1, 2013).

219 *See* Jeannie Nuss, *Dustin McDaniel: Options 'Limited' for Future of Arkansas Death Penalty*, ARK. BUS. (July 25, 2013, 7:13 AM), http:// www.arkansasbusiness.com/article/93707/dustin-mcdanieloptionslimited-for-future-of-arkansas-death-penalty?page_all.

220 *See supra* Part III.

221 *See* Tim Hoover, *Wanted: Execution Drug*, DENVER POST, Mar. 13, 2013, at A4; Ariane de Vogue, *Drug Shortage Disrupts Lethal-Injection Mix*, ABC NEWS (Mar. 16, 2011), http://abcnews.go.com/Politics/death-penalty-drug-shortage-disrupts-execution-lethal-injection/story?id_13148874; *State by State LethalInjection*, *supra* note 186.

222 *See supra* notes 30-33 and accompanying text.

223 *See supra* Part III.

224 *See supra* notes 31-33 and accompanying text.

225 *See* Boodoo, *supra* note 32, at 232-34.

226 *See The Special Risks of Pharmacy Compounding*, FDA 1 (Dec. 2012), http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM107839.pdf.

227 *See id.*

228 *See*DAVID L. COWEN & WILLIAM H. HELFAND, PHARMACY: AN ILLUSTRATED HISTORY 186 (1990).

229 *See id.*

230 *See* Boodoo, *supra* note 32, at 222.

231 Hinkley, *supra* note 37, at 23.

232 *Id.*

233 *See supra* note 226; *Pharmacy Compounding and the FDA: Questions and Answers*, FDA, http:// www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764 (last updated Dec. 2, 2013); *see also Accreditation Council for Pharmacy Educ., Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*, ACCREDITATION COUNCIL FOR PHARMACY EDUCATION app. D, at xxii (2011), https://www.acpe-accredit.org/pdf/finals2007Guidelines2.0.pdf (listing compounding as a competency that pharmacy students should achieve before entering advanced pharmacy practice experiences).

234 *See State Regulation of Compounding Pharmacies*, *supra* note 37.

235 *See Licensure Transfer*, NAT'L ASS'N BOARDS PHARMACY, http:// www.nabp.net/programs/licensure/licensure-transfer (last visited Feb. 18, 2014) (noting that each state board of pharmacy provides its own set of requirements that a prospective pharmacist must meet before a license is issued and providing a link to each state board of pharmacy for further information on their requirements).

236 *See*SCOTT GIBERSON ET AL., IMPROVING PATIENT AND HEALTH SYSTEM OUTCOMES THROUGH ADVANCED PHARMACY PRACTICE: A REPORT TO THE U.S. SURGEON GENERAL 26 (2011). In New York State, for example, part III of the pharmacist licensing examinations is a written and practical examination in which the pharmacist must complete written math compounding components as well as hands-on drug compounding components. *See License Requirements*, N.Y. ST. EDUC. DEP'T, http://www.op.nysed.gov/prof/pharm/pharmlic.htm#exam (last visited July 15, 2013).

237 *See* Alicia Gallegos, *Physicians Entangled in Tainted Drugs Lawsuits*, AM. MED. NEWS (Feb. 11, 2013), http://www.amednews.com/article/20130211/profession/130219977/2.

238 *See* Jennifer Gudeman et al., *Potential Risks of Pharmacy Compounding*, 13 DRUGS R&D 1, 6 (2012), *available at* http://link.springer.com/article/10.1007%2Fs40268-013-0005-9.

239 *See Pharmacy Compounding and the FDA: Questions and Answers*, *supra* note 233 ("Compounded drugs are not FDA-approved. This means that FDA does not verify the quality, safety and effectiveness of compounded drugs.").

240 Gallegos, *supra* note 237.

241 *See id.*

242 *See*OFFICE OF REP. EDWARD J. MARKEY, *supra* note 33, at 5.

243 *See* FDA, COMPLIANCE POLICY GUIDES MANUAL § 460.200 (2002) (reissuing the compliance guide concerning pharmacy compounding, which was originally issued in 1992).

244 *See*OFFICE OF REP. EDWARD J. MARKEY, *supra* note 33, at 5.

245 *See*S. REP. NO. 105-43, at 67 (1997).

246 Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 127, 111 Stat. 2296, 2328 (1997).

247 *See id.*

248 *Id.* at 2328-29.

249 *See id.* at 2328-30.

250 *See* Jessica Dye, *Senate Committee Advances Drug Compounding Bill*, REUTERS (May 22, 2013), http://www.reuters.com/article/2013/05/22/us-fda-drugs-legislation-idUSBRE94L1AU20130522.

251 *See*H.R. REP. NO. 105-399, at 94 (1997) (Conf. Rep.).

252 *See*STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 7.

253 *See FDA's Electronic Reading Room--Warning Letters*, FDA, http:// www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm (search "To find specific Warning Letters" for "Compounding Pharmacy") (last visited July 19, 2013) (listing states that have received warning letters, including Alabama, Arizona, Arkansas, California, Connecticut, Florida, Idaho, Illinois, Indiana, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, Virginia, and Wyoming); *see also*OFFICE OF REP. EDWARD J. MARKEY, *supra* note 33, app. A, at 19 (listing a detailed timeline of media reports and FDA enforcement actions on compounding pharmacies).

254 *See*JANET HEINRICH, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-195T, PRESCRIPTION DRUGS: STATE AND FEDERAL OVERSIGHT OF DRUG COMPOUNDING BY PHARMACIES 5 (2003).

255 *See Report: Limited FDA Survey of Compounded Drug Products*, FDA, http:// www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155725.htm (last visited July 19, 2013).

256 *See 2006 Limited FDA Survey of Compounded Drug Products*, FDA, http:// www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm204237.htm (last visited July 19, 2013).

257 *See*STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 8.

258 *See* Reid Paul, *New Bill on Pharmacy Compounding Stirs Concern*, MOD. MED. (Apr. 2, 2007), http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-featurearticles/new-bill-pharmacy-compounding-stirs.

259 *Multi-State Meningitis Outbreak--Current Case Count*, *supra* note 34. For more information on the meningitis outbreak and the continually developing outcomes, see Gottlieb, *Compounding a Crisis at FDA*, *supra* note 34.

260 *See*STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 10; *see also supra* note 34 and accompanying text.

261 *Summary: 2013 FDA Pharmacy Inspection Assignment*, *supra* note 35.

262 Hamburg, *supra* note 35. In her post, Dr. Margaret A. Hamburg, the commissioner of the U.S. Food and Drug Administration (FDA), linked the summary of the 2013 FDA pharmacy inspection assignment to reference the inspections conducted. *See id.* Reportedly, the FDA used "highly-skilled, certified drug investigators who have specialized experience and specific training to evaluate pharmaceutical production and determine a firm's compliance with sterile production standards." *Summary: 2013 FDA Pharmacy Inspection Assignment*, *supra* note 35. In the inspections, investigators observed "the production environment, equipment used to make the drugs, the design of the facility, and personnel practices and behavior." *Id.* The FDA also interviewed the technicians who worked at each pharmacy to learn about the operations, standard operating procedures, and products as well as the effectiveness of any sterilization methods and drug stability programs. If necessary, investigators collected samples of abnormalities and compliance failures. *See id.*

263 *See*STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 2-3.

264 *See* Pollack, *supra* note 37.

265 *See* Hinkley, *supra* note 37, at 22, 23; *State Regulation of Compounding Pharmacies*, *supra* note 37.

266 *See State Regulation of Compounding Pharmacies*, *supra* note 37.

267 *Id.*; *see also* Hinkley, *supra* note 37.

268 High-risk sterile compounding is termed as such because the practice involves drug products that require a heightened level of unique safeguards during compounding to prevent injury or death to patients who receive them. *See*HEINRICH, *supra* note 254, at 3. "[S]terile compounding requires cleaner facilities than nonsterile compounding, as well as specific training for pharmacy personnel and testing of the compounded drug for sterility." *Id.* Despite the many similarities among the bills, they do vary in several important areas, including their definitions of true compounding and the requirements needed to satisfy that classification.

269 *See* S. 959, 113th Cong. (2013).

270 *Id.* § 2.

271 *See* Memorandum from the House Comm. on Energy & Commerce Democratic Staff to the House Comm. on Energy & Commerce Democratic Members & Staff, Subcomm. on Health (July 15, 2013) [hereinafter Memorandum from the House Comm.], *available at* http:// democrats.energycommerce.house.gov/sites/default/files/documents/Memo-Health-Drug-Compounding-Reform-2013-7-15-pdf.

272 *See* Press Release, U.S. Senate Comm. on Health, Educ., Labor, & Pensions, Senate Health Committee Passes Alexander and Colleagues' Bill to Fix Responsibility for Safety of Sterile Compounded Drugs (May 22, 2013), *available at* http:// www.help.senate.gov/newsroom/press/release/?id_63b96a98-9b19-4c5f-8a6f-b0df57afe138.

273 *See* Dye, *supra* note 250; Press Release, U.S. Senate Comm. on Health, Educ., Labor, & Pensions, *supra* note 272.

274 Press Release, Senate Comm. on Health, Educ., Labor, & Pensions, Health Committee Leaders Urge Senate Vote on Compounding Legislation "to Prevent Further Tragedies" (June 9, 2013), *available at* http:// www.help.senate.gov/newsroom/press/release/?id_c57674f7-e3cf-4d1c-a119-7d3cabd78013.

275 *See* Verifying Authority and Legality in Drug (VALID) Compounding Act of 2013, H.R. 2186, 113th Cong. (2013).

276 *Id.*

277 *See* Memorandum from the House Comm., *supra* note 271.

278 As defined by the VALID Compounding Act, "'high-risk sterile compounding' means compounding sterile drug products using nonsterile ingredients, nonsterile devices, or nonsterile components." H.R. 2186 § 2.

279 *See* H.R. 2186; *Updated House Bill Would Require FDA to Regulate Pharmacies Involved in High-Risk Compounding and Interstate Commerce*, NAT'L ASS'N BOARDS PHARMACY (June 5, 2013), http://www.nabp.net/news/updated-house-bill-would-require-fda-to-regulate-pharmacies-involved-inhighrisk-compounding-and-interstate-commerce.

280 *See* H.R. 2186.

281 *Id.* § 2.

282 *See* Compounding Clarity Act, H.R. 3089, 113th Cong. (2013), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-113hr3089ih/pdf/BILLS-113hr3089ih.pdf.

283 *See id.*

284 *See id.*

285 *See* Memorandum from the House Comm., *supra* note 271.

286 *See* H.R. 2186.

287 *See* Memorandum from the House Comm., *supra* note 271.

288 *See Reforming the Drug Compounding Regulatory Framework: Hearing on H.R. 2186, H.R. 3089, and S. 959 Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 113th Cong. (2013).

289 *See id.* (statement of Carmen Catizone, Executive Director, National Association of Boards of Pharmacy).

290 *See id.* at 2, 4.

291 *See id.* at 3.

292 Drug Quality and Security Act of 2013, H.R. 3204, 113th Cong. (2013).

293 *See id.*

294 Press Release, Imprimis Pharmaceuticals Inc., Imprimis Optimistic After Congressional Passage of the Drug Quality and Security Act (Nov. 19, 2013), *available at* http://online.wsj.com/article/PRCO-20131119-905263.html? dsk=y.

295 *See* H.R. 3204.

296 *See id.*

297 *See id.*

298 *See id.*

299 *See* Press Release, Ranking Member Lamar Alexander, Senate Comm. on Health, Educ., Labor, and Pensions, HELP Committee Members Call for Senate Passage of Drug Quality and Security Act (Sept. 28, 2013), *available at* http://www.help.senate.gov/newsroom/press/release/?id_cce67150-6a23-454e-a60c-09643348c6e0; Sabrina Tavernise, *Bill on Drug Compounding Clears Congress a Year After a Meningitis Outbreak*, N.Y. TIMES, Nov. 19, 2013, at A15.

300 *See* Kevin Outterson, *The Drug Quality and Security Act--Mind the Gaps*, 370 NEW ENG. J. MED. 97, 97 (2014).

301 *See* H.R. 2186.

302 *See State by State* ***LethalInjection***, *supra* note 186.

303 *See id.*

304 *See supra* note 237 and accompanying text.

305 *See supra* notes 237-41 and accompanying text.

306 *See generally* **Denno**, ***LethalInjection*** *Quandary*, *supra* note 1.

307 *See* Verifying Authority and Legality In Drug Compounding Act of 2013, H.R. 2186, 113th Cong. (2013).

308 *See* **Denno**, *Getting to Death*, *supra* note 1, at 352-54, 385-86; **Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 94-95; **Denno**, *When Legislatures Delegate*, *supra* note 1, at 64 n.2.

309 *See* Press Release, Reprieve, South Dakota Carries Out Execution Using Contaminated Compounded Drugs (Oct. 17, 2012), http:// www.reprieve.org.uk/press/2012_10_17_compound_pharmacy_death_penalty/; *State by State* ***LethalInjection***, *supra* note 186.

310 *See* Press Release, Reprieve, South Dakota Covers Up Source of 'DIY' Death Penalty Drugs Ahead of Execution (Oct. 30, 2012), *available at* http:// www.reprieve.org.uk/press/2012_10_30_South_Dakota_execution_drugs/ (providing a link to the certificate of analysis "showing that the ingredients used to make South Dakota's execution drugs were contaminated").

311 *See South Dakota Murderer Executed by* ***LethalInjection*** *for Beating to Death Prison Guard with Pipe During Botched Escape*, DAILY MAIL (Oct. 15, 2012, 23:49 EST), http://www.dailymail.co.uk/news/article-2218181.

312 *See* Donald Gilliland, *Pennsylvania Gets Its Execution Drugs from Same Type of Pharmacy as the One Responsible for Bacterial Meningitis Outbreak*, PENN LIVE (Nov. 06, 2012, 7:45 AM), http:// www.pennlive.com/midstate/index.ssf/2012/11/ pennsylvania_gets_its_ executio.html.

313 *See id.*

314 *See* Donald Gilliland, *Lawsuit Has Potential to Stay All Executions in Pennsylvania*, PENN LIVE (Nov. 5, 2012, 6:27 AM), http:// www.pennlive.com/midstate/index.ssf/2012/11/pennsylvania_death_row.html.

315 Hoover, *supra* note 221.

316 *See* Kate Brumback, *Georgia to Use Compounding Pharmacy for Execution Drug*, AUGUSTA CHRON. (July 11, 2013), http:// chronicle.augusta.com/news/metro/2013-07-11/georgia-use-compoundingpharmacyexecution-drug.

317 *See id.*

318 *See* H.B. 122, 152d Gen. Assemb., Reg. Sess. (Ga. 2013).

319 *Id.*

320 *See infra* notes 321-23 and accompanying text.

321 *See* S. 237, 89th Gen. Assemb., Reg. Sess. (Ark. 2013).

322 *See* S. 154, 108th Gen. Assemb., Reg. Sess. (Tenn. 2013).

323 S. 36, 88th Leg. Assemb., Reg. Sess. (S.D. 2013).

324 *See* Ellyde Roko, *Executioner Identities: Toward Recognizing a Right to Know Who Is Hiding Beneath the Hood*, 75 FORDHAM L. REV. 2791, 2796 n.39 (2007).

325 *See id.* at 2799-2800.

326 *See* **Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 53-59, 77-91.

327 *See* Roko, *supra* note 324, at 2809-12; *see also State Appeals Stay of Execution in Hill Case*, WALB NEWS (July 26, 2013, 5:44 PM), http:// www.walb.com/story/22943909/state-appeals-stay-ofexecutionin-hill-case (noting state attorneys' contention

that "a new state law barring the release of information about where Georgia obtains its execution drug .... [is] necessary to discourage retaliation against those who take part in executions").

328 *See* **Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 56.

329 The possible usage of compounded drugs, however, introduces a new component into the execution process because of the heightened risk of problems associated with compounding pharmacies. Specifically, certain compounding pharmacies have been found to encounter serious dosage errors, delivering drugs with up to 450% of the prescribed dosage. *See* Gilliland, *supra* note 312. Even further, there are significant compliance and contamination issues already associated with compounded drugs, evidenced by the recent reports revealed after the 2013 FDA investigation. *See* Hamburg, *supra* note 35.

330 *See generally* **Denno**, ***LethalInjection*** *Quandary*, *supra* note 1 (detailing the challenges with lack of transparency in this country's execution processes).

331 *See generally* **Denno**, *When Legislatures Delegate*, *supra* note 1 (explaining and analyzing the results of Study One).

332 *See* **Denno**, ***LethalInjection*** *Quandary*, *supra* note 1, at 91-101 (explaining and analyzing the results of Study Two).

333 *Id.* at 96-101.

334 *See supra* note 1 and accompanying text.

335 *See supra* notes 1, 39 and accompanying text.

336 DEL. CODE ANN. tit. 29, ch. 100 (2003).

337 *See* Freedom of Information Act Appeal Concerning Department of Correction, Del. Op. Att'y Gen. 11-IIB14 (2011), 2011 WL 4062225.

338 *See* Tex. Att'y Gen. Op. OR2012-07088 (2012), 2012 WL 1821071.

339 *Id.* "[F]reedom from physical harm is an independent interest protected under law, untethered to the right of privacy." *Id.* (quoting Tex. Dep't of Pub. Safety v. Cox Tex. Newspapers, L.P., 343 S.W.3d 112, 117 (Tex. 2011) (internal quotation marks omitted)).

340 *See* Della Hasselle, *State Must Reveal Details of Death-Penalty Practices, Federal Magistrate Rules*, LENS (June 5, 2013, 3:15 PM), http:// thelensnola.org/2013/06/05/state-must-reveal-details-of-deathpenaltypractices-federal-judge-rules/.

341 *See* Hill v. Owens, No. 2013-CV-233771, slip op. at 7 (Ga. Super. Ct. filed July 18, 2013), *available at* http:// www.deathpenaltyinfo.org/documents/HillStayOrder.pdf.

342 *See id.* at 2-4. The state had filed an appeal to the Georgia Supreme Court seeking to overturn the lower court decision. *See State Appeals Stay of Execution in Hill Case*, *supra* note 327. On February 17, 2014, the Georgia Supreme Court heard oral arguments on the state's appeal; a ruling is expected sometime in summer 2014. *See* Max Blau, *Georgia's Supreme Court Hears Oral Arguments in Warren Hill Appeal*, CREATIVE LOAFING (Feb. 17, 2014, 3:30 PM), http://www.clatl.com/freshloaf/archives/2014/02/17/georgias-supreme-court-hears-oral-arguments-in-warren-hill-appeal.

343 *See* Karen Augé, *ACLU Suit: Public Is Entitled to Know How Nathan Dunlap Will Be Killed*, DENVER POST (May 21, 2013, 12:21 PM), http:// www.denverpost.com/breakingnews/ci_23291066/aclusuitpublic-is-entitled-know-how-nathan.

344 *See* ACLU of Colo. v. Colo. Dep't of Corr., No. 13CV32325 (Dist. Ct., City & Cnty. of Denver, Colo. filed Aug. 1, 2013), *available at* http:// aclu-co.org/case/aclu-v-colorado-department-of-corrections.

345 *See Judge: Redacted Execution Protocol Can Be Released*, CBS DENVER (Aug. 1, 2013, 6:40 PM), http:// denver.cbslocal.com/2013/08/01/judge-redacted-execution-protocol-can-be-released/.

346 *See ACLU of Colo.*, No. 13CV32325.

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January 21, 2011

ASA Statement on Sodium Thiopental's Removal From the Market

The American Society of Anesthesiologists (ASA) and its members are extremely troubled to learn that the anesthetic drug, sodium thiopental (Pentothal®), will no longer be available to patients in the United States due to the unfortunate circumstances in Italy that led the sole manufacturer, Hospira, to cease production of the drug.

Sodium thiopental is an important and medically necessary anesthetic agent that has been used for years to induce anesthesia in patients undergoing surgical procedures. Although its use has decreased in recent years due to the introduction of newer medications, such as propofol, sodium thiopental is still considered a first-line anesthetic in many cases including those involving geriatric, neurologic, cardiovascular and obstetric patients, for whom the side effects of other medications could lead to serious complications.

The ASA certainly does not condone the use of sodium thiopental for capital punishment, but we also do not condone using the issue as the basis to place undue burdens on the distribution of this critical drug to the United States. It is an unfortunate irony that many more lives will be lost or put in jeopardy as a result of not having the drug available for its legitimate medical use.

ASA has been working diligently in recent years to address the increasing problem of drug shortages that jeopardize patient safety. In November, ASA co-sponsored a Drug Shortage Summit with our coalition partners in an attempt to develop solutions to address these ongoing issues. Today's announcement underscores the need to develop those solutions, such as redundancies within the manufacturing and distribution systems, to ensure that our patients have the necessary drugs available when they are needed. ASA will continue its efforts to work with the federal government and its coalition partners to address this important patient safety issue.

Death row inmate executed using pentobarbital in lethal injection

From **Divina Mims**
December 16, 2010 8:24 p.m. EST

John David Duty was sentenced to die for killing his cellmate while he was incarcerated on rape and robbery charges.

STORY HIGHLIGHTS

- **NEW**: John David Duty pronounced dead at 6:18 p.m. CT
- Pentobartibal is used to euthanize animals
- Sodium thiopental, usually used for executions, is in short supply

(CNN) -- An Oklahoma death row inmate received a drug commonly used to euthanize animals Thursday because of a nationwide shortage of sodium thiopental, the drug usually used as the sedative in its three-drug execution cocktail.

John David Duty was convicted and sentenced to die for strangling his 22-year-old cellmate, Curtis Wise, with shoe laces in 2001. At the time, he was serving three life sentences for rape, robbery and shooting with intent to kill from a 1978 conviction.

"To the family of Curtis Wise, I'd like to make my apology. I hope one day you will be able to forgive me, not for my sake but for your own. My family and friends are here too. Thank you. You've all been a blessing. Thank you. Lord Jesus, I am ready to go home," Duty said before he was executed.

Duty's execution was the last in the United States in 2010 and is believed to be the first in the country to use pentobarbital in a lethal injection.

Sodium thiopental is a rapid-onset, short-acting barbiturate that causes unconsciousness. Duty's attorneys argued that pentobarbital was risky and unsafe. But an Oklahoma judge disagreed and last month approved its use in place of sodium thiopental.

The sedative is the first drug in Oklahoma's lethal injection protocol. It is followed by vecuronium bromide, a drug that causes paralysis and stops breathing. The third drug, potassium chloride, stops the heart.

Pentobarbital is used in a similar manner for animal euthanizations.

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EXECUTIONS

Botched Executions

> *"With each development in the technology of execution, the same promises have been made, that each new technology was safe, reliable, effective and humane. Those claims have not generally been fulfilled." -Austin Sarat*

It is estimated that 3% of U.S. executions in the period from 1890 to 2010 were botched. In the 2014 book, Gruesome Spectacles: Botched Executions and America's Death Penalty, Austin Sarat, a professor of jurisprudence and political science at Amherst College, describes the history of flawed executions in the U.S. during that period. Sarat reports that over those 120 years, 8,776 people were executed and 276 of those executions (3.15%) went wrong in some way. Lethal injection had the highest rate of botched executions. In his book, he defines a botched execution as follows:

> Botched executions occur when there is a breakdown in, or departure from, the "protocol" for a particular method of execution. The protocol can be established by the norms, expectations, and advertised virtues of each method or by the government's officially adopted execution guidelines. Botched executions are "those involving unanticipated problems or delays that caused, at least arguably, unnecessary agony for the prisoner or that reflect gross incompetence of the executioner." Examples of such problems include, among other things, inmates catching fire while being electrocuted, being strangled during hangings (instead of having their necks broken), and being administered the wrong dosages of specific drugs for lethal injections.

Method	Total Executions	Botched Executions	Botched Execution Rate
Hanging	2,721	85	3.12%
Electrocution	4,374	84	1.92%
Lethal Gas	593	32	5.4%
Lethal Injection	1,054	75	7.12%
Firing Squad	34	0	0%
All Methods	8,776	276	3.15%

Source: Austin Sarat, "Gruesome Spectacles: Botched Executions and America's Death Penalty" (Stanford Univ. Press 2014).

A report in the Salt Lake City Tribune takes a different view of the suggestion that there have been no botched executions by firing squad since 1890. The paper reports that in September 1951, a Utah firing squad shot Eliseo J. Mares in the hip and abdomen and that it was "several minutes" before he was declared dead. Utah's May 16, 1879 firing-squad execution of Wallace Wilkerson also was botched. See Botched Executions in American History.

Examples of Post-Furman Botched Executions

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Last addition: March 1, 2018

NOTE: The cases below are not presented as a comprehensive catalogue of all botched executions, but simply a listing of examples that are well-known. There are 51 executions or attempted executions listed: 2 by asphyxiation, 10 by electrocution, and 39 by lethal injection, including 3 failed executions that were halted when execution personnel were unable to set an IV line.

1. August 10, 1982. Virginia. Frank J. Coppola. Electrocution. Although no media representatives witnessed the execution and no details were ever released by the Virginia Department of Corrections, an attorney who was present later stated that it took two 55-second jolts of electricity to kill Coppola. The second jolt produced the odor and sizzling sound of burning flesh, and Coppola's head and leg caught on fire. Smoke filled the death chamber from floor to ceiling with a smoky haze.[1]

2. April 22, 1983. Alabama. John Evans. Electrocution. After the first jolt of electricity, sparks and flames erupted from the electrode attached to Evans's leg. The electrode burst from the strap holding it in place and caught on fire. Smoke and sparks also came out from under the hood in the vicinity of Evans's left temple. Two physicians entered the chamber and found a heartbeat. The electrode was reattached to his leg, and another jolt of electricity was applied. This resulted in more smoke and burning flesh. Again the doctors found a heartbeat. Ignoring the pleas of Evans's lawyer, a third jolt of electricity was applied. The execution took 14 minutes and left Evans's body charred and smoldering.[2]

3. Sept. 2, 1983. Mississippi. Jimmy Lee Gray. Asphyxiation. Officials had to clear the room eight minutes after the gas was released when Gray's desperate gasps for air repulsed witnesses. His attorney, Dennis Balske of Montgomery, Alabama, criticized state officials for clearing the room when the inmate was still alive. Said noted death penalty defense attorney David Bruck, "Jimmy Lee Gray died banging his head against a steel pole in the gas chamber while the reporters counted his moans (eleven, according to the Associated Press)."[3] Later it was revealed that the executioner, Barry Bruce, was drunk.[4]

4. December 12, 1984. Georgia. Alpha Otis Stephens. Electrocution. "The first charge of electricity … failed to kill him, and he struggled to breathe for eight minutes before a second charge carried out his death sentence …"[5] After the first two minute power surge, there was a six minute pause so his body could cool before physicians could examine him (and declare that another jolt was needed). During that six-minute interval, Stephens took 23 breaths. A Georgia prison official said, "Stephens was just not a conductor" of electricity.[6]

5. March 13, 1985. Texas. Stephen Peter Morin. Lethal Injection. The Associated Press reported that, because of Morin's history of drug abuse, the execution technicians were forced to probe both of Morin's arms and one of his legs with needles for nearly 45 minutes before they found a suitable vein.[7]

6. October 16, 1985. Indiana. William E. Vandiver. Electrocution. After the first administration of 2,300 volts, Vandiver was still breathing. The execution eventually took 17 minutes and five jolts of electricity.[8] Vandiver's attorney, Herbert Shaps, witnessed the execution and observed smoke and the smell of burning. He called the execution "outrageous." The Department of Corrections admitted the execution "did not go according to plan."[9]

7. August 20, 1986. Texas. Randy Woolls. Lethal Injection. A drug addict, Woolls helped the execution technicians find a useable vein for the execution.[10]

8. June 24, 1987. Texas. Elliot Rod Johnson. Lethal Injection. Because of collapsed veins, it took nearly an hour to complete the execution.[11]

9. December 13, 1988. Texas. Raymond Landry. Lethal Injection. Pronounced dead 40 minutes after being strapped to the execution gurney and 24 minutes after the drugs first started flowing into his arms.[12] Two minutes after the drugs were administered, the syringe came out of Landry's vein, spraying the deadly chemicals across the room toward witnesses. The curtain separating the witnesses from the inmate was then pulled, and not reopened for fourteen minutes while the execution team reinserted the catheter into the vein. Witnesses reported "at least one groan." A spokesman for the Texas Department of Correction, Charles Brown (sic), said, "There was something of a delay in the execution because of what officials called a 'blowout.' The syringe came out of the vein, and the warden ordered the (execution) team to reinsert the catheter into the vein."[13]

10. May 24, 1989. Texas. Stephen McCoy. Lethal Injection. He had such a violent physical reaction to the drugs (heaving chest, gasping, choking, back arching off the gurney, etc.) that one of the witnesses (male) fainted, crashing into and knocking over another witness. Houston attorney Karen Zellars, who represented McCoy and witnessed the execution, thought the fainting would catalyze a chain reaction. The Texas Attorney General admitted the inmate "seemed to have had a somewhat stronger reaction," adding, "The drugs might have been administered in a heavier dose or more rapidly."[14]

11. July 14, 1989. Alabama. Horace Franklin Dunkins, Jr. Electrocution. It took two jolts of electricity, nine minutes apart, to complete the execution. After the first jolt failed to kill the prisoner (who was mildly retarded), the captain of the prison guard opened the door to the witness room and stated "I believe we've got the jacks on wrong."[15] Because the cables had been connected improperly, it was impossible to dispense sufficient current to cause death. The cables were reconnected before a second jolt was administered. Death was pronounced 19 minutes after the first electric charge. At a post-execution news conference, Alabama Prison Commissioner Morris Thigpen said, "I regret very very much what happened. [The cause] was human error."[16]

12. May 4, 1990. Florida. Jesse Joseph Tafero. Electrocution. During the execution, six-inch flames erupted from Tafero's head, and three jolts of power were required to stop his breathing. State officials claimed that the botched execution was caused by "inadvertent human error" — the inappropriate substitution of a synthetic sponge for a natural sponge that had been used in previous executions.[17] They attempted to support this theory by sticking a part of a synthetic sponge into a "common household toaster" and observing that it smoldered and caught fire.[18]

13. September 12, 1990. Illinois. Charles Walker. Lethal Injection. Because of equipment failure and human error, Walker suffered excruciating pain during his execution. According to Gary Sutterfield, an engineer from the Missouri State Prison who was retained by the State of Illinois to assist with Walker's execution, a kink in the plastic tubing going into Walker's arm stopped the deadly chemicals from reaching Walker. In addition, the intravenous needle was inserted pointing at Walker's fingers instead of his heart, prolonging the execution.[19]

14. October 17, 1990. Virginia. Wilbert Lee Evans. Electrocution. When Evans was hit with the first burst of electricity, blood spewed from the right side of the mask on Evans's face, drenching Evans's shirt with blood and causing a sizzling sound as blood dripped from his lips. Evans continued to moan before a second jolt of electricity was applied. The autopsy concluded that Evans suffered a bloody nose after the voltage surge elevated his high blood pressure.[20]

15. August 22, 1991. Virginia. Derick Lynn Peterson. Electrocution. After the first cycle of electricity was applied, and again four minutes later, prison physician David Barnes inspected Peterson's neck and checked him with a stethoscope, announcing each time "He has not expired." Seven and one-half minutes after the first attempt to kill the inmate, a second cycle of electricity was applied. Prison officials later announced that in the future they would routinely administer two cycles before checking for a heartbeat.[21]

16. January 24, 1992. Arkansas. Rickey Ray Rector. Lethal Injection. It took medical staff more than 50 minutes to find a suitable vein in Rector's arm. Witnesses were kept behind a drawn curtain and not permitted to view this scene, but reported hearing Rector's eight loud moans throughout the process. During the ordeal Rector (who suffered from serious brain damage) helped the medical personnel find a vein. The administrator of State's Department of Corrections medical programs said (paraphrased by a newspaper reporter) "the moans did come as a team of two medical people that had grown to five worked on both sides of his body to find a vein." The administrator said "That may have contributed to his occasional outbursts." The difficulty in finding a suitable vein was later attributed to Rector's bulk and his regular use of antipsychotic medication.[22]

17. April 6, 1992. Arizona. Donald Eugene Harding. Asphyxiation. Death was not pronounced until 10 1/2 minutes after the cyanide tablets were dropped.[23] During the execution, Harding thrashed and struggled violently against the restraining straps. A television journalist who witnessed the execution, Cameron Harper, said that Harding's spasms and jerks lasted 6 minutes and 37 seconds. "Obviously, this man was suffering. This was a violent death … an ugly event. We put animals to death more humanely."[24] Another witness, newspaper reporter Carla McClain, said, "Harding's death was extremely violent. He was in great pain. I heard him gasp and moan. I saw his body turn from red to purple."[25] One reporter who witnessed the execution suffered from insomnia and assorted illnesses for several weeks; two others were "walking vegetables" for several days.[26]

18. March 10, 1992. Oklahoma. Robyn Lee Parks. Lethal Injection. Parks had a violent reaction to the drugs used in the lethal injection. Two minutes after the drugs were dispensed, the muscles in his jaw, neck, and abdomen began to react spasmodically for approximately 45 seconds. Parks continued to gasp and violently gag until death came, some eleven minutes after the drugs were first administered. Tulsa World reporter Wayne Greene wrote that the execution looked "painful," "scary and ugly." "It was overwhelming, stunning, disturbing — an intrusion into a moment so personal that reporters, taught for years that intrusion is their business, had trouble looking each other in the eyes after it was over."[27]

19. April 23, 1992. Texas. Billy Wayne White. Lethal Injection. White was pronounced dead some 47 minutes after being strapped to the execution gurney. The delay was caused by difficulty finding a vein; White had a long history of heroin abuse. During the execution, White attempted to assist the authorities in finding a suitable vein.[28]

20. May 7, 1992. Texas. Justin Lee May. Lethal Injection. May had an unusually violent reaction to the lethal drugs. According to one reporter who witnessed the execution, May "gasped, coughed and reared against his heavy leather restraints, coughing once again before his body froze …."[29] Associated Press reporter Michael Graczyk wrote, "Compared to other recent executions in Texas, May's reaction to the drugs was more violent. He went into a coughing spasm, groaned and gasped, lifted his head from the death chamber gurney and would have arched his back if he had not been belted down. After he stopped breathing, his eyes and mouth remained open."[30]

21. May 10, 1994. Illinois. John Wayne Gacy. Lethal Injection. After the execution began, the lethal chemicals unexpectedly solidified, clogging the IV tube that led into Gacy's arm, and prohibiting any further passage. Blinds covering the window through which witnesses observed the execution were drawn, and the execution team replaced the clogged tube with a new one. Ten minutes later, the blinds were then reopened and the execution process resumed. It took 18 minutes to complete.[31] Anesthesiologists blamed the problem on the inexperience of prison officials who were conducting the execution, saying that proper procedures taught in "IV 101" would have prevented the error.[32]

22. May 3, 1995. Missouri. Emmitt Foster. Lethal Injection. Seven minutes after the lethal chemicals began to flow into Foster's arm, the execution was halted when the chemicals stopped circulating. With Foster gasping and convulsing, the blinds were drawn so the witnesses could not view the scene. Death was pronounced thirty minutes after the execution began, and three minutes later the blinds were reopened so the witnesses could view the corpse.[33] According to William "Mal" Gum, the Washington County Coroner who pronounced death, the problem was caused by the tightness of the leather straps that bound Foster to the execution gurney; it was so tight that the flow of chemicals into the veins was restricted. Foster did not die until several minutes after a prison worker finally loosened the straps. The coroner entered the death chamber twenty minutes after the execution began, diagnosed the problem, and told the officials to loosen the strap so the execution could proceed.[34] In an editorial, the St. Louis Post-Dispatch called the execution "a particularly sordid chapter in Missouri's capital punishment experience."[35]

23. January 23, 1996. Virginia. Richard Townes, Jr. Lethal Injection. This execution was delayed for 22 minutes while medical personnel struggled to find a vein large enough for the needle. After unsuccessful attempts to insert the needle through the arms, the needle was finally inserted through the top of Mr. Townes's right foot.[36]

24. July 18, 1996. Indiana. Tommie J. Smith. Lethal Injection. Because of unusually small veins, it took one hour and nine minutes for Smith to be pronounced dead after the execution team began sticking needles into his body. For sixteen minutes, the execution team failed to find adequate veins, and then a physician was called.[37] Smith was given a local anesthetic and the physician twice attempted to insert the tube in Smith's neck. When that failed, an angio-catheter was inserted in Smith's foot. Only then were witnesses permitted to view the process. The lethal drugs were finally injected into Smith 49 minutes after the first attempts, and it took another 20 minutes before death was pronounced.[38]

25. March 25, 1997. Florida. Pedro Medina. Electrocution. A crown of foot-high flames shot from the headpiece during the execution, filling the execution chamber with a stench of thick smoke and gagging the two dozen official witnesses. An official then threw a switch to manually cut off the power and prematurely end the two-minute cycle of 2,000 volts. Medina's chest continued to heave until the flames stopped and death came.[39] After the execution, prison officials blamed the fire on a corroded copper screen in the headpiece of the electric chair, but two experts hired by the governor later concluded that the fire was caused by the improper application of a sponge (designed to conduct electricity) to Medina's head.

26. May 8, 1997. Oklahoma. Scott Dawn Carpenter. Lethal Injection. Carpenter was pronounced dead some 11 minutes after the lethal injection was administered. As the drugs took effect, Carpenter began to gasp and shake. "This was followed by a guttural sound, multiple spasms and gasping for air" until his body stopped moving, three minutes later.[40]

27. June 13, 1997. South Carolina. Michael Eugene Elkins. Lethal Injection. Because Elkins's body had become swollen from liver and spleen problems, it took nearly an hour to find a suitable vein for the insertion of the catheter. Elkins tried to assist the executioners, asking "Should I lean my head down a little bit?" as they probed for a vein. After numerous failures, a usable vein was finally found in Elkins's neck.[41]

28. April 23, 1998. Texas. Joseph Cannon. Lethal Injection. It took two attempts to complete the execution. After making his final statement, the execution process began. A vein in Cannon's arm collapsed and the needle popped out. Seeing this, Cannon lay back, closed his eyes, and exclaimed to the witnesses, "It's come undone." Officials then pulled a curtain to block the view of the witnesses, reopening it fifteen minutes later when a weeping Cannon made a second final statement and the execution process resumed.[42]

29. August 26, 1998. Texas. Genaro Ruiz Camacho. Lethal Injection. The execution was delayed approximately two hours due, in part, to problems finding suitable veins in Camacho's arms.[43]

30. October 5, 1998. Nevada. Roderick Abeyta. Lethal Injection. It took 25 minutes for the execution team to find a vein suitable for the lethal injection.[44]

31. July 8, 1999. Florida. Allen Lee Davis. Electrocution. "Before he was pronounced dead … the blood from his mouth had poured onto the collar of his white shirt, and the blood on his chest had spread to about the size of a dinner plate, even oozing through the buckle holes on the leather chest strap holding him to the chair."[45] His execution was the first in Florida's new electric chair, built especially so it could accommodate a man Davis's size (approximately 350 pounds). Later, when another Florida death row inmate challenged the constitutionality of the electric chair, Florida Supreme Court Justice Leander Shaw commented that "the color photos of Davis depict a man who — for all appearances — was brutally tortured to death by the citizens of Florida."[46] Justice Shaw also described the botched executions of Jesse Tafero and Pedro Medina (q.v.), calling the three executions "barbaric spectacles" and "acts more befitting a violent murderer than a civilized state."[47] Justice Shaw included pictures of Davis's dead body in his opinion.[48] The execution was witnessed by a Florida State

Senator, Ginny Brown-Waite, who at first was “shocked” to see the blood, until she realized that the blood was forming the shape of a cross and that it was a message from God saying he supported the execution.[49] (See Photos taken after execution—graphic images).

32. May 3, 2000. Arkansas. Christina Marie Riggs. Lethal Injection. Riggs dropped her appeals and asked to be executed. However, the execution was delayed for 18 minutes when prison staff couldn’t find a suitable vein in her elbows. Finally, Riggs agreed to the executioners’ requests to have the needles in her wrists.[50]

33. June 8, 2000. Florida. Bennie Demps. Lethal Injection. It took execution technicians 33 minutes to find suitable veins for the execution. “They butchered me back there,” said Demps in his final statement. “I was in a lot of pain. They cut me in the groin; they cut me in the leg. I was bleeding profusely. This is not an execution, it is murder.” The executioners had no unusual problems finding one vein, but because Florida protocol requires a second alternate intravenous drip, they continued to work to insert another needle, finally abandoning the effort after their prolonged failures.[51]

34. December 7, 2000. Texas. Claude Jones. Lethal Injection. Jones was a former intravenous drug abuser. His execution was delayed 30 minutes while the execution team struggled to insert an IV into a vein. One member of the execution team commented, “They had to stick him about five times. They finally put it in his leg.” Jim Willett, the warden of the Walls Unit and the man responsible for conducting the execution, wrote: “The medical team could not find a vein. Now I was really beginning to worry. If you can’t stick a vein then a cut-down has to be performed. I have never seen one and would just as soon go through the rest of my career the same way. Just when I was really getting worried, one of the medical people hit a vein in the left leg. Inside calf to be exact. The executioner had warned me not to panic as it was going to take a while to get the fluids in the body of the inmate tonight because he was going to push the drugs through very slowly. Finally, the drug took effect and Jones took his last breath.”[52]

35. June 28, 2000. Missouri. Bert Leroy Hunter. Lethal Injection. Hunter had an unusual reaction to the lethal drugs, repeatedly coughing and gasping for air before he lapsed into unconsciousness.[53] An attorney who witnessed the execution reported that Hunter had “violent convulsions. His head and chest jerked rapidly upward as far as the gurney restraints would allow, and then he fell quickly down upon the gurney. His body convulsed back and forth like this repeatedly. … He suffered a violent and agonizing death.”[54] However, three reporters who witnessed the execution did not substantiate these observations, with two reporting that Hunter simply coughed several times and the third stating that he saw no violent reaction to the drugs. [55]

36. November 7, 2001. Georgia. Jose High. Lethal Injection. High was pronounced dead some one hour and nine minutes after the execution began. After attempting to find a useable vein for “15 to 20 minutes,” the emergency medical technicians under contract to do the execution abandoned their efforts. Eventually, one needle was stuck in High’s hand, and a physician was called in to insert a second needle between his shoulder and neck.[56]

37. May 2, 2006. Ohio. Joseph L. Clark. Lethal Injection. It took 22 minutes for the execution technicians to find a vein suitable for insertion of the catheter. But three or four minutes thereafter, as the vein collapsed and Clark’s arm began to swell, he raised his head off the gurney and said five times, “It don’t work. It don’t work.” The curtains surrounding the gurney were then closed while the technicians worked for 30 minutes to find another vein. Media witnesses later reported that they heard “moaning, crying out and guttural noises.”[57] Finally, death was pronounced almost 90 minutes after the execution began. A spokeswoman for the Ohio Department of Corrections told reporters that the execution team included paramedics, but not a physician or a nurse.[58]

38. December 13, 2006. Florida. Angel Diaz. Lethal Injection. After the first injection was administered, Mr. Diaz continued to move, and was squinting and grimacing as he tried to mouth words. A second dose was then administered, and 34 minutes passed before Mr. Diaz was declared dead. At first a spokesperson for the Florida Department of Corrections claimed that

this was because Mr. Diaz had some sort of liver disease.[59] After performing an autopsy, the Medical Examiner, Dr. William Hamilton, stated that Mr. Diaz's liver was undamaged, but that the IV catheters (which had been inserted in both arms) had gone through Mr. Diaz's veins and out the other side, so the deadly chemicals were injected into soft tissue, rather than the vein. Two days after the execution, Governor Jeb Bush temporarily suspended all executions in the state and appointed a commission "to consider the humanity and constitutionality of lethal injections."[60] In 2014, pictures from the autopsy of Mr. Diaz's body, along with a long article describing his painful death, were published in THE NEW REPUBLIC.[61]

39. May 24, 2007. Ohio. Christopher Newton. Lethal Injection. According to the Associated Press, "prison medical staff" at the Southern Ohio Correctional Facility struggled to find veins on each of Newton's arms during the execution. Newton, who weighted 265 pounds, was declared dead almost two hours after the execution process began. The execution "team" stuck Newton at least ten times with needles before getting the shunts in place were the needles are injected.[62]

40. June 26, 2007. Georgia. John Hightower. Lethal Injection. It took approximately 40 minutes for the nurses to find a suitable vein to administer the lethal chemicals, and death was not pronounced until 7:59, 59 minutes after the execution process began.[63]

41. June 4, 2008. Georgia. Curtis Osborne. Lethal Injection. After a 55-minute delay while the U.S. Supreme Court reviewed his final appeal, prison medical staff began the execution by trying to find suitable veins in which to insert the IV. The executioners struggled for 35 minutes to find a vein, and it took 14 minutes after the fatal drugs were administered before death was pronounced by two physicians who were inside the death chamber.[64]

42. Sept. 15, 2009. Ohio. Romell Broom (pictured, after execution attempt). Attempted Lethal Injection. Efforts to find a suitable vein and to execute Mr. Broom were terminated after more than two hours when the executioners were unable to find a useable vein in Mr. Broom's arms or legs. During the failed efforts, Mr. Broom winced and grimaced with pain. After the first hour's lack of success, on several occasions Broom tried to help the executioners find a good vein. "At one point, he covered his face with both hands and appeared to be sobbing, his stomach heaving.[65] Finally, Ohio Governor Ted Strickland ordered the execution to stop, and announced plans to attempt the execution anew after a one-week delay so that physicians could be consulted for advice on how the man could be killed more efficiently.[66] The executioners blamed the problems on Mr. Broom's history of intravenous drug use. As of March 1, 2018, Mr. Broom remained on Ohio's death row.

43. Sept. 27, 2010. Georgia. Brandon Joseph Rhode. Lethal Injection. After the Supreme Court rejected his appeals, "Medics then tried for about 30 minutes to find a vein to inject the three-drug concoction." It then took 14 minutes for the lethal drugs to kill him. The execution had been delayed six days because a prison guard had given Rhode a razor blade, which Rhode used to attempt suicide.[67]

44. Jan. 16, 2014. Ohio. Dennis McGuire. Lethal Injection. McGuire gasped for air for some 25 minutes while the drugs used in the execution, hydromorphone and midazolam, slowly took effect. Witnesses reported that after the drugs were injected, McGuire was struggling, with his stomach heaving and fist clenched, making "horrible" snorting and choking sounds.[68] In a lawsuit filed after the execution, Mr. McGuire's family alleged that the inmate experienced "repeated cycles of snorting, gurgling and arching his back, appearing to writhe in pain," the lawsuit said. "It looked and sounded as though he was suffocating."[69]

45. April 29, 2014. Oklahoma. Clayton D. Lockett. Lethal Injection. Despite prolonged litigation and numerous warnings from defense attorneys about the dangers of using an experimental drug protocol with the drug midazolam, Oklahoma went ahead and scheduled the executions of Clayton Lockett and Charles Warner. Plans for the execution and the drugs used were cloaked in secrecy, with the state refusing to release information about the source and efficacy of the lethal drugs, making it impossible to accurately predict the effects of the combination of drugs. Nonetheless, Oklahoma Governor Mary Fallon pressured the Courts to allow the execution, a bill was introduced in the Oklahoma House of Representatives to impeach the Justices who had voted to stay the execution, and the state Supreme Court allowed the executions to go forward.

Mr. Lockett was the first who was scheduled to die. An hour before the execution began, the governor was notified that the executioner (a "phlebotomist") was having problems finding a usable vein, but she did not intervene. After an hour, a vein was finally found in Mr. Lockett's "groin area," and the execution went forward. Ten minutes after the administration of the first drug, a sedative, the physician supervising the process (whose very presence violated ethical standards of several medical organizations) announced that the inmate was unconscious, and therefore ready to receive the other two drugs that would actually kill him. Those two drugs were known to cause excruciating pain if the recipient was conscious. However, Mr. Lockett was not unconscious. Three minutes after the latter two drugs were injected, "he began breathing heavily, writhing on the gurney, clenching his teeth and straining to lift his head off the pillow."[70] Officials then lowered the blinds to prohibit witnesses from seeing what was going on, and 15 minutes later the witnesses were ordered to leave the room.

Twenty minutes after the first drugs were administered, the Director the Oklahoma Department of Corrections halted the execution, and issued a two-week stay (later extended by extensive litigation) for the execution of Mr. Warner. Mr. Lockett died 43 minutes after the execution began, of a heart attack, while still in the execution chamber.[71]

46. July 23, 2014. Arizona. Joseph R. Wood. Lethal Injection. After the chemicals (midazolam and hydromorphone) were injected, Mr. Wood repeatedly gasped for one hour and 40 minutes before death was pronounced. During the ordeal, Mr. Wood's attorneys filed an emergency appeal to a Federal District Court and placed a phone call to Supreme Court Justice Anthony Kennedy in a failed effort to halt the botched execution. Meanwhile, a spokesperson for the Arizona Attorney General's office claimed that Mr. Wood was asleep and was simply snoring. In the days before the execution, defense attorneys won a stay from the U.S. Court of Appeals for the Ninth Circuit on their motion to compel the state to reveal the source of the drugs and the training of the executioners. However, this stay was later overturned by the Supreme Court.[72] A reporter for the Arizona Republic who witnessed the execution, Michael Kiefer, said that he counted 640 gasps from Wood before he finally died.[73]

47. December 9, 2015. Georgia. Brian Keith Terrell. Lethal Injection. "[I]t took an hour for the nurse assigned to the execution to get IVs inserted into both of the condemned man's arms. She eventually had to put one into Terrell's right hand. Terrell winced several times, apparently in pain."[74]

48. February 3, 2016. Georgia. Brandon Jones. Lethal Injection. After spending 24 minutes unsuccessfully trying to insert an IV into Jones' left arm, the executioners spent 8 minutes trying to insert it in his right arm, and when that failed they again attempted to insert it in his left arm. They then asked a physician to violate several codes of medical ethics for assistance, and he or she spent 13 minutes inserting and stitching the IV near Jones' groin. Six minutes later, Jones' eyes popped open. He was 72 years old at the time of his execution.[75]

49. December 8, 2016. Alabama. Ronald Bert Smith, Jr. Lethal Injection. Smith (a former Eagle Scout and Army reservist) was convicted of a 1994 murder of a convenience store clerk, and his jury at trial (after anti-death penalty citizens were removed) voted 7-5 to recommend a punishment of life imprisonment without parole. Alabama, however, requires neither unanimity nor a majority jury vote before the trial judge can sentence a defendant to death. Smith heaved, gasped and coughed while struggling for breath for 13 minutes after the lethal drugs were administered, and death was pronounced 34 minutes after the execution began. He also "clenched his fists and raised his head during the early part of the procedure." Alabama used the controversial sedative midazolam (a "valium-like drug") in the execution.[76]

50. November 15, 2017. Ohio. Alva Campbell. Lethal Injection. "The execution team first worked on both of Alva Campbell's arms for about 30 minutes Wednesday while he was on a gurney in the state's death chamber and then tried to find a vein in his right leg below the knee. … About 80 minutes after the execution was scheduled to begin, the 69-year-old Campbell

shook hands with two guards after it appeared the insertion was successful. About two minutes later, media witnesses were told to leave without being told what was happening. … Gary Mohr, head of the Ohio Department of Rehabilitation and Correction, … [then] called off the execution after talking with the medical team [saying] 'It was my decision that it was not likely that we're going to access veins.' … Prison officials brought Campbell into the death chamber in a wheelchair and provided him a wedge pillow on the gurney, which was meant to help him breathe. Campbell has suffered from breathing problems related to a longtime smoking habit. His attorneys said he has required a walker, relied on a colostomy bag and needed breathing treatments four times a day." [77]

51. February 22, 2018. Alabama. Doyle Lee Hamm. Lethal Injection (failed). Despite several warnings from defense counsel that it would be impossible to find a vein in which to insert the catheter (Hamm suffered from advanced lymphatic cancer and carcinoma), the State went forward with the execution. For 2.5 hours, the executioners tried to find a vein, leaving Hamm with a ten-twelve puncture marks, including six in his groin and others that punctured his bladder and penetrated his femoral artery. Finally, approaching a midnight deadline that prohibited further attempts, the execution was called off. Alabama Corrections Commissioner Jeff Dunn later told reporters, "I wouldn't necessarily characterize what we had tonight as a problem."[78] [NOTE: On March 5, 2018, attorneys for Doyle Hamm submitted a preliminary report from an anesthesiologist who evaluted Hamm on February 25. WARNING: Report contains graphic images and descriptions.]

SOURCES

ENDNOTES

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OKLAHOMA DEPARTMENT OF PUBLIC SAFETY

The Execution of Clayton D. Lockett

Case Number 14-0189SI

Executive Summary

Table of Contents

I. BACKGROUND

The State of Oklahoma, through the Office of the Attorney General (OAG), filed an *Application for Execution Date* for Clayton Derrell Lockett on January 13, 2014. Lockett had been convicted of first degree murder for a 1999 case in Noble County and sentenced to death. On January 22, the Oklahoma Court of Criminal Appeals ordered the execution to be set for March 20. Motions were later filed on behalf of Lockett and another offender sentenced to death, Charles Warner, that challenged Oklahoma's execution-secrecy law and execution protocol. On March 18, the Court of Criminal Appeals vacated Lockett's execution date and it was reset for April 22. This order also rescheduled Warner's execution from March 27 to April 29.

On April 9, the Court of Criminal Appeals denied an application for stay made by both offenders. On April 21, the Oklahoma Supreme Court issued a stay of execution for Lockett and Warner. In response, Governor Mary Fallin issued Executive Order 2014-08, which granted a stay of Lockett's execution and rescheduled it for April 29, based on the Supreme Court not having constitutional authority to issue a stay. On April 23, the Supreme Court dissolved their stay. Between April 23 and April 29, an application for extraordinary relief was denied by the courts, as was another request for a stay.

On the morning of April 29, Oklahoma Department of Corrections (DOC) personnel began procedures to prepare for Lockett's and Warner's executions at the Oklahoma State Penitentiary (OSP) in McAlester, Oklahoma. Lockett's execution was scheduled to begin at 6:00 p.m. Lockett was removed from his cell that morning and taken to the Institutional Health Care Center (IHCC), located on prison grounds, for self-inflicted lacerations to the inside of his arms and his pre-execution medical examination. Lockett remained at IHCC until later that afternoon, when he was returned to H-Unit to await his execution.

Lockett was taken to the execution chamber, placed onto the table, and after failed attempts in other locations, an intravenous (IV) line was started in Lockett's right groin area. On the order of Warden Anita Trammell, the administration of execution drugs began. Several minutes into the process, it was determined there was a problem with the IV patency. The execution was stopped and Lockett later died in the execution chamber.

On April 30, Governor Fallin issued Executive Order 2014-11, which appointed Secretary of Safety and Security and Department of Public Safety (DPS) Commissioner Michael Thompson to conduct an independent review of the events leading up to and during Lockett's execution. This order stated the review should include:

1. An inquiry into the cause of death by a forensic pathologist;
2. An inquiry into whether DOC correctly followed their current protocol for executions;
3. Recommendations to improve the execution protocol used by DOC. The order further directed that the Office of the Chief Medical Examiner (OCME) authorize the Southwestern Institute of Forensics Science (SWIFS) in Dallas, Texas to perform the autopsy, additional examination, and all other related testing of Lockett's remains.

In order to effectuate the examination, OCME was directed to transport Lockett's remains to and from SWIFS. OCME was also ordered to appropriately maintain Lockett's remains until they were released to his family. Commissioner Thompson assembled a team of DPS investigators to conduct this investigation and report its findings. This executive summary, along with its attachments and supporting documentation, are the result of the investigation conducted by this team.

II. INVESTIGATION

This investigation was conducted by a team of six investigators assigned full-time to the case. Nine investigators and a criminal intelligence analyst were also utilized part-time to assist with the case. All investigators were sworn, law enforcement members of the Oklahoma Highway Patrol (OHP) Division of DPS. A medical expert was also consulted during the investigation to assist the investigators in understanding the various technical aspects related to the medical procedures that were performed during the execution. The expert was a current, American Board of Surgery certified physician with more than 35 years of experience in the medical field. The remainder of this section outlines the methodology utilized by the team to complete this investigation.

A. Autopsy of Clayton D. Lockett

On April 29, at 7:50 p.m., DOC released Lockett's body to the OCME designated transport contractor, Ray Francisco's Embalming Service, who transported the body to OCME in Tulsa, Oklahoma. On the morning of April 30, OCME pathologists began an external examination of the body. A portion of the superficial veins of the right and left arms were explored, photographed and removed. Personnel also obtained a blood sample from the left femoral artery/vein. Around 11:30 a.m., pathologists were notified to stop the examination pursuant to the aforementioned Executive Order. They had not started a posterior body inspection or internal examination. OCME staff sealed the body and evidence in a body bag and placed it in storage. Later that day, Lockett's body and evidence were transported by Ray Francisco's Embalming Service to SWIFS and the transport was monitored by a member of the investigation team.

On May 1, the autopsy of Lockett's body was conducted by Dr. Joni McClain and other SWIFS staff. A member of the investigation team observed the autopsy and evidence processing procedures. Dr. McClain completed the external and internal examinations of the body utilizing SWIFS' normal procedures and protocols. After the autopsy was complete, Lockett's body was released to Ray Francisco's Embalming Service and transported back to OCME in Tulsa.

During this investigation, the investigation team met with the SWIFS pathologists and staff to gain a better understanding of their autopsy process and its findings. The results of the autopsy and the toxicology tests that were completed are summarized in the *Findings* section of this report.

B. Tour of the Oklahoma State Penitentiary

On May 5, the investigation team met with Warden Trammell and several OSP staff members to prepare for a tour of H-Unit and IHCC. The team was escorted through H-Unit, where they viewed the holding cells, shower, execution chamber, executioners' room and medical room. The team also collected evidence during the tour. The team was then escorted to IHCC and viewed the area where Lockett was treated for his self-inflicted wounds and the cell where he was held, until being returned to H-Unit. After the tour, the team met with Warden Trammell and her staff to collect additional evidence and

retrieve documents requested for the investigation. Several measurements and photographs were taken during the tour to document the execution facilities, which were later used to construct Diagram II.1.

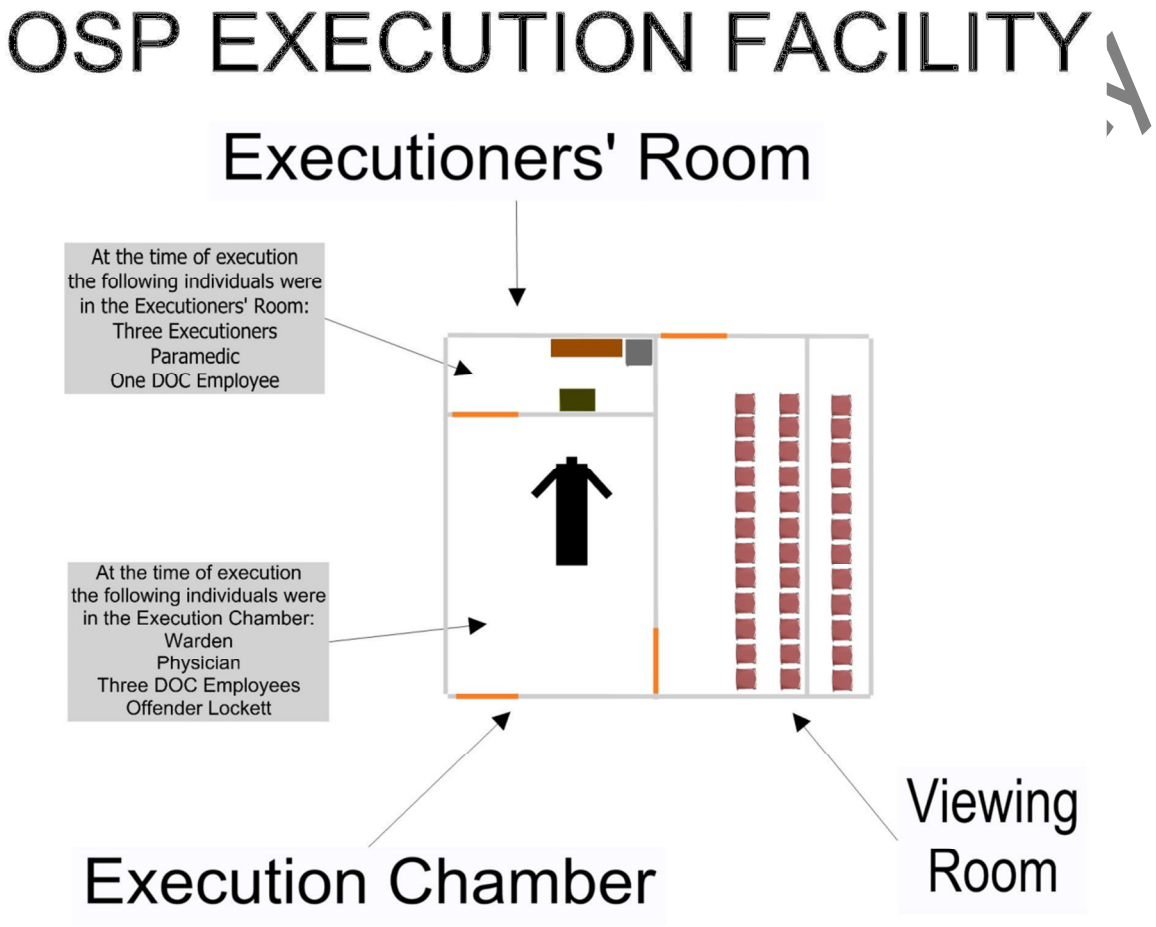

Diagram II.1

On June 30, members of the investigation team returned to OSP to gather additional information from the execution chamber. A team member was strapped to the execution table by two OSP strap-down team members who had strapped Lockett to the table. OSP staff observed the process to ensure that every strap was utilized in the same manner it was on the day of Lockett's execution. The team measured the ability for a person to move and their range of motion, once secured to the table, and took photographs from the viewing room to show the different perspectives from the various seating locations.

C. Collection of Evidence

Numerous items of evidence were collected and preserved during this investigation. This evidence included digital photographs, audio recordings, video recordings, documents and other items of physical evidence. The remainder of this section is a summary of the evidence collected.

During their examination, OCME staff collected a blood sample from Lockett's left femoral artery/vein. An aliquot of that sample was submitted by OCME to NMS Labs in Willow Grove, Pennsylvania, to test for the presence and concentration of midazolam and vecuronium bromide. On June 12, the investigation team obtained another aliquot of that sample and submitted it to ExperTox Laboratory in Deer Park, Texas, to test for the presence and concentration of potassium. In accordance with their normal procedure, OCME had not requested NMS Labs to test for the presence and concentration of potassium. The results of these examinations are included in the *Findings* section of this summary. The remainder of the sample is being stored by OCME.

On May 1, evidentiary items related to the administration of execution drugs to Lockett were released by SWIFS to the investigation team. These items were delivered by a team member to ExperTox. Evidence items that were inside Lockett's body bag and body are being maintained at SWIFS, the Oklahoma State Bureau of Investigation Laboratory or the OHP evidence storage facility. The team also collected the execution drugs and containers that were prescribed to offender Charles Warner. Custody was transferred from OSP personnel to a team member, who hand-delivered them to ExperTox for testing.

On May 5, approximately 200 items of evidence were collected at OSP, during the facility tour. They consisted of items from Lockett's cell, the execution chamber, the executioners' room and video footage from inside the facility prior to the execution. Executions are not recorded; therefore, there was no video footage of the actual execution. These items are being maintained at the OHP evidence storage facility.

D. Review of Surveillance and Camcorder Video

Thirty-two compact disks containing surveillance and camcorder video footage were collected and viewed. Following is a summary of this video provided by DOC:

1. Video surveillance footage from OSP for April 29, from 5:15 a.m. to 5:22 p.m., that recorded Lockett's movements in H-Unit and IHCC;
2. Camcorder video footage for the planned use of force that showed the extraction of Lockett from his cell on the morning of April 29. The footage contained statements explaining the force, restraints to be used and each extraction team member's duties. The footage also captured his treatment at H-Unit medical, his transport to IHCC, his treatment at IHCC and his X-ray;
3. Camcorder video footage of Lockett refusing a meal on April 29. The footage captured Lockett refusing a meal and had a statement from DOC personnel that Lockett had refused all three meals that day.

E. Documentation Provided by Oklahoma Department of Corrections

Throughout this investigation, several hundred pages of documents were requested and obtained from DOC. This team requested any documentation related to Lockett and his execution, including but not limited to logs, incident reports, timelines and historical medical records. Following is a non-inclusive summary of those documents obtained from DOC.

1. Memorandums from Warden Trammel to OSP personnel;
2. Legal documentation related to Lockett's court proceedings;
3. Use-of-force documentation from April 29, including TASER training records;
4. Property inventory and log of items sent to Lockett's family;
5. Sequence of events, execution logs and execution timeline;
6. Lockett's historical medical records, mental health check information and case manager reports;
7. Execution drugs chain-of-custody forms;
8. Execution duties listed by department and training/practice logs;
9. Lockett's 30-day notification packets;
10. DOC execution procedures;
11. Various incident reports;
12. Affidavit of Warden Anita Trammell related to the execution drugs;
13. Diagram of the execution chamber;
14. Death warrant for Clayton Lockett;

15. Execution debrief personnel log;
16. Execution chamber key log;
17. Interoffice memorandums, emails and training documents related to the execution duties of DOC personnel.

F. Interviews

During this investigation, 113 people were identified to interview. Of those, 108 were interviewed, four media witnesses who viewed the execution declined to interview and one OCME employee was on extended leave and not available to interview. Follow-up interviews of select witnesses were also conducted. Each interview, with the exception of four, was audio recorded and reduced to a typed report by a transcription service. The four interviews that were not recorded included the three executioners and the pharmacist. Below is a summary of those that were interviewed:

1. The physician, Warden Trammell and three additional DOC personnel that were in the execution chamber at the time of the execution;
2. The paramedic, one DOC employee and the three executioners that were in the executioners' room at the time of the execution;
3. Persons that viewed the execution from the viewing room or overflow area, including personnel from DOC, Office of the Attorney General, media outlets, Lockett's attorneys, members of the Neiman family, the Noble County District Attorney and Sheriff's offices, the Perry Police Department and the Secretary of Safety and Security;
4. Governor Fallin and eight members of her staff;
5. Members of DOC's administrative staff including the Director, Associate Director, District Manager, current and former members of DOC's General Counsel staff;
6. OSP corrections officers involved in different aspects of the execution, including staff who interacted with Lockett several days leading up to the execution;
7. DOC medical and mental health staff members;
8. OCME staff involved in the examination and chain-of-custody of Lockett's body and evidence;

9. Employees of Ray Francisco's Embalming Service responsible for the transport of Lockett's body;
10. The pharmacist that filled the prescription of execution drugs.

III. FINDINGS

After reviewing and considering all interviews, documentation and evidence gathered during this investigation, this team has reached several conclusions regarding Lockett's execution. Some factors ultimately contributed to the issues that arose during the process, while others directly affected how those issues were handled by the personnel in the execution chamber. Each of this team's findings is listed below, along with a detailed timeline of events.

A. Timeline

The following is a timeline of events that occurred in regards to Lockett's execution. The approximate times associated with each event have been compiled utilizing witness accounts and documentation obtained during this investigation.

April 29, 2014

12:00-4:30 a.m. DOC personnel conducted a unit check and count in H-Unit every 30 minutes. At 12:30 a.m., personnel conducted a welfare check of Lockett and no problems were noted or discovered.

4:30-5:05 a.m. The Correctional Emergency Response Team (CERT) arrived at H-Unit and began preparations to remove Lockett from cell SW-3-JJ to escort him to IHCC for x-rays.

5:06 a.m. CERT arrived at cell SW-3-JJ and Lockett refused to comply with orders. He was covered by a blanket and moving, but would not uncover or approach the cell door to be restrained.

5:09-5:50 a.m. CERT exited the area of cell SW-3-JJ to prepare for cell entry and extraction. Blood was observed by DOC personnel inside cell SW-3-JJ. A use of force plan was established and approval was given by DOC administration to utilize a TASER.

5:30 a.m.	DOC personnel performed another check and Lockett failed to comply with the order to approach the cell door and uncover himself.
5:50 a.m.	CERT arrived at cell SW-3-JJ for extraction and determined Lockett had attempted to jam the door. The door was forced open, Lockett refused to comply with verbal commands and a TASER was deployed. CERT members observed self-inflicted lacerations on Lockett's arms.
5:53 a.m.	Lockett was secured by CERT, removed from the cell, placed on a gurney and transported to H-Unit medical. A razor blade from an issued, disposable shaving razor was located inside the cell and confiscated.
5:53-6:45 a.m.	Lockett was medically evaluated at H-Unit medical.
6:35 a.m.	Lockett was transported from H-Unit medical to IHCC. He was placed in IHCC holding cell S2 and remained in handcuffs and leg irons.
6:45 a.m.	DOC personnel entered cell S2 and medical staff evaluated Lockett's lacerations.
7:00-8:15 a.m.	DOC personnel entered cell S2 every 15 minutes to check Lockett.
8:15 a.m.	Lockett was removed from cell S2 and taken to the IHCC emergency room to be examined by DOC medical staff.
8:40 a.m.	Lockett was returned to cell S2.
8:50-9:35 a.m.	DOC personnel entered cell S2 every 10-15 minutes to check Lockett.
9:15 a.m.	Lockett refused visits from his attorneys.
9:42 a.m.	Lockett refused a food tray.
9:55 a.m.	DOC personnel entered cell S2 to check Lockett.
10:15-10:30 a.m.	DOC personnel entered cell S2 to check Lockett every 15 minutes.
10:25 a.m.	Lockett confirmed his refusal to visit with his attorneys.
10:45 a.m.	DOC personnel entered cell S2 to check Lockett and adjust restraints.
11:11 a.m.	Lockett refused a food tray.

11:20 a.m.	DOC personnel entered cell S2 to check Lockett and adjusted restraints.
11:35a.m.-3:55p.m.	DOC personnel entered cell S2 to check Lockett every 15-20 minutes.
3:35 p.m.	DOC personnel retrieved the execution drugs from refrigerated storage at OSP for transport to the execution chamber.
4:10 p.m.	DOC personnel entered cell S2 to adjust restraints, redress and prepare Lockett for transport from IHCC to H-Unit.
4:15 p.m.	DOC personnel placed the execution drugs in the executioners' room.
4:31 p.m.	The three executioners and paramedic entered the executioners' room and began preparation.
4:40 p.m.	Lockett was transported to H-Unit and placed into shower SW-4.
4:55-5:10 p.m.	Lockett visited with a DOC mental health staff member.
5:19 p.m.	The five strap-down team members and Warden Trammell entered the cell area to remove Lockett from shower SW-4.
5:21 p.m.	Lockett was removed from shower SW-4 and escorted to the execution chamber.
5:22 p.m.	Lockett was placed onto the execution table and strapped down.
5:26 p.m.	The strap-down team exited the execution chamber.
5:27-6:18 p.m.	The paramedic and physician attempted IV placement access in multiple locations and were unsuccessful. The physician believed he started an IV in Lockett's right groin area.
5:45-5:57 p.m.	Victim's witnesses, media personnel, and Lockett's attorneys were summoned to the viewing room and seated.
6:18 p.m.	The paramedic and physician determined the IV line was viable.
6:20 p.m.	The paramedic re-entered the executioners' room.
6:22 p.m.	DOC Director Robert Patton and selected officials were summoned and seated in the viewing room.

6:23 p.m. Director Patton received approval from the Governor's Office to proceed with the execution. He then approved Warden Trammell to proceed. The blinds between the viewing room and execution chamber were raised and Lockett was asked if he wished to make a statement. He refused and Warden Trammell announced that the execution was to begin.

The full dose of midazolam and an appropriate saline flush were administered. A DOC employee began to keep time on a stopwatch.

6:30 p.m. The signal was given that five minutes had elapsed and the physician determined Lockett was conscious. DOC personnel began to keep additional time on a stopwatch.

6:33 p.m. The signal was given that two minutes had elapsed and the physician determined Lockett was unconscious. Warden Trammel signaled for the execution to continue. The full dose of vecuronium bromide, an appropriate saline flush and a majority of the potassium chloride were administered.

6:33-6:42 p.m. Lockett began to move and make sounds on the execution table. It should be noted that the interview statements of the witnesses regarding Lockett's movements and sounds were inconsistent.

The physician inspected the IV insertion site and determined there was an issue, which was relayed to Warden Trammell.

6:42 p.m. At the direction of Warden Trammell, the blinds were lowered. The executioner stopped administering the potassium chloride.

6:42-7:06 p.m. It should be noted that the interview statements of the individuals in the execution chamber were inconsistent. However, it was determined the following events did occur inside the execution chamber during this time period.

- The paramedic re-entered the execution chamber to assist the physician.
- The physician attempted IV access into Lockett's left, femoral vein. However, no access was completed.

- When questioned by Warden Trammell, the physician initially believed that Lockett may not have received enough of the execution drugs to induce death. He also believed there were not enough execution drugs left to continue the execution.
- The physician and paramedic continued to monitor Lockett's heart rate utilizing an EKG machine. While attempting to gain the IV access, it was observed that Lockett's heart rate continued to decrease.
- The physician made the observation that the drugs appeared to be absorbing into Lockett's tissue.
- The physician and paramedic concluded that Lockett's heart rate had entered a state of bradycardia and eventually slowed to an observed six beats per minute.
- There were three different recollections of Lockett's movements during this period. Four reported that Lockett did not move, one reported he moved slightly and the last recalled a more aggressive movement.

The following events occurred outside the viewing room door in the H-Unit hallway.

- Director Patton, OAG representatives Tom Bates and John Hadden and Secretary Thompson removed themselves from the viewing room and discussed with the Governor's Office about how to proceed.

6:56 p.m. Director Patton halted/stopped the execution, which was relayed to the execution chamber.

6:57-7:06 p.m. Witnesses were escorted out of the viewing room.

7:06 p.m. The physician pronounced Lockett deceased.

7:50 p.m. After being unstrapped from the execution table, Lockett's body was removed from OSP and transferred to the Office of the Chief Medical Examiner transport.

B. Autopsy Results for Clayton D. Lockett

Based on the autopsy, Lockett's cause of death was listed as *Judicial Execution by Lethal Injection*. The manner of death was listed as *Judicially Ordered Execution*. SWIFS pathologists concluded that Lockett died as the result of judicial execution by lethal injection. Following is a summary of the findings made by SWIFS personnel during their examination of Lockett's body and additional information obtained by the investigation team from SWIFS or through the investigation:

1. Judicial execution with:
    a. Execution protocol medications used: midazolam, vecuronium and potassium chloride.
    b. History of difficulty finding intravenous access sites resulting in numerous attempts to start an IV.
    c. Attempts in both antecubital fossa, both inguinal regions, left subclavian region, right foot and right jugular region.
2. Superficial incised wounds of the upper extremities consistent with history of self-inflicted incised wounds with a safety razor.
3. Contusions and abrasions of extremities.
4. Cardiac hypertrophy (480 grams)
5. Mild coronary artery atherosclerosis.
6. Hydroxyzine detected.
    a. Lockett was prescribed hydroxyzine, but the prescription had ended March 3. There were emails from DOC personnel alleging Lockett had been hoarding medication. SWIFS personnel stated there were higher than therapeutic levels of hydroxyzine present in Lockett's system and hydroxyzine should not have interfered with the execution drugs administered. They also could not determine when or how much of the hydroxyzine was taken.
7. No evidence of dehydration.
8. No Taser marks on the body.
9. Toxicology indicated elevated concentrations of midazolam in the tissue near the insertion site in the right groin area, which is indicative of it not being administered into the vein as prescribed in execution protocols. The presence of midazolam in the psoas muscle indicates midazolam was distributed

throughout Lockett's body during the execution. According to SWIFS pathologists, the concentration of midazolam located in Lockett's blood was greater than the therapeutic level necessary to render an average person unconscious.

10. Vecuronium bromide was found in the femoral blood sample taken from Lockett's body. The presence of vecuronium bromide in the psoas muscle indicates vecuronium bromide was distributed throughout Lockett's body during the execution.
11. Potassium was found in the femoral blood sample taken from Lockett's body.

C. DOC Execution Protocols

Regarding whether DOC correctly followed their current execution protocols, it was determined there were minor deviations from specific requirements outlined in the protocol in effect on April 29. Despite those deviations, it was determined the protocol was substantially and correctly complied with throughout the entire process. None of the identified deviations contributed to the complications encountered during this execution.

D. IV Insertion, Viability and Administration of Execution Drugs

The physician and paramedic made several attempts to start a viable IV access point. They both believed the IV access was the major issue with this execution. This investigation concluded the viability of the IV access point was the single greatest factor that contributed to the difficulty in administering the execution drugs.

While exploring this issue, several DOC personnel made statements referencing Lockett purposefully dehydrating himself. Lockett made statements to the paramedic that he had been dehydrating himself for three days. However, SWIFS pathologists found no indication that Lockett was dehydrated at the time of his execution. SWIFS also concluded Lockett's blood loss from the self-inflicted wounds to his arms should not have caused issues with the IV access.

Interviews and documentation indicated several vein checks had been performed by DOC medical personnel leading up to and on the day of the execution. Each check indicated that Lockett's veins were "good". At least three interviews of DOC medical personnel indicated they viewed Lockett's veins on the morning of the execution. Their observations concluded his veins were "good" and acceptable for IV access.

The IV insertion process was started by an emergency medical technician licensed as a paramedic. The paramedic had been licensed in emergency medical services for more than 40 years and as a paramedic for over 20 years. This person had also instructed at the intermediate level. The licenses possessed at the time of the execution were valid until 2015 and were from the Oklahoma State Department of Health and the National Registry of Emergency Medical Technicians. The paramedic provided the prison a copy of the above licenses in January or February 2014. The paramedic estimated he/she had been involved in every lethal injection execution in Oklahoma, except for two. His/her specific assignments were to start an IV, ensure a proper infusion of saline, attach a cardiac monitor to Lockett and during the execution, make sure the executioners did their part of the procedure aseptically, at the correct time and the correct speed.

The IV access was completed by a physician licensed as a medical doctor. The physician graduated medical school over 15 years ago, currently worked in emergency medicine and was certified in family medicine. His license expires July 1 of each year and was current at the time of the execution. He had not provided a current copy of his license to DOC prior to April 29, but days later was called and asked for a copy. This was his second execution with the first being four to five years earlier. The physician understood his duties were to assess Lockett to determine if he was unconscious and ultimately to pronounce his death. He was contacted two days prior to the execution date and asked to fill in for another physician that had a scheduling conflict.

Before Lockett was moved into the chamber, the paramedic prepared the IV lines and available execution tools. He/she also verified the drugs were properly labeled and were for Lockett. After Lockett was brought to the chamber and secured to the execution table, the paramedic began to assess his veins. The paramedic first attempted access in the left arm and found a vein with an 18-gauge needle/catheter and observed flashback, a condition sought during IV placement. The paramedic did not have adhesive tape on

his/her person to secure the catheter. Before the tape was retrieved, the vein became unviable. The paramedic then attempted two additional IV insertions into the left arm using the same type needles/catheters, but never observed flashback.

After these attempts, the physician became involved and attempted IV access into Lockett's left, external jugular vein utilizing a 1¼ inch, 14-gauge needle/catheter. During his interview, the physician stated he penetrated this vein and obtained flashback. Seconds later, it became unviable and he was unable to continue with that vein. As the physician was attempting this access, the paramedic was attempting IV access into Lockett's right arm. After three attempts, the paramedic was unable to start a viable IV access point in this arm.

Next, the physician attempted to locate the subclavian vein on Lockett's left side utilizing a central venous catheritization kit. During the attempt, the physician observed a very small amount of flashback, but he was unable to repeat it. The physician believed the needle was penetrating through the vein. He noted during his interview he did not have access to an ultrasound machine, which is a commonly used tool to locate and penetrate veins.

As the physician attempted subclavian access, the paramedic attempted IV access in two separate locations on Lockett's right foot with 20 gauge needles/catheters. The paramedic said the veins rolled and disappeared during those attempts. The paramedic believed the needle penetrated the veins, but flashback was never observed. The paramedic did not attempt access into any other veins because the physician made the decision to attempt access into a femoral vein.

The physician requested a longer needle/catheter for the femoral access. The paramedic attempted to locate a 2 or 2½-inch, 14-gauge needle/catheter, but none were readily available. The physician also asked for an intraosseous infusion needle, but was told the prison did not have those either. Both agreed their preferred needle/catheter length would have been 1¾ to 2½ inches. The physician had never attempted femoral vein access with a 1¼ inch needle/catheter; however, it was the longest DOC had readily available. An additional central venous catheterization kit was available, but the physician did not think about utilizing one for femoral access.

Lockett's scrub pants and underwear were cut in order to expose the femoral area. The physician located the femoral vein and believed the vein was penetrated because he observed good flashback. The paramedic taped the catheter to Lockett's body, and stated during his/her interview it became positional. The physician believed it was bending because of its length. He and the paramedic positioned the catheter where they were able to observe slow infusion of saline and secured it with adhesive tape. The autopsy did not conclude the femoral vein was punctured. However, SWIFS personnel indicated they only examined the portion of the femoral vein that had been dissected by OCME and not the entire vein.

The physician was asked about starting a second IV line. He stated he was not going to make another attempt. The physician and paramedic were comfortable with the IV placement and the infusion of saline through the line. This was not the first execution in Oklahoma where only one IV access point had been obtained and protocol allowed for only one access point.

Warden Trammell decided to cover Lockett's body with a sheet, including the IV insertion area, which, according to her, was normal in all executions. Another reason for her decision was to maintain Lockett's dignity and keep his genital area covered. From that time, no one had visual observation of the IV insertion point until it was determined there was an issue and the physician raised the sheet. Warden Trammell acknowledged it would be her normal duty to observe an IV insertion point for problems. She believed if the IV insertion point had been viewed, the issue would have been detected earlier. The physician added that an IV would normally be monitored by watching the flow of the IV line and the area around the insertion point for any signs of infiltration. This investigation found that neither of these observations occurred, which led to the issue being discovered several minutes after the execution began.

After the IV insertion was complete, the paramedic went into the executioners' room and the physician remained in the execution chamber. Once Warden Trammell announced it was time to begin the execution, the paramedic began the procedure to administer the drugs. The paramedic first used a hemostat to clamp the IV line above the access port, to stop the flow of execution drugs from going up the line. The IV drip was never reestablished after that point. The midazolam and the appropriate flushes were

administered into the single access port by the executioners in the order they were presented by the paramedic. The paramedic and executioners were certain the drugs were pushed steady and in the proper manner because of their past experiences in performing the same roles. The DOC employee in the executioners' room then began to keep time using a stopwatch.

According to execution protocol, the vecuronium bromide shall not be administered until at least five minutes after the administration of midazolam. Prior to the execution, DOC administration determined if Lockett was not unconscious after five minutes, he would be checked every two minutes, until he was declared unconscious. Five minutes after the administration of midazolam, the physician determined Lockett was conscious. After an additional two minutes, the physician determined that Lockett was unconscious.

Warden Trammell signaled for the execution process to continue. The executioners, with assistance from the paramedic, began administering the vecuronium bromide, the potassium chloride and the appropriate saline flushes. Both syringes of the vecuronium bromide, appropriate saline flushes, the first full syringe of potassium chloride and a portion of the second syringe of potassium chloride were administered. At some point during the administration of these two drugs, Lockett began to move and the physician recognized there was a problem.

The physician approached Lockett and indicated to Warden Trammell that something was wrong. He looked under the sheet and recognized the IV had infiltrated. At this same time, Warden Trammell viewed what appeared to be a clear liquid and blood on Lockett's skin in the groin area. The physician observed an area of swelling underneath the skin and described it as smaller than a tennis ball, but larger than a golf ball. The physician believed the swelling would have been noticeable if the access point had been viewed during the process.

The execution process was stopped as one of the executioners was administering the second syringe of potassium chloride. The executioner immediately stopped pushing the syringe with approximately 10 milliliters of potassium chloride remaining. The remainder of the drug was later wasted into a bio-hazard bin by the paramedic.

The blinds to the execution chamber were lowered and the paramedic exited the executioners' room to assist the physician. The physician told the paramedic the catheter dislodged. The paramedic observed the catheter was tilted to one side and believed it was no longer penetrating the vein. The physician decided to attempt IV insertion into the left-side femoral vein. The physician first penetrated Lockett's femoral artery and another access point into the vein was never completed because the physician believed the drugs were being absorbed into his tissue.

The physician and paramedic were unsure when the catheter became dislodged and how much of each drug had made it into Lockett's vein. The autopsy indicated elevated concentrations of midazolam in the tissue near the insertion site in the right groin area, which was indicative of the drugs not being administered into the vein as intended. Thus, the IV access was not viable as early as the administration of the midazolam.

E. Toxicology Results of Femoral Blood Sample: Clayton D. Lockett

On May 14 and May 19, OCME documented the toxicology results they received from NMS Labs on an aliquot of the femoral blood sample they obtained from Lockett's body on April 30. The results indicated a midazolam concentration of 0.57 mcg/mL and a vecuronium concentration of 320 ng/mL. On June 26, ExperTox completed toxicology testing of an aliquot of the same femoral blood sample. The results of this test indicated a potassium concentration of 0.74 mole/L. It should be noted that testing for the concentration of potassium after death can be problematic due to the body's natural processes, which cause an increase in the concentrations of potassium in the blood over time.

F. Toxicology Results of Execution Supplies: Clayton D. Lockett

On May 5, ExperTox completed testing of the execution supplies utilized during Lockett's execution. They analyzed the contents by liquid chromatography/triple quad mass spectrometry (LC/MSMS) and inductively coupled argon plasma-mass spectrometry (ICP-MS) for the detection and quantitation of midazolam, vecuronium bromide and potassium chloride. ExperTox reported the following:

1. The two syringes labeled midazolam contained residues consistent with the listed label content of 5 mg/mL.
2. The two syringes labeled vecuronium bromide contained residues consistent with the listed label content of 1 mg/mL.
3. The two syringes labeled potassium chloride contained residues consistent with the listed label content of 2 meq/mL.
4. The IV Tubing connected to two 0.9% NaCl one liter IV bags contained sodium chloride, blood, residues of vecuronium bromide at the final concentration of 0.013 g/mL and residues of potassium chloride at the final concentration of 1.3 meq/mL.

G. Toxicology Results of Execution Drugs: Charles Warner

On May 5, ExperTox completed testing of the drugs intended for use during the execution of Charles Warner. They analyzed the contents by LC/MSMS and ICP-MS for the detection and quantitation of midazolam, vecuronium bromide and potassium chloride. These tests were also utilized to determine drug agent potency. ExperTox reported the following:

1. The two 0.9% NaCl injection USP 1 liter IV bags tested consistent with the listed contents.
2. The seven 0.9% NaCl 50 mL bags tested consistent with the listed contents.
3. The two syringes labeled midazolam tested consistent with the listed label content of 5 mg/mL.
4. The two syringes labeled vecuronium bromide tested consistent with the listed label content of 1 mg/mL.
5. The two syringes labeled potassium chloride tested consistent with the listed label content of 2 meq/mL.

H. Execution Protocol Training of Execution Team

This investigation determined that DOC personnel did conduct training sessions as required by the protocol in effect on April 29. The sessions were conducted during the weeks and days leading up to the execution and consisted of planning meetings, on-the-job training for each of the respective positions in the execution chamber and

executioners' room and walk-through training sessions for all involved staff members. The paramedic, physician and the three executioners were not included in this training prior to the day of the execution. The final training session included DOC administrative staff reviewing the sequence of events with all parties in the execution chamber just prior to the execution.

Field Memorandum OSP-040301-01, *Procedure for the Execution of Offenders Sentenced to Death*, outlines the training requirements that should occur prior to an execution. The following is a summary of the training procedures that were conducted prior to Lockett's execution.

1. A deputy warden or designee was required to review the sequence of events inside the executioners' room with the executioners and paramedic prior to each execution. Documentation and interviews substantiated this requirement was completed on April 29 at 5:06 p.m.
2. The paramedic was required to give the following instructions to the executioners, "Administer the drugs at a steady flow without pulling back on the plunger of the syringe." The paramedic did not give this statement prior to this execution. However, the three involved executioners had been involved in multiple executions prior to Lockett's and each acknowledged their roles and duties. The paramedic also acknowledged his/her role to ensure the executioners did their job aseptically, at the correct time, speed and dosage.
3. The warden was required to review the sequence of events with the physician and other DOC personnel in the execution chamber prior to beginning the execution. Interviews and documentation indicated this occurred on April 29 at 5:15 p.m.
4. DOC protocol required the strap-down team to conduct a walk-through of the strap-down procedures no later than two weeks prior to the execution. There were multiple walk-through training sessions conducted prior to Lockett's execution. The last session was conducted within two weeks of Lockett's execution, as required by protocol.

This investigation revealed areas of training that need to be addressed. It was noted there was no formal training process involving the paramedic, the physician or the executioners and their specific roles. They were not involved in any pre-execution training or exercises to ensure they understood the overall process. For those individuals, the current protocol had very minimal training requirements. The executioners only receive formal training from the paramedic on the day of the execution and informal training from previous executioners during actual executions.

Warden Trammell and Director Patton both acknowledged the training DOC personnel received prior to the execution was inadequate. Warden Trammell stated the only training she received was on-the-job training and that DOC had no formalized training procedures or processes concerning the duties of each specific position's responsibility. The warden and director both indicated DOC had no training protocols or contingency plans on how to proceed with an execution if complications occur during the process.

I. Contingency Planning for Executions

The DOC execution protocol in effect on April 29 had limited provisions for contingencies once the execution process began. One contingency allowed the physician to assist with initial IV access and the other concerned life-saving measures if a stay was granted. After it was determined that problems were present during Lockett's execution, personnel involved with the execution were unaware of how to proceed due to the lack of policies and/or protocols in place at that time. It was determined that no contingency actions were taken inside the chamber other than the physician attempting to locate the femoral vein on Lockett's left side, which was never completed prior to his death.

J. Cessation of Execution Protocols

When an issue with the administration of execution drugs was discovered, the blinds between the chamber and viewing room were lowered. Several conversations took place inside and outside the chamber regarding how to proceed. The conversation outside the chamber included whether to continue or how to stop the execution. The conversations inside the chamber included whether to provide life-saving measures.

Outside the execution chamber, there were several conversations between Director Patton, Secretary Thompson, OAG representatives at the execution and General Counsel Steve Mullins with the Governor's Office. It was determined between Director Patton and General Counsel Mullins, who had conversed with the Governor, that the execution would be stopped. Director Patton then relayed to the witnesses and the personnel in the chamber that the execution was being stopped. In an additional conversation, General Counsel Mullins further told Director Patton that they would begin preparing a stay at the direction of the Governor. Lockett died prior to the order for a stay being relayed to the personnel inside the execution chamber. There was conversation inside the chamber about administering life-saving measures to Lockett, including transporting him to the emergency room, but no order was given.

K. Two Executions Scheduled on the Same Day

It was apparent the stress level at OSP was raised because two executions had been scheduled on the same day. This was the first time since 2000 two offenders were scheduled to be executed the same day. Four days prior to the execution, the protocol was revised to accommodate the logistics for two offenders.

Several comments were made about the feeling of extra stress. Warden Trammell believed this caused extra stress for all staff. The paramedic stated he/she felt stress and a sense of urgency in the air. This was based on him/her having been involved in numerous executions.

L. Maintenance of Daily Logs

In accordance with protocol, OSP staff maintained a daily log of events and occurrences related to Lockett. Protocol stated, "Seven days prior to the execution of an offender sentenced to death, a daily log will be kept regarding every aspect of the proceedings except names." This investigation determined the information recorded on the logs was incomplete.

M. Use of Midazolam, Vecuronium Bromide and Potassium Chloride

The new three drug protocol utilized in this execution included the administration of midazolam, vecuronium bromide and potassium chloride. It was determined vecuronium bromide and potassium chloride had both been used in previous executions as the second and third drugs to be administered. This was the first Oklahoma execution where midazolam was used.

On April 14, midazolam was the newest drug added to the protocol after it was determined pentobarbital was not available. Pursuant to the death warrant, a dosage of 100 mg was ordered and administered to Lockett. According to protocol, vecuronium bromide was to be administered at a total quantity of 40 mg and the potassium chloride at a total quantity of 200 meq. These dosages were equivalent to the quantities used in other Oklahoma three-drug methods dating back to at least 2011.

This investigation could not make a determination as to the effectiveness of the drugs at the specified concentration and volume. They were independently tested and found to be the appropriate potency as prescribed. The IV failure complicated the ability to determine the effectiveness of the drugs.

On the day of the execution, OAG representatives presented an affidavit to Warden Trammell related to the execution drugs. The warden signed the affidavit and attested that the drugs had been obtained legally from a licensed pharmacy and had been handled appropriately, since their acquisition. Interviews of DOC and OAG staff revealed this type of affidavit had been signed in the past, but never on the day of an execution. According to OAG representatives, the affidavit was executed on the day of the execution, due to ongoing litigation concerns regarding the drugs.

N. Historical Incident Reports and Medical Records

The investigation team obtained historical incident reports, emails and medical records from OSP regarding Lockett. The incident reports included approximately 42 instances where Lockett was disciplined for behavioral issues and for contraband located or suspected by DOC personnel. Examples include:

1. A cellular telephone was discovered in Lockett's cell several months prior to the execution;

2. DOC personnel suspected Lockett had been hoarding Vistaril (hydroxyzine) from a prescription that ended March 3;
3. A homemade rope was discovered on the floor of Lockett's cell during his extraction on the day of the execution;
4. A razor blade from an issued, disposable shaving razor was discovered in Lockett's cell on the day of the execution.

The review of Lockett's medical records by a medical professional indicated that he had no past medical conditions or factors that would be considered problematic for IV insertion or drug administration.

O. Lockett's Movements and Sounds after Drug Administration

The description of Lockett's movements and sounds varied among the witnesses. The movement descriptions ranged from quivering to thrashing, but most agreed Lockett's head did rise off the table. There were differing recollections regarding whether Lockett's eyes opened after he was deemed unconscious. The sound descriptions varied from mumbling to Lockett making statements. The recollections varied greatly; therefore it was difficult to determine what was said, if anything.

Several conclusions were made pursuant to the execution table assessment. While strapped to the table, the team member made attempts to move all parts of his body. He was able to rotate his feet inward and outward, move his shoulders slightly and his head had a full range of motion. He was not able to bend or move his knees and had minimal movement in his hips as he attempted to move from side to side. He could not move his hips up and down. The hands had no movement and the arms had minimal movement due to the elbow having limited motion. Based on what was observed, witnesses would have a different perspective of the amount of movement depending on where they were seated. Due to the restrictiveness of the straps, the movements were minimal to non-existent with the exception of the head and feet.

IV. RECOMMENDATIONS

Based on the findings, the following recommendations are made for future lethal injection executions in Oklahoma. DOC, the Office of the Attorney General and any other entity or individual responsible for execution protocols in this state are urged to thoroughly research, review and deliberate these recommendations prior to their implementation. Further, DOC should review and consider policies and protocols from other states responsible for executions. Any changes to the current policies and protocols should comply with Oklahoma and federal law.

A. Observation of IV Insertion Point(s) and Infusion

1. The IV catheter insertion point(s) should remain visible during all phases of the execution and continuously observed by a person with proper medical training in assessing the ongoing viability of an IV. This person should remain inside the execution chamber during the entire process.
2. Once the appropriate saline infusion has started, it should not be stopped, except for the times that execution drugs are being administered. It should be continuously monitored to assist in ensuring IV viability in accordance with current medical practices and standards;
3. After one hour of unsuccessful IV attempts, DOC should contact the Governor to advise the status and potentially request a postponement of the execution.

B. Training and Maintenance of Execution Log for Condemned Offenders

1. Conduct formal, specific training related to information documented on all execution logs.
2. The information to be recorded on execution logs should include, but not be limited to:
    a. all statements or behaviors that could be detrimental to completing an execution;
    b. all meals provided to an offender and what portions of the meals the offender consumed or refused;

c. all medication provided to an offender and the observations made by personnel as to whether the offender ingested the medication as prescribed;
d. all liquids consumed by the offender.

C. Additional Execution Supplies

DOC should maintain and provide their own equipment and supplies ensuring their operability prior to each execution.

1. DOC should obtain from the selected pharmacist, one complete, additional set of each execution drug being utilized for an execution to be used in the event an issue arises with the primary set.
2. DOC should consult with appropriate medical personnel to determine any and all supplies or equipment necessary including, but not limited to the following:
    a. Heart monitoring equipment;
    b. Venous ultrasound equipment;
    c. Appropriate needle/catheters to coincide with the IV access options listed in protocol.

D. Contingency Plans in Protocols/Policy

DOC should evaluate and establish protocols and training for possible contingencies if an issue arises during the execution procedure. DOC should consider planning for contingencies including, but not limited to:

1. Issues with execution equipment or supplies;
2. Issues with offender IV access, including obtaining alternate IV access site(s);
3. The offender is not rendered unconscious after execution drug administration;
4. A combative offender;
5. Unanticipated medical or other issues concerning the offender or an execution team member;
6. Issues regarding order, security or facilities at OSP.

E. Formal and Continuing Training Program for Execution Personnel

DOC should establish formal and continual training programs for all personnel involved in the execution process. They should explore successful training procedures used by other correctional institutions and implement accordingly.

F. Formal After-Action Review of the Execution Processes

At the conclusion of each execution, all personnel with assigned execution duties should attend an after-action review. The review should be completed within five business days and conducted by the director or his designee. The events that occurred during the execution should be discussed in detail and each involved person should discuss their responsibilities and observations. The review should serve as an opportunity for all involved personnel to voice their opinions, concerns and/or recommendations in order for continuous improvement to the process. The review should be formally documented and retained for future reference.

G. Defined Execution Terminology

It was apparent during this investigation that specific terminology should be clearly defined so they are understood by all personnel involved in the execution process. This will allow DOC, OAG and Governor's Office personnel to have a common understanding of how each term affects the execution process and the actions that should take place, if such terms are used. Defined terms should include, but are not limited to "stop," "stay," and "halt".

H. Completion of One Execution per Seven Calendar Days

Due to manpower and facility concerns, executions should not be scheduled within seven calendar days of each other.

I. Updated Methods of Communication

The current communication methods used during the execution process are antiquated and require unnecessary multi-tasking from key personnel in the execution chamber. DOC should explore options on how to update the following:

1. Communication between the execution chamber and executioners' room.
    a. DOC should research and implement modern methods that allow personnel in these two areas to communicate clearly.
    b. The current processes, including the use of color pencils and hand signals, could be used as a contingency if other modern methods fail.
2. Communication between DOC and the Governor's Office.
    a. DOC should research and implement methods to modernize the communication link that would allow direct, constant contact between the personnel in the execution chamber and the Governor's Office.

J. Disposition of Executed Offender's Property

DOC should explore maintaining an executed offender's personal property and any items removed from his/her cell until the autopsy report is completed. This would allow DOC administrative personnel time to determine if such property should be maintained for an additional period of time, if appropriate circumstances exist. In any event, no property should be released until it has been properly searched and inventoried.

K. Execution Witness Briefing

As a result of the changing execution protocols and procedures, DOC should conduct a prepared pre-execution briefing with all attending witnesses. This briefing should include, but not be limited to the following:

1. An overview of the events the witnesses will view during the execution process, including an explanation that witnesses will not be allowed to view all aspects of the execution;
2. Requirements regarding the conduct of witnesses throughout the process.

U.S. Department of Justice

Federal Bureau of Prisons

Office of the Director *Washington, D.C. 20534*

November 27, 2017

MEMORANDUM FOR THE ATTORNEY GENERAL

THROUGH: THE DEPUTY ATTORNEY GENERAL

Robert K. Hur
Principal Associate Deputy Attorney General

James A. Crowell, IV
Chief of Staff and Associate Deputy Attorney General

FROM: Mark Inch
Director
Federal Bureau of Prisons

SUBJECT: Approval of Bureau of Prisons' Death Penalty Protocol Addendum

I. Introduction

The Federal Bureau of Prisons ("BOP"), along with the United States Marshals Service ("USMS"), is responsible for implementing federal death sentences. *See* 28 CFR Part 26. Those regulations require BOP to use lethal injection as the method of execution. Prior to 2003, BOP's lethal injection protocol consisted of three drugs: sodium pentothal, pancuronium bromide, and potassium chloride.[1] No federal execution has occurred since 2003, in part, because of the unavailability of sodium pentothal.

BOP has studied the issue and now requests the approval of an Addendum to its Federal Execution Protocol ("Addendum") that provides for the use of a single drug, pentobarbital sodium ("pentobarbital"), as the lethal agent. *See* Tab 1, Addendum. This new Addendum will replace the three-drug procedure previously used in federal executions.

BOP believes it has a viable plan to obtain pentobarbital, which would allow it to resume federal executions. This Memorandum discusses BOP's analysis underlying requested protocol and its plan to implement the amended Protocol if approved.

[1] BOP carried out the executions of Timothy McVeigh (2001), Juan Garza (2001), and Louis Jones (2003) using this drug compound.

II. Background

Implementation of the federal death penalty is governed by 18 U.S.C. §§ 3596-3597. These provisions require BOP to carry out death sentences "in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a). Federal regulation further clarifies that BOP must implement death sentences "by intravenous injection of a lethal substance or substances in a quantity sufficient to cause death." 28 C.F.R. § 26.2(3).[2] The Director of BOP is charged with determining what "substance or substances" should be used in federal executions. 28 C.F.R. § 26.3(4).

A. Use of Pentobarbital

All states use lethal injection as their primary method of execution. State protocols comprise of one-, two-, and three-drug methods. The three-drug protocol typically involves an anesthetic or sedative, followed by pancuronium bromide to paralyze the inmate, and finally potassium chloride to stop the inmate's heart. The one- or two-drug protocols typically use a lethal dose of an anesthetic or sedative.

There has been much litigation regarding death penalty protocols. In *Baze v. Rees*, 553 U.S. 35 (2008), the Supreme Court upheld Kentucky's use (along with at least 30 other states) of a three-drug combination, including sodium pentothal, pancuronium bromide, and potassium chloride.[3] While *Baze* cleared legal obstacles that states faced in carrying out the death penalty, practical obstacles soon emerged as pharmaceutical companies began refusing to supply the drugs used to implement the death sentences. *See Glossip v. Gross*, 135 S.Ct. 2726, 2733 (2015). Specifically, the sole American manufacturer of sodium pentothal stopped producing the drug because of its use in the death penalty.[4]

After the availability of sodium pentothal declined, states developed an alternative drug combination that replaced sodium pentothal with pentobarbital, another barbiturate. *Glossip*, 135 S.Ct. at 2733. On December 16, 2010, Oklahoma was the first state to execute an inmate using pentobarbital in place of sodium pentothal in its three-drug compound. *Id.*[5] The following year,

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[2] All 31 states that currently permit the death penalty allow for lethal injection as the primary execution method, which complies with 18 U.S.C. § 3596. *See* Death Penalty Information Center, *Authorized Methods*, *available at* https://deathpenaltyinfo.org/methods-execution.

[3] Under the Court's precedent, to successfully challenge a state's lethal injection protocol under the Eighth Amendment, a condemned prisoner must: (1) "establish[ ] that the State's lethal injection protocol creates a demonstrated risk of severe pain[;]" and (2) "show that the risk is substantial when compared to the known and available alternatives." *Baze*, 553 U.S. at 61

[4] Hospira, Press Release, Hospira Statement Regarding Pentothal (sodium thiopental) Market Exit (Jan. 21, 2011).

[5] *See also* Divinda Mims, *Death row inmate executed using pentobarbital in lethal injection*, CNN, December 16, 2010, *available at* http:// http://www.cnn.com/2010/CRIME/12/16/oklahoma.execution.

Ohio used pentobarbital in a one-drug execution.[6] In the years since, many states incorporated pentobarbital into their protocols. In fact, all 43 executions carried out in 2012 reportedly used pentobarbital.[7]

Currently, fourteen states have used pentobarbital, either as part of a three-drug combination or by itself, in executions. An additional five states have announced plans to use it.[8] Georgia, Idaho, Missouri, South Dakota, and Texas administer a single-drug pentobarbital protocol, as BOP seeks to do, as the primary method of execution. Both Missouri and Texas have extensive experience with this method, executing 20 and 60 inmates, respectively, with single-drug pentobarbital since approximately 2012.[9] Eight of twenty-one executions in 2017 used single-drug pentobarbital.[10] Although various media outlets have reported complications with lethal injection executions, none of those executions appear to have resulted from the use of single-drug pentobarbital.[11]

B. Use of Compounded Pentobarbital

The supply of pentobarbital significantly declined in 2011 after advocates lobbied its sole worldwide producer of injectable pentobarbital to stop selling it for use in executions. *Glossip*, 135 S.Ct. at 2733.[12] Currently, pentobarbital's manufacturers place restrictions on its domestic distribution to prevent it from being sold to departments of corrections for use in executions.

With limited drug availability directly from the manufacturers, states began taking alternative steps to secure lethal substances for their execution procedures. At least ten states have either used, or intend to use, compounding pharmacies to obtain their drugs for lethal injection.[13] In general, compounding pharmacies are entities where a licensed pharmacist or physician combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. In October 2012, South Dakota became the first state to carry out an execution using compounded pentobarbital.[14] Missouri followed suit and used pentobarbital from a compounding pharmacy in November 2013, and Texas did the same in October 2013.[15]

Circuit courts have consistently denied prisoners relief when challenging a compounded pentobarbital lethal injection protocol. *See Zink v. Lombardi*, 783 F.3d 1089, 1102 (8th Cir.

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[6] Deborah W. Denno, *Lethal Injection Chaos Post-Baze*, 102 GEO. L.J. 1331, 1382 (2014).
[7] *Glossip*, 135 S.Ct. 2733 (citing Death Penalty Institute, Execution List 2012, online at www.deathpenaltyinfo.org/execution-list-2012).
[8] Death Penalty Information Center, *State by State Lethal Injection, available at* www.deathpenaltyinfo.org/state-lethal-injection (last visited October 30, 2017).
[9] Death Penalty Information Center, *supra* note 9.
[10] *Id.*
[11] Death Penalty Information Center, *Botched Executions, available at* https://deathpenaltyinfo.org/some-examples-post-furman-botched-executions.
[12] Eric Berger, *Lethal Injection Secrecy and Eighth Amendment Due Process*, 55 B.C. L. Rev. 1367, 1380 (2014).
[13] Death Penalty Information Center, *supra* note 9.
[14] *Id.*
[15] *Id.*

2015); *Whitaker v. Livingston,* 732 F.3d 465, 468 (5th Cir. 2013); *Wellons v. Comm'r Ga. Dep't of Corr.,* 754 F.3d 1260, 1265 (11th Cir. 2014). *See also Owens v. Hill*, 758 S.E.2d 794, 802-03 (Ga. 2014); *West v. Schofield*, -- S.W.3d --. 2017 WL 1376946, at *13 (Tenn. Mar. 28, 2017).

C. Development of Addendum

In 2011, BOP began exploring pentobarbital and other methods of conducting executions. That year, BOP personnel visited several states to observe executions. Based upon research, observation, and the opinion of medically trained personnel, BOP developed the single-drug pentobarbital protocol.

As part of its research and study, BOP examined a three-drug process using pentobarbital as the first anesthetic. BOP disfavored this method because of the complications inherent in obtaining multiple drugs. BOP also considered the use of midazolam as part of a three-drug process. As stated earlier, several states experienced some complications with this drug during executions. In the end, BOP determined that the single-drug pentobarbital protocol was the most suitable method based on its widespread use by the states and its acceptance by many courts.

The Addendum provides for the use of five grams of pentobarbital during executions. The Addendum calls for three syringes to be prepared, with the first two containing 2.5 grams of pentobarbital sodium (in diluent) and the final syringe containing 60 mL of saline flush. Addendum ¶ H (Tab 1). Supervisory personnel are then to direct the administration of each syringe. *Id.*

BOP's draft procedures are similar to execution protocols adopted by Georgia, Ohio, Tennessee, Missouri, and Arizona. Texas's protocol utilizes one injection of 5 grams of pentobarbital.[16]

BOP consulted with the USMS Office of General Counsel regarding the Addendum. USMS concurred with the Addendum and noted their deference to BOP on all matters related to the time, place, and manner of carrying out federal executions.

BOP also retained a medical consulting firm to review the Addendum in anticipation of litigation. If the Addendum is approved, BOP anticipates its protocol will be subject to vigorous litigation. Currently, one federal case is pending in the District of Columbia challenging BOP's method of execution and will be reopened upon the adoption of a protocol. *See Roane, et al. v. Gonzales*, No. 05-2337 (D.D.C.). In May and October 2017, BOP, in connection with the U.S. Attorney's Office in the District of Columbia consulted with Dr. Joseph F. Antognini, M.D., a clinical professor of anesthesiology and pain medicine at University of California Davis School of Medicine. Dr. Antognini concurs with the Addendum and is prepared to submit an expert report in defense of the protocol.

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[16] State protocols can be found at Death Penalty Information Center, *State by State Lethal Injection, available at* https://deathpenaltyinfo.org/state-lethal-injection.

III. Implementation of Protocol

Following approval of the Addendum, BOP is prepared to implement the amended Protocol. BOP has the necessary facilities and staff to resume federal executions and is prepared to conduct executions at its facilities in Terre Haute, Indiana. BOP, for example, regularly trains staff in the execution Protocol and conducts training exercises. A training occurred as recently as the week of October 23, 2017.

BOP also believes it has a viable plan to obtain pentobarbital. BOP intends to import powdered pentobarbital from a foreign FDA-registered facility.[17] Once inside the United States, a compounding pharmacy will be used to modify the drug into an injectable solution. BOP plans to have the compounded pentobarbital tested to ensure proper concentration. The shelf-life for this pentobarbital is approximately two years.

In preparation for this option, BOP consulted with the Drug Enforcement Administration ("DEA") Office of General Counsel. DEA foresees no issues arising from the transportation of the compounded pentobarbital.

IV. Pending Litigation and Death Penalty Eligible Inmates

Once a protocol is adopted and BOP obtains pentobarbital, execution dates may be set for ten of the 60 inmates with federal death sentences. Each one of the following ten inmates have exhausted their appeals (although they may potentially file a collateral challenge once a date is set):

Inmate	Supreme Ct. Cert. Pet. Denial Date	District
Brandon Bernard	January 19, 2016	W.D. Tex.
Meier Brown	October 6, 2014 and December 1, 2014 (rehearing)	S.D. Ga.
Sherman Fields	June 8, 2015	W.D. Tex.
Dustin Higgs	December 10, 2012	D. Md.
Norris Holder	October 5, 2015	E.D. Mo.
Dustin Honken	October 5, 2015	N.D. Iowa
William Lecroy	March 9, 2015	N.D. Ga.
Daniel Lee	April 17, 2017	E.D. Ark.
Wesley Purkey	October 14, 2014	W.D. Mo.
Christopher Vialva	February 29, 2016	W.D. Tex.

[17] In consultations with the FDA, the agency has stated that imported bulk pentobarbital from a foreign FDA-registered facility would be subject to its enforcement discretion and that the shipment should be allowed into the country.

ADDENDUM TO BOP EXECUTION PROTOCOL
FEDERAL DEATH SENTENCE IMPLEMENTATION PROCEDURES
EFFECTIVE TBA

A. Federal death sentences are implemented by an intravenous injection of a lethal substance or substances in a quantity sufficient to cause death, such substance or substances to be determined by the Director, Federal Bureau of Prisons (BOP) and to be administered by qualified personnel selected by the Warden and acting at the direction of the United States Marshal. 28 CFR 26.3. The procedures utilized by the BOP to implement federal death sentences shall be as follows unless modified at the discretion of the Director or his/her designee, as necessary to (1) comply with specific judicial orders; (2) based on the recommendation of on-site medical personnel utilizing their clinical judgment; or (3) as may be required by other circumstances.

B. The identities of personnel considered for and/or selected to perform death sentence-related functions, any documentation establishing their qualifications and the identities of personnel participating in federal judicial executions or training for such judicial executions shall be protected from disclosure to the fullest extent permitted by law.

C. The lethal substances to be utilized in federal lethal injections shall be Pentobarbital Sodium.

D. Not less than fourteen (14) days prior to a scheduled execution, the Director or designee, in conjunction with the United States Marshal Service, shall make a final selection of qualified personnel to serve as the executioner(s) and their alternates. See BOP Execution Protocol, Chap. 1, §§ III (F) and IV (B) & (E). Qualified personnel includes currently licensed physicians, nurses, EMTs, Paramedics, Phlebotomists, other medically trained personnel, including those trained in the United States Military having at least one year of professional experience and other personnel with necessary training and experience in a specific execution-related function. Non-medically licensed or certified qualified personnel shall participate in a minimum of ten (10) execution rehearsals a year and shall have participated in at least two (2) execution rehearsals prior to participating in an actual execution. Any documentation establishing the qualifications, including training, of such personnel shall be maintained by the Director or designee.

E. The Director or designee shall appoint a senior-level ~~Bureau~~ BOP employee to assist the United States Marshal in implementing the federal death sentence. The Director or designee shall appoint an additional senior-level BOP~~ureau~~ employee to supervise the activities of personnel preparing and administering the lethal substances.

ADDENDUM TO BOP EXECUTION PROTOCOL
FEDERAL DEATH SENTENCE IMPLEMENTATION PROCEDURES
EFFECTIVE TBA

F. The lethal substances shall be prepared by qualified personnel in the following manner unless otherwise directed by the Director, or designee, on the recommendation of medical personnel. The lethal substances shall be placed into three sets of numbered and labeled syringes. One of the sets of syringes is used in the implementation of the death sentence and two sets are available as a backup.

G. Approximately thirty (30) minutes prior to the scheduled implementation of the death sentence, the condemned individual will be escorted into the execution room. The condemned individual will be restrained to the execution table. The leads of a cardiac monitor will be attached by qualified personnel. A suitable venous access line or lines will be inserted and inspected by qualified personnel and a slow rate flow of normal saline solution begun.

H. Lethal substances shall be administered intravenously. The Director or designee shall determine the method of venous access (1) based on the training and experience of personnel establishing the intravenous access; (2) to comply with specific orders of federal courts; or (3) based upon a recommendation from qualified personnel.

A set of syringes will consist of:

Syringe #1 contains 2.5 grams of Pentobarbital Sodium in 50 mL of diluent
Syringe #2 contains 2.5 grams of Pentobarbital Sodium in 50 mL of diluent
Syringe #3 contains 60 mL of saline flush.

Each syringe will be administered in the order set forth above when directed by supervisory personnel.

If peripheral venous access is utilized, two separate lines shall be inserted in separate locations and determined to be patent by qualified personnel. A flow of saline shall be started in each line and administered at a slow rate to keep the line open. One line will be used to administer the lethal substances and the second will be reserved in the event of the failure of the first line. Any failure of a venous access line shall be immediately reported to the Director or designee.

U.S. Department of Justice

Federal Bureau of Prisons

Office of the Director *Washington, DC 20534*

Privileged and Confidential

March 7, 2018

MEMORANDUM FOR THE ATTORNEY GENERAL

THROUGH: THE DEPUTY ATTORNEY GENERAL

FROM: Mark S. Inch, Director
Federal Bureau of Prisons

SUBJECT: Use of Fentanyl in Executions

I. Introduction

The Federal Bureau of Prisons ("Bureau"), along with the United States Marshals Service, is responsible for implementing federal death sentences. *See* 28 CFR Part 26. Under those regulations, the Bureau is required to utilize lethal injection as the method of execution. Recently, an inquiry was made to the Bureau regarding the use of the opiate fentanyl in executions.

II. Fentanyl

Fentanyl (fentanyl citrate) is a synthetic narcotic introduced in 1960 to replace morphine for cardiac surgery. Fentanyl was lauded for its much greater potency and margin of safety. Several other members of the fentanyl class, each with unique characteristics, have been developed and used over the years, including sufentanil, alfentanil, and remfentanil. These four drugs are the most commonly used narcotics in clinical anesthesia. Fentanyl is approximately 50 to 100 times stronger than morphine.[1] Fentanyl is commercially sold in the in the United States for

[1] Randall S. Glidden MD, The National Medical Series for Independent Study (NIMS): Anesthesiology (Neil Marquardt ed., 2003) 31.

intravenous use by Janssen Pharmaceutical Company under the registered trademark name, Sublimaze®. Janssen Pharmaceuticals (originally a Belgian company) was purchased by New Jersey based Johnson & Johnson in 1961. However, numerous companies manufacture the generic version of this drug.

III. States Using Fentanyl in Their Protocols

No known state or other entity has used fentanyl in any execution to date. However, in 2017, two states promulgated execution protocols that include fentanyl.

A. Nebraska

Nebraska's current protocol involves a complex four-drug method. First, the inmate is injected intravenously with two-milligram doses of Diazepam (Valium) per kilogram of body weight. These doses are followed with a 50 cc saline flush which is to be administered after each injection until the inmate is unconscious. Second, the inmate is injected with 25 micrograms of fentanyl citrate per kilogram of body weight, followed by a 50cc saline flush. Third, the inmate is injected with 1.6 milligrams per kilogram of body weight with cisatracurium besylate (paralytic) followed by a 50cc saline flush. Finally, the inmate is injected with 240 milliequivalents of potassium chloride (stops electrical activity in the heart) followed by a 50cc saline flush.

We located two inmate death sentence enforcement notifications, dated November 9, 2017 (inmate Jose Sandovol #59147) and January 19, 2018 (inmate Carey Moore #32947), but to date, no execution warrant has been set by the Nebraska Supreme Court in accordance state law, nor could we locate a legal challenge to Nebraska's current protocol. Our assumption is the inmates are waiting for an execution date to be set before filing an 8th Amendment challenge to the new protocol.

B. Nevada

Nevada's current proposed three-drug execution protocol which includes fentanyl was developed by Nevada's former chief medical officer in 2017 "in a matter of minutes."[2] Although the protocol itself is currently under seal, a review of filings in Nevada's active litigation clearly identifies the proposed protocol. Under the proposed protocol the process begins with the administration of 50 milligrams of Diazepam (valium), followed by a verbal consciousness check. If the inmate responds, a supplemental dose of 25 milligrams will be injected. Again, a consciousness check will be administered and supplemental injection will be administered as needed. Once the inmate fails to respond, the second drug, fentanyl, will be administered at 5000 micrograms over two minutes. At this point, the attending physician will administer painful stimuli. If a response is noted another 2,500 micrograms of fentanyl will be administered. This continues until no response is noted. Then the third drug, 100 milligrams of

[2] William Wan, "Execution drugs are scarce. Here's how one doctor decided to go with opioids," The Washington Post 11 December 2017, Post Nation. The Chief resigned in October 2017.

Cisatracurium (a paralytic), is to be administered. After five minutes, another 100 milligrams of Cisatracurium is to be administered. This protocol is being challenged in court.[3]

On December 15, 2017, Nevada Department of Corrections ("NDOC") filed a petition for writ of mandamus in the Supreme Court of the State of Nevada. The NDOC challenged the Nevada District Court's finding that NDOC's proposed use of the paralytic drug (Cisatracurim) presented a substantial risk of harm in violation of the State and Federal constitution. The District Court found the proposed use of Cisatracurium presented the risk that the inmate might suffer "air hunger" if he is not sufficiently unconscious when the paralytic is injected. If that happened, the inmate would be at risk of being aware, yet paralyzed and suffocating to death. The District Court believed that the execution should still proceed with a proposed two-drug cocktail consisting of diazepam and fentanyl. The NDOC rejected that proposal, requested a stay of the execution. The petition is still currently pending.[4]

IV. Availability of Fentanyl for Federal Executions

Commercial drug companies are ensuring distributors are not supplying states and the federal government with execution drugs via contractual arrangements, purchase order verifications, etc. Therefore, we can no longer obtain commercial drugs from third party distributers with our DEA license.

However, we have located a compounding pharmacy who is willing to lawfully provide us with commercially manufactured medications as they are available. This source is lawfully licensed, is located in the United States, and appears to be able and willing to compound fentanyl as needed, to the extent the dosage we need is not commercially available.

V. Issues with Obtaining Fentanyl

In accordance with the law of the state in which our current compounding pharmacy is located, they must first provide us with commercially available fentanyl if it is available. On March 5, 2018, many different concentrations of injectable fentanyl are available for sale to us with our current licensure. However, these drugs are made by manufacturers who would most likely take action against the Bureau of Prisons if they discovered the drugs were used for the purpose of execution, regardless of how we obtained them. Recently, various drug manufacturers having begun sending correspondence to various departments of corrections, including the Federal Bureau of Prisons, seeking assurance their drugs are not being used for executions. Some have threatened to refuse to provide medications used for clinical treatment of inmates should they find out their drugs are being used for executions. Obviously, we do not want to put the clinical treatment of inmates under our care at risk.

Our current compounding pharmacy indicates if the specific concentration required by the client is not commercially available, they can then legally manufacture (compound) the drug themselves, without involving the larger drug manufacturers. Our preliminary research indicates the ideal lethal concentration of fentanyl is not currently commercially manufactured. It appears

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[3] *Nev. Dep't of Corr. v. Eighth Jud. Dist. Ct. et al.*, No. 74679, at 14 (Nev. filed Dec. 15, 2017).
[4] *Id.*

we would be seeking to order concentrations of at least 5000 micrograms (mcg's) per 50 milliliters (ml). However, the solubility of fentanyl would need to be examined in consultation with experts, to determine the appropriate dosage.

Additionally, there is an issue as to whether there is a need for a prescription. Our preliminary determination is that a prescription is not needed; however, we would need to fill out appropriate forms to purchase narcotics, which is permitted under our current DEA licensure.

The source indicates that it would take three to five weeks from the date of order to compound and test an order for fentanyl similar to the one we would place.

Finally, costs do not appear to be a concern. No specific quote has been provided yet, but a 5ml vial with a concentration of 50 mcg's per ml costs $56.75 at the commercial rate. We can assume the cost to us will be somewhere in the same range.

VI. Other Considerations

Three possible negative factors should be considered with the use of fentanyl. First are the potential side effects of an injection of a large dosage of fentanyl. According to the manufacturer's product information sheet, the biggest risk for injection of a large dosage of fentanyl may be muscle rigidity, which can be reduced with premedication with benzodiazepines (valium is an example). This may explain Nebraska and Nevada's decision to use valium with their protocols. We are not sure at this point if this step is necessary. Second, fentanyl has never been used in an execution and has not been fully litigated. Finally, there may be negative publicity associated with using a drug to which so many Americans are addicted to as an execution drug.

ADDENDUM TO BOP EXECUTION PROTOCOL
FEDERAL DEATH SENTENCE IMPLEMENTATION PROCEDURES
EFFECTIVE TBA

A. Federal death sentences are implemented by an intravenous injection of a lethal substance or substances in a quantity sufficient to cause death, such substance or substances to be determined by the Director, Federal Bureau of Prisons (BOP) and to be administered by qualified personnel selected by the Warden and acting at the direction of the United States Marshal. 28 CFR 26.3. The procedures utilized by the BOP to implement federal death sentences shall be as follows unless modified at the discretion of the Director or his/her designee, as necessary to (1) comply with specific judicial orders; (2) based on the recommendation of on-site medical personnel utilizing their clinical judgment; or (3) as may be required by other circumstances.

B. The identities of personnel considered for and/or selected to perform death sentence related functions, any documentation establishing their qualifications and the identities of personnel participating in federal judicial executions or training for such judicial executions shall be protected from disclosure to the fullest extent permitted by law.

C. The lethal substances to be utilized in federal lethal injections shall be Pentobarbital Sodium.

D. Not less than fourteen (14) days prior to a scheduled execution, the Director or designee, in conjunction with the United States Marshal Service, shall make a final selection of qualified personnel to serve as the executioner(s) and their alternates. See BOP Execution Protocol, Chap. 1, §§ III (F) and IV (B) & (E). Qualified personnel includes currently licensed physicians, nurses, EMTs, Paramedics, Phlebotomists, other medically trained personnel, including those trained in the United States Military having at least one year professional experience and other personnel with necessary training and experience in a specific execution related function. Non-medically licensed or certified qualified personnel shall participate in a minimum of ten (10) execution rehearsals a year and shall have participated in at least two (2) execution rehearsals prior to participating in an actual execution. Any documentation establishing the qualifications, including training, of such personnel shall be maintained by the Director or designee.

E. The Director or designee shall appoint a senior level Bureau employee to assist the United States Marshal in implementing the federal death sentence. The Director or designee shall appoint an additional senior level Bureau employee to supervise the activities of personnel preparing and administering the lethal substances.

ADDENDUM TO BOP EXECUTION PROTOCOL
FEDERAL DEATH SENTENCE IMPLEMENTATION PROCEDURES
EFFECTIVE TBA

F. The lethal substances shall be prepared by qualified personnel in the following manner unless otherwise directed by the Director, or designee, on the recommendation of medical personnel. The lethal substances shall be placed into three sets of numbered and labeled syringes. One of the sets of syringes is used in the implementation of the death sentence and two sets are available as a backup.

G. Approximately thirty (30) minutes prior to the scheduled implementation of the death sentence, the condemned individual will be escorted into the execution room. The condemned individual will be restrained to the execution table. The leads of a cardiac monitor will be attached by qualified personnel. A suitable venous access line or lines will be inserted and inspected by qualified personnel and a slow rate flow of normal saline solution begun.

H. Lethal substances shall be administered intravenously. The Director or designee shall determine the method of venous access (1) based on the training and experience of personnel establishing the intravenous access; (2) to comply with specific orders of federal courts; or (3) based upon a recommendation from qualified personnel.

A set of syringes will consist of:

Syringe #1 contains 2.5 grams of Pentobarbital Sodium in 50 mL of diluent
Syringe #2 contains 2.5 grams of Pentobarbital Sodium in 50 mL of diluent
Syringe #3 contains 60 mL of saline flush,

Each syringe will be administered in the order set forth above when directed by supervisory personnel.

If peripheral venous access is utilized, two separate lines shall be inserted in separate locations and determined to be patent by qualified personnel. A flow of saline shall be started in each line and administered at a slow rate to keep the line open. One line will be used to administer the lethal substances and the second will be reserved in the event of the failure of the first line. Any failure of a venous access line shall be immediately reported to the Director or designee.

U.S. Department of Justice

Federal Bureau of Prisons

Office of the Director *Washington, DC 20534*

July 24, 2019

MEMORANDUM FOR THE ATTORNEY GENERAL

THROUGH: THE DEPUTY ATTORNEY GENERAL

FROM: Hugh J. Hurwitz
Acting Director
Federal Bureau of Prisons

SUBJECT: The Federal Bureau of Prisons' Federal Execution Protocol Addendum

The Federal Bureau of Prisons ("BOP") Addendum to its Federal Execution Protocol provides for the use of a single drug, pentobarbital sodium, as the lethal agent. The BOP has a viable source for the drug, and the BOP is prepared to implement the Addendum.

RECOMMENDATION: The Attorney General directs the Acting Director of the Federal Bureau of Prisons to adopt the Addendum to the Federal Execution Protocol.

DIRECT: _____
Date: July 24, 2019

DO NOT DIRECT: _____

OTHER: _____

Attachments

U.S. Department of Justice

Federal Bureau of Prisons

Office of the Director *Washington, D.C. 20534*

July 24, 2019

MEMORANDUM FOR THE ATTORNEY GENERAL

THROUGH: THE DEPUTY ATTORNEY GENERAL

FROM: Hugh J. Hurwitz
Acting Director
Federal Bureau of Prisons

SUBJECT: Summary of the Federal Bureau of Prisons' Federal Execution Protocol Addendum

I. Introduction

The Federal Bureau of Prisons ("BOP"), along with the United States Marshals Service ("USMS"), is responsible for implementing federal death sentences. *See* 28 C.F.R. Part 26. These regulations require the sentence be implemented by, " . . . intravenous injection of a lethal substance or substances in a quantity sufficient to cause death, such substance or substances to be determined by the Director of the Federal Bureau of Prisons . . . ." *See* 28 C.F.R. § 26.3(a)(4). Prior to 2003, BOP's lethal injection protocol consisted of three drugs: sodium pentothal, pancuronium bromide, and potassium chloride.[1] No federal execution has occurred since 2003, in part, because of the unavailability of sodium pentothal.

BOP has studied the issue and is prepared to approve an Addendum to its Federal Execution Protocol ("Addendum") that provides for the use of a single drug, pentobarbital sodium ("pentobarbital"), as the lethal agent. *See* Attachment. This new Addendum will replace the three-drug procedure previously used in federal executions. BOP has a viable domestic source to obtain pentobarbital, which would allow it to resume federal executions.

This Memorandum discusses BOP's proposed Addendum.

[1] BOP carried out the executions of Timothy McVeigh (2001), Juan Garza (2001), and Louis Jones (2003) using this drug compound.

II. Background

Implementation of the federal death penalty is governed by 18 U.S.C. §§ 3596-3597. These provisions require BOP to carry out death sentences "in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a). As noted above, the Federal regulation further clarifies that BOP must implement death sentences "by intravenous injection of a lethal substance or substances in a quantity sufficient to cause death." 28 C.F.R. § 26.2(a)(2). The Director of BOP is charged with determining what "substance or substances" should be used in federal executions. 28 C.F.R. § 26.3(a)(4).

A. Use of Pentobarbital

All states that currently permit the death penalty allow for lethal injection as their primary method of execution.[2] State protocols comprise of one-, two-, and three-drug methods. The three-drug protocol typically involves an anesthetic or sedative, followed by pancuronium bromide to paralyze the inmate, and finally potassium chloride to stop the inmate's heart. The one- or two-drug protocols typically use a lethal dose of an anesthetic or sedative.

There has been much litigation regarding death penalty protocols. In *Baze v. Rees*, 553 U.S. 35 (2008), the Supreme Court upheld Kentucky's use (along with at least 30 other states) of a three-drug combination, including sodium pentothal, pancuronium bromide, and potassium chloride.[3] While *Baze* provided clear approval of a specific protocol for states to carry out the death penalty, practical obstacles soon emerged as pharmaceutical companies began refusing to supply the drugs used to implement the death sentences. *See Glossip v. Gross*, 135 S.Ct. 2726, 2733 (2015). Specifically, the sole American manufacturer of sodium pentothal stopped producing the drug because of its use in the death penalty.[4]

After the availability of sodium pentothal declined, states developed an alternative drug combination that replaced sodium pentothal with pentobarbital. *Glossip*, 135 S.Ct. at 2733. On December 16, 2010, Oklahoma was the first state to execute an inmate using pentobarbital in place of sodium pentothal in its three-drug compound. *Id.*[5] The following year, Ohio used

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[2] Death Penalty Information Center, https://deathpenaltyinfo.org/lethal-injection.

[3] To successfully challenge a state's lethal injection protocol under the Eighth Amendment, a condemned prisoner must: (1) "establish[ ] that the State's lethal injection protocol creates a demonstrated risk of severe pain[;]" and (2) "show that the risk is substantial when compared to the known and available alternatives." *Baze*, 553 U.S. at 61. On April 1, 2019, the Supreme Court held that a death row inmate's as-applied Eighth Amendment challenge to Missouri's one drug lethal injection protocol using pentobarbital must meet the same standard applied to facial challenges as set forth in *Baze*. *Bucklew v. Precythe*, 139 S.Ct. 1112, 1126-30 (2019).

[4] Hospira, Press Release, Hospira Statement Regarding Pentothal (sodium thiopental) Market Exit (Jan. 21, 2011).

[5] Divinda Mims, *Death row inmate executed using pentobarbital in lethal injection*, CNN, December 16, 2010, *available at* http://www.cnn.com/2010/CRIME/12/16/oklahoma.execution.

pentobarbital in a one-drug execution.[6] Subsequently, many states incorporated pentobarbital into their protocols and all 43 executions carried out in 2012 reportedly used pentobarbital.[7]

Currently, fourteen states have used pentobarbital, either as part of a three-drug combination or by itself, in executions. An additional five states have announced plans to use it.[8] Georgia, Idaho, Missouri, South Dakota, and Texas administer a single-drug pentobarbital protocol, as BOP seeks to do, as the primary method of execution. Both Missouri and Texas have extensive experience using the single-drug pentobarbital method, executing 20 and 78 inmates, respectively, since approximately 2012.[9] Of the 25 executions in 2018, 16 used a single-drug pentobarbital protocol.[10] Of the ten executions thus far in 2019, five used the single-drug pentobarbital protocol.[11] Although various media outlets have reported complications with lethal injection executions, none of those executions appear to have resulted from the use of single-drug pentobarbital.[12]

B. Development of Addendum

In 2011, BOP began exploring pentobarbital and other methods of conducting executions. That year, BOP personnel visited several states to observe executions. Based upon research, observation, and the opinion of medically trained personnel, as described below, BOP developed the single-drug pentobarbital protocol.

As part of its research and study, BOP examined a three-drug process using pentobarbital as the first anesthetic. BOP disfavored this method because of the complications inherent in obtaining multiple drugs. Further, a one-drug protocol simplifies the procedure and therefore reduces the risk of administration mishaps. The BOP determined that the single-drug pentobarbital protocol is the most suitable method based on its widespread use by the states and its acceptance by many courts.[13]

The Addendum provides for the use of five grams of pentobarbital during executions. The Addendum calls for three syringes to be prepared, with the first two containing 2.5 grams of

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[6] Deborah W. Denno, *Lethal Injection Chaos Post-Baze*, 102 GEO. L.J. 1331, 1382 (2014).
[7] *Glossip*, 135 S.Ct. 2733 (citing Death Penalty Institute, Execution List 2012, online at www.deathpenaltyinfo.org/execution-list-2012).
[8] Death Penalty Information Center, *State by State Lethal Injection*, available at https://deathpenaltyinfo.org/state-lethal-injection.
[9] Death Penalty Information Center, *supra* note 8.
[10] https://deathpenaltyinfo.org/execution-list-2018
[11] https://deathpenaltyinfo.org/execution-list-2019
[12] Death Penalty Information Center, *Botched Executions*, https://deathpenaltyinfo.org/some-examples-post-furman-botched-executions?scid=8&did=478.
[13] Courts have held that the use of pentobarbital in executions does not violate the Eighth Amendment. *See, e.g.*, *Ladd v. Livingston*, 777 F.3d 286 (5th Cir. 2015); *Zink v. Lombardi*, 783 F.3d 1089, 1102 (8th Cir. 2015); *Jackson v. Danberg*, 656 F.3d 157 (3d Cir. 2011); *DeYoung v. Owens*, 646 F.3d 1319 (11th Cir. 2011); and *Pavatt v. Jones*, 627 F.3d 1336 (10th Cir. 2010). *See also Bucklew*, 139 S.Ct. at 1129-1132 (finding that death row inmate challenging Missouri's method of execution using a single-drug pentobarbital protocol failed to show a feasible and readily implemented alternative method of execution that would significantly reduce a substantial risk of severe pain).

pentobarbital sodium (in diluent) and the final syringe containing 60 mL of saline flush. *See* Attachment at ¶ H. Supervisory personnel then direct the administration of each syringe. *Id.*

BOP's draft procedures are similar to execution protocols adopted by Georgia, Ohio, South Dakota, Missouri, and Arizona. Texas's protocol utilizes one injection of 5 grams of pentobarbital.[14] These states have successfully effectuated executions, therefore the protocols are instructive to the proposed BOP protocols.

BOP consulted with the USMS Office of General Counsel regarding the Addendum. USMS concurred with the Addendum and noted their deference to BOP on all matters related to the time, place, and manner of carrying out federal executions.

BOP also retained a medical consulting firm to review the Addendum in anticipation of litigation. If the Addendum is approved, BOP anticipates its protocol will be subject to vigorous litigation both facially and as applied to specific inmates. Currently, one federal case is pending in the District of Columbia challenging BOP's method of execution. *See Roane et al. v. Gonzales*, No. 05-2337 (D.D.C.). Upon adoption of a protocol, that case will be reopened and the protocol will be a subject of that litigation. There are three additional cases pending in the District of Columbia, which challenge the method of execution, but in which an official stay of execution has not been issued.[15] In May and October 2017, BOP in coordination with the U.S. Attorney's Office in the District of Columbia consulted with Dr. Joseph F. Antognini, M.D., a clinical professor of anesthesiology and pain medicine at University of California Davis School of Medicine. Dr. Antognini concurs with the Addendum and is prepared to submit an expert report in defense of the protocol.

III. Implementation of Amended Protocol

BOP has a viable domestic source to obtain pentobarbital, and has confirmed with the Drug Enforcement Administration ("DEA") that the manufacturer is properly registered as a bulk manufacturer of pentobarbital. The manufacturer has produced samples of the active pharmaceutical ingredient ("API"), which were subject to quality assurance testing, further supporting the selection of this manufacturer. Additionally, BOP has secured a compounding pharmacy to store the API and to convert the API into injectable form as needed. BOP worked with DEA to ensure the compounding pharmacy is properly registered. The compounding pharmacy has performed its own testing of the injectable form, and it has additionally worked with two independent laboratories on quality testing.

Following approval of the Addendum, BOP is prepared to implement the amended Federal Execution Protocol. BOP has the necessary facilities and staff to resume federal executions and is prepared to conduct executions at its facilities in Terre Haute, Indiana. BOP regularly trains staff in the Federal Execution Protocol and conducts training exercises, most recently in April 2019. BOP has additionally confirmed with DEA that the BOP facility in Terre Haute, Indiana, meets the regulatory requirements for storage and handling of pentobarbital.

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[14] Death Penalty Information Center, *supra* note 8.

[15] *Bourgeois v. U.S. Dept. of Justice, et al.*, 1:12-cv-00782 (D.D.C.); *Robinson v. Mukasey*, No. 1:07-cv-02145 (D.D.C.); *Fulks v. U.S. Dept. of Justice, et al.*, No. 1:13-cv-00938 (D.D.C.).

Further, pursuant to 28 C.F.R. § 26.3(a)(1), the Director of the BOP will set execution dates for inmates with federal death sentences who are identified by the Attorney General.

ADDENDUM TO BOP EXECUTION PROTOCOL
FEDERAL DEATH SENTENCE IMPLEMENTATION PROCEDURES
EFFECTIVE JULY 25, 2019

A. Federal death sentences are implemented by an intravenous injection of a lethal substance or substances in a quantity sufficient to cause death, such substance or substances to be determined by the Director, Federal Bureau of Prisons (BOP) and to be administered by qualified personnel selected by the Warden and acting at the direction of the United States Marshal. 28 CFR 26.3. The procedures utilized by the BOP to implement federal death sentences shall be as follows unless modified at the discretion of the Director or his/her designee, as necessary to (1) comply with specific judicial orders; (2) based on the recommendation of on-site medical personnel utilizing their clinical judgment; or (3) as may be required by other circumstances.

B. The identities of personnel considered for and/or selected to perform death sentence related functions, any documentation establishing their qualifications and the identities of personnel participating in federal judicial executions or training for such judicial executions shall be protected from disclosure to the fullest extent permitted by law.

C. The lethal substances to be utilized in federal lethal injections shall be Pentobarbital Sodium.

D. Not less than fourteen (14) days prior to a scheduled execution, the Director or designee, in conjunction with the United States Marshal Service, shall make a final selection of qualified personnel to serve as the executioner(s) and their alternates. See BOP Execution Protocol, Chap. 1, §§ III (F) and IV (B) & (E). Qualified personnel includes currently licensed physicians, nurses, EMTs, Paramedics, Phlebotomists, other medically trained personnel, including those trained in the United States Military having at least one year professional experience and other personnel with necessary training and experience in a specific execution related function. Non-medically licensed or certified qualified personnel shall participate in a minimum of ten (10) execution rehearsals a year and shall have participated in at least two (2) execution rehearsals prior to participating in an actual execution. Any documentation establishing the qualifications, including training, of such personnel shall be maintained by the Director or designee.

E. The Director or designee shall appoint a senior level Bureau employee to assist the United States Marshal in implementing the federal death sentence. The Director or designee shall appoint an additional senior level Bureau employee to supervise the activities of personnel preparing and administering the lethal substances.

ADDENDUM TO BOP EXECUTION PROTOCOL
FEDERAL DEATH SENTENCE IMPLEMENTATION PROCEDURES
EFFECTIVE JULY 25, 2019

F. The lethal substances shall be prepared by qualified personnel in the following manner unless otherwise directed by the Director, or designee, on the recommendation of medical personnel. The lethal substances shall be placed into three sets of numbered and labeled syringes. One of the sets of syringes is used in the implementation of the death sentence and two sets are available as a backup.

G. Approximately thirty (30) minutes prior to the scheduled implementation of the death sentence, the condemned individual will be escorted into the execution room. The condemned individual will be restrained to the execution table. The leads of a cardiac monitor will be attached by qualified personnel. A suitable venous access line or lines will be inserted and inspected by qualified personnel and a slow rate flow of normal saline solution begun.

H. Lethal substances shall be administered intravenously. The Director or designee shall determine the method of venous access (1) based on the training and experience of personnel establishing the intravenous access; (2) to comply with specific orders of federal courts; or (3) based upon a recommendation from qualified personnel.

A set of syringes will consist of:

Syringe #1 contains 2.5 grams of Pentobarbital Sodium in 50 mL of diluent
Syringe #2 contains 2.5 grams of Pentobarbital Sodium in 50 mL of diluent
Syringe #3 contains 60 mL of saline flush,

Each syringe will be administered in the order set forth above when directed by supervisory personnel.

If peripheral venous access is utilized, two separate lines shall be inserted in separate locations and determined to be patent by qualified personnel. A flow of saline shall be started in each line and administered at a slow rate to keep the line open. One line will be used to administer the lethal substances and the second will be reserved in the event of the failure of the first line. Any failure of a venous access line shall be immediately reported to the Director or designee.

BOP EXECUTION PROTOCOL

SENSITIVE - LIMITED OFFICIAL USE ONLY 2004

FEDERAL BUREAU OF PRISONS
EXECUTION PROTOCOL MANUAL

INTRODUCTION: GENERAL PROVISIONS

I. Purpose of Manual

The purpose of this manual is to outline Federal Bureau of Prisons (BOP) policy and procedures for planning and carrying out the execution of a person convicted of a capital offense. These procedures should be observed and followed as written unless deviation or adjustment is required, as determined by the Director of the BOP or the Warden. This manual explains internal government procedures and does not create any legally enforceable rights or obligations.

II. Organization

This manual provides specific time related checklists for pre-execution, execution and post execution procedures as well as detailed procedures related to the execution process, command center operations, contingency planning, news media procedures, and handling stays, commutations and other delays.

III. Cross References

A. Title 28, Code of Federal Regulations, Chapter 1, Part 26

B. Title 28, Code of Federal Regulations, Chapter 1, Part 1

C. Inmate Systems Management - Program Statement 5800.13, Paragraph 807

D. Searching, Detaining, Non-Inmates; Arresting Authority; Metal Detectors - Program Statement 5510.09

E. Contact with News Media - Program Statement 1480.05

F. Accounting Management Manual - Program Statement 2000.02, Chapter 10950

G. Command Centers - Operations Memorandum 075.92

IV. Policy

A. It is the policy of the BOP that the execution of a person sentenced to death under Federal law by a court of competent authority and jurisdiction be carried out in an efficient and humane manner.

B. The BOP will make every effort in the planning and preparation of an execution to ensure that the execution process:

1. faithfully adheres to the letter and intent of the law;

2. is handled in a manner that minimizes the negative impact on the safety, security, and operational integrity of the correctional institution in which it occurs and the BOP in general;

3. accommodates the public's right to obtain information concerning the event;

4. reasonably addresses the privacy interests of those persons for whom the law and BOP policy require such privacy;

5. provides sufficient contingency planning to ensure that unforeseen problems can be addressed and overcome;

6. allows for stays of execution, commutations and other delays in the execution countdown;

7. provides an opportunity for interested persons to exercise their First Amendment rights to demonstrate for or against capital punishment in a lawful manner; and

8. ensures a firm and adequate response to unlawful civil disobedience, trespass, or other violations of the law by persons attempting to disrupt or prevent the execution.

C. The BOP will seek the arrest and encourage the prosecution of persons, including but not limited to those who:

1. violate prohibitions against filming, taping, broadcasting, or otherwise electronically documenting the death of the condemned individual;

2. trespass or otherwise enter upon BOP property without proper permission and clearance from the Warden;

3. participate in unlawful demonstrations;

4. unlawfully attempt to disrupt, prevent, or otherwise interfere with the execution;

5. being inmates, are involved in disruptive, assaultive, or other lawfully proscribed behavior related to an execution; or

6. unlawfully threaten, intimidate, or terrorize persons involved in the execution process.

D. BOP staff involved in the execution will make every effort, within the limits of these policies and procedures and the laws of the United States, to:

1. display appropriate levels of professionalism, restraint, and courtesy in interaction with witnesses, demonstrators, news media, and other non-staff persons during the execution process;

2. prevent emotion or intimidation from hindering efforts to carry out assigned duties; and

3. conduct themselves at all times in a manner reflecting the solemnity and sensitivity of the occasion.

E. BOP Mental Health and Religious Services personnel will be available for counseling sessions with all personnel participating directly in an execution process, before and after an execution.

F. Each execution will be fully evaluated by the institution, region, and Central Office staff. If warranted, recommendations will be made and considered in order to improve procedures.

CHAPTER 1: PRE-EXECUTION CHECKLIST

I. General Provisions

A. Purpose of Chapter

1. The purpose of this chapter is to provide a checklist of procedures and events that should occur between the period of time prior to the establishment of an execution date and 24 hours prior to the execution.

2. Full detail will not be provided for each procedure or event in this chapter. For detail, refer to specific chapters which follow.

3. This chapter covers the following time periods:

a. prior to the execution date being established;

b. establishment of the execution date to thirty days prior to the execution;

c. twenty-nine to fourteen days prior to the execution;

d. thirteen to seven days prior to the execution;

e. six to three days prior to the execution; and

f. forty-eight to twenty-four hours prior to the execution.

B. Policy

1. A systematic countdown to execution must be completed to ensure that all procedures and events necessary to adequately prepare for the execution are completed in a timely manner.

2. Absent intervention by the court system or the President as noted in Chapter 7, delays in the countdown process will only occur in extraordinary situations relating to the security and good order of the institution as approved by the Director of the BOP.

II. Establishing an Execution Date

After a sentencing hearing is conducted in a United States District Court resulting in a determination that a criminal defendant be sentenced to death for commission of an offense

described in a Federal statute, and the sentencing judge signs the appropriate Judgment and Order:

A. Except to the extent a court orders otherwise, the Director of the BOP will designate a date, time, and place for the execution of the sentence. On June 18, 1993, the Director of the BOP established the United States Penitentiary, Terre Haute, Indiana, as the site of such executions. The following individuals/offices will be advised in writing of the execution date: the sentencing judge, Attorney General, Office of the Deputy Attorney General, Office of the Pardon Attorney, the Assistant Attorney General for the Criminal Division, the Chief of the Capital Case Unit, Director of the United States Marshals Service (USMS), the Office for Victims of Crime, Assistant Director for Correctional Programs Division, Assistant Director for General Counsel and Review Division, appropriate Regional Director, United States Attorney's Office for the district of conviction, United States Attorney's Office for the Southern District of Indiana and Warden of USP Terre Haute.

B. Under current federal regulations, the date established will be no sooner than 60 days from the entry of the judgment of death (28 C.F.R. § 26.3(a)(1)) and notice of it must be given to the defendant no later than 20 days before the execution (28 C.F.R. § 26.4(a)). If the date designated passes by reason of a stay of execution, then a new date will be promptly designated by the Director of the BOP when the stay is lifted.

C. The Warden of USP Terre Haute will notify, in writing, the condemned individual under sentence of death, of the date designated by the Director for execution at least 90 days in advance. If the designated execution date is stayed, notice of the new execution date must be given no later than 20 days before the execution, if time permits and if not, as soon as possible. If the execution date is set by a judge, the Warden will notify the condemned individual, in writing, as soon as possible. The Warden will include information concerning the clemency application process in the written notice. Under 28 C.F.R. §1.10(b), a petition for commutation of sentence should be filed no later than 30 days after the condemned individual has received notification from the Warden of the execution date.

D. Unless the President interposes, the execution of the sentence will not be stayed on the basis of the condemned individual filing a petition for executive clemency.

III. Period of Time Between Establishment of an Execution Date to Thirty Days Prior to the Execution

The following procedures should be completed between the time an execution date is set and 30 days prior to the execution.

A. Briefing the Condemned Individual

As soon as practical after establishment of the execution date, the Warden at USP Terre Haute or designee, will personally brief the condemned individual regarding relevant aspects of the execution process including information contained in items C through F of this section. A briefing sheet outlining these aspects of the execution will be given to the condemned individual. If requested, a copy of the briefing sheet will be given to a representative identified by the condemned individual. In addition, the Warden will ascertain the inmate's religious preference.

B. Condemned Individual's Choice of Witnesses

When the condemned individual is informed by the Warden of the execution date, he/she will be advised that he/she may designate not more than one spiritual adviser, two defense attorneys, and three adult friends or relatives (at least 18 years old) to be present at the execution. The condemned individual will be asked to submit the list of his/her witnesses to the Warden no later than 30 days after notification of the date of the scheduled execution.

C. Disposition of Personal Property and Accounts

The Warden will review the options available to the inmate for property/account distribution and will ask the condemned individual to provide instructions, no later than 14 days prior to the execution, concerning the disposition of the personal property and funds in any accounts controlled or administered by the BOP. If the condemned individual fails to provide instructions for such disposition, the property/accounts will be disposed of in accordance with the Accounting Management Manual and Inmate Systems Management Manual.

D. Organ Donation

The condemned individual's body will not be used for organ donation.

E. Disposition of Body

The Warden will review options available to the condemned individual following the release of the body to the Vigo County Coroner. The Warden will ask the condemned

individual to provide instructions concerning the disposition of his/her body no later than 14 days prior to the execution. If the condemned individual fails to provide instructions, the body will be handled in accordance with the Accounting Management Manual.

F. Designation of Persons Required to Assist with the Execution

1. Those persons necessary to carry out the execution will be identified.

   a. The Warden, with the assistance of the Director, USMS, and the Director, BOP, will be responsible for identifying, selecting and obtaining the services of the individuals administering the lethal injection.

   b. The Warden is responsible for selection of the persons involved in perimeter security, transportation, and command post operations, as well as crowd control, support functions and access screening.

2. Individuals will be identified for placement in all vital or important positions. Alternates will also be identified. The Assistant Director, Correctional Programs Division, Regional Director, and the Warden will determine which positions require alternates and will ensure adequate coverage is provided

3. No officer or employee of the Department of Justice will be required to be in attendance at or participate in any execution if such attendance or participation is contrary to the moral or religious convictions of the officer or employee. Staff participation in the execution process must be on a voluntary basis.

G. Other Approved Witnesses

1. In addition to the United States Marshal designated by the Director of the USMS (hereafter called the "Designated United States Marshal") and the Warden, the following persons will be present at the execution.

   a. Necessary personnel selected by the Designated United States Marshal and the Warden.

   b. Those attorneys of the Department of Justice whom the Deputy Attorney General determines are necessary.

c. Not more than the following numbers of persons selected by the Warden:

(1) eight citizens (in identifying these individuals, the Warden, no later than 30 days after the setting of an execution date, will ask the United States Attorney for the jurisdiction in which the condemned individual was prosecuted to recommend up to eight individuals who are victims or victim family members to be witnesses of the execution); and

(2) ten representatives of the press.

2. No other person will be present at the execution, unless such person's presence is granted by the Director of the BOP. No person younger than 18 years of age will witness the execution.

3. The Warden will notify all witnesses of the date, time and place of the execution as soon as practicable before the designated time of execution.

H. Contact with the Vigo County Coroner

1. The Warden will contact the Vigo County Coroner to coordinate the Coroner's role.

2. The Vigo County Coroner will be requested to provide direction concerning:

a. transfer of custody of the body of the executed individual from the Warden to the Vigo County Coroner;

b. transportation of the body from the Execution Room to the Vigo County Coroner's facility; and

c. security arrangements during the transfer.

I. Briefing of Institution Staff

1. It is necessary to maintain, as nearly as possible, normal prison operations throughout the execution process.

2. Local prison administrators should be briefed by the Warden, as appropriate, on plans for the execution, restrictions on access, crowd control, additional security procedures, etc., on an on-going basis.

3. As soon as plans begin to evolve which will affect general prison operations, briefings should begin and continue until operations return to normal.

IV. Period of Time Between Twenty-Nine to Fourteen Days Prior to the Execution

A. Witnesses

1. To the extent possible, the Warden will develop a final list of citizen and condemned individual's witnesses.

2. All witnesses/participants will be required to sign an agreement prior to being cleared and added to the witness list. Included in the document will be an agreement to be searched before entering the Execution Facility and not to photograph or make any other visual or audio recording of the execution (see Appendix A).

B. Qualified Person

The Warden will finalize arrangements for a qualified person to be present at the execution and to declare the executed individual deceased.

C. Condemned Individual's Property and Accounts

The Warden will finalize arrangements for disposition of the condemned individual's property and accounts no later than 14 days prior to the scheduled execution date.

D. Disposition of Body

The Warden will finalize arrangements with the Vigo County Coroner for disposition of the body, security for the Vigo County Coroner's vehicle, and transfer of custody of the body in accordance with appropriate State and local laws.

E. Selection of Executioner(s)

The Warden, with the assistance of the Director, USMS and Director, BOP, will finalize the selection of executioner(s) and their alternates.

F. Training

1. The Warden will ensure that appropriate training sessions are held for persons involved in the various aspects of the execution event.

2. Not all of the persons involved need to practice together. Individual teams will practice as units, with inter-team practices scheduled, as necessary by the Warden, to facilitate coordination and smooth interaction.

V. Period of Time Between Thirteen to Seven Days Prior to the Execution

A. Condemned Individual's Property and Accounts

All paperwork regarding disposition of property and accounts should be completed.

B. Food Services

At least seven days prior to execution, the Warden or designee will contact the condemned individual to arrange for his/her last meal.

C. Purchase of Substances to be Used in Lethal Injection

The Warden will ensure the purchase of lethal substances to be used in the execution. Once purchased, these lethal substances will be secured in the institution until called for by the Warden.

D. Law Enforcement Coordination

1. The Warden will meet with Federal, State, and local law enforcement personnel to coordinate support related to the execution.

2. Joint practices should be conducted between law enforcement staff involved to ensure coordination and interaction is well defined and understood.

E. Restrictions on Condemned Individual's Visitors

Beginning seven days prior to the designated date of execution, the condemned individual will have access only to his/her spiritual advisers (not to exceed two), his/her defense attorneys, members of his/her family, and designated officers and employees of the BOP. Upon approval of the Director of the BOP, the Warden may grant access to such other proper persons as the condemned individual may request.

VI. Period of Time Between Six to Three Days Prior to the Execution

A. Witnesses

Non-media witness agreements should be signed by the witnesses and reviewed by the Warden or designee.

1. The Warden will provide a final list of witnesses to the:

   a. Assistant Director, Correctional Programs Division;

   b. Assistant Director, Information, Policy, and Public Affairs Division;

   c. Regional Director;

   d. Director, USMS; and

   e. Designated United States Marshal

   f. United States Attorney's Office - district of conviction

   g. United States Attorney's Office - Southern District of Indiana

2. Persons who refuse to sign agreements will not be allowed to attend the execution.

B. Brief Affected Law Enforcement Agencies

The Warden will ensure that staff from other law enforcement agencies who have not participated in practice sessions or have not otherwise been briefed previously will be briefed and their responsibilities explained.

C. Condemned Individual's Property and Accounts

Verify arrangements are complete.

D. Executioner(s)

An individual designated by the Warden will:

1. review with executioner(s) and alternates arrangements for their transportation and escort to the Execution Facility; and

2. review with participants' arrangements for security of executioner(s) and protection of their identities.

E. Equipment Check/Inventory

All equipment necessary to conduct the execution will be inventoried and checked at least 72 hours prior to the execution by individuals designated by the Warden.

VII. Period of Time Between Two Days to One Day Prior to the Execution

[redacted]

[redacted]

[redacted]

B. Practices

Final practices will be conducted as directed by the Warden.

C. Equipment Checks

Maintenance staff should verify necessary installation of and test electrical, heating/air conditioning and communications equipment in:

1. BOP Execution Facility;

2. Command Center.

D. Warden Contacts

1. To ensure that coordination efforts are in place, the following entities will be contacted by the Warden:

   a. Department of Justice Command Center (to ensure communications, if required, by the Attorney General, the Supreme Court, the President of the United States and the affected United States Attorneys Offices);

   b. BOP Director's Office;

   c. USMS Director's Office; and

   d. affected law enforcement agencies.

2. Identify specific individuals who are contact persons for the entities/individuals listed in Subsection 1 above.

E. Equipment Check Verification by Warden

1. The Warden will ensure completion of pre-execution inventory and equipment check in the BOP Execution Facility.

2. The Warden will verify that the Execution Facility's equipment checks have been completed.

[redacted]

CHAPTER 2: EXECUTION CHECKLIST

I. General Provisions

A. Purpose of Chapter

1. This chapter provides a checklist of procedures and events that should occur during the final 24 hours prior to the execution.

B. Policy

1. It is the policy of the BOP that the countdown to the execution will be accomplished in a carefully coordinated manner.

2. The execution will be carried out in a manner consistent with Federal law.

II. Period of Time Between Twenty-Four to Twelve Hours Prior to the Execution

[redacted]

B. Condemned Individual Communication

1. Excluding calls to the condemned individual's Attorney(s) of Record and calls specifically approved by the Warden, the condemned individual's telephone privileges will be terminated 24 hours prior to the execution.

2. The condemned individual's Attorney(s) of Record, spiritual adviser(s), immediate family members or other persons approved by the Director of the BOP, will be given visiting privileges during the final 24 hours as determined by the Warden. Visiting privileges will be suspended when preparations for the execution require suspension.

C. Food Services

The Warden will contact the condemned individual to finalize arrangements for his/her final meal and ensure that it is properly prepared and served by staff.

[redacted]

D. Maintenance Response Team

Beginning eight hours prior to an execution, the Facility Manager or other appropriate individual will ensure that a Maintenance Response Team is available to provide necessary maintenance and repair of systems at the Execution Facility or in other areas of the institution.

E. Access to the Execution Facility

[redacted]

III. Period of Time Between Twelve to Three Hours Prior to the Execution

A. Final Briefing

[redacted]

2. A final briefing will be held, attended by senior BOP and Marshals Service staff, the Warden, and representatives deemed appropriate by the Warden. The Warden will conduct the meeting, with senior staff providing guidance and policy decisions, as needed.

3. During the briefing, participants will:

a. identify problems, develop solutions, and specify time lines;

b. provide status reports;

c. coordinate support services involvement; and

d. conduct a final review of procedures.

[redacted]

B. Food Service

The condemned individual will be served a final meal at a time determined by the Warden.

C. Visits

Visits by family, attorneys, religious representatives, and other persons approved by the Director of the BOP, will be at the discretion of the Warden.

D. Restricting Access to Prison Property

1. During the final 12 hours prior to the execution, access to prison property will be limited to:

   a. on-duty staff;

   b. on-duty contract workers;

   c. volunteers deemed necessary by the Warden;

   d. approved delivery vehicles;

   e. law enforcement personnel on business-related matters;

   f. routine inmate visitors; and

   g. other persons approved by the Warden.

2. During the final eight hours:

   a. all off-duty Department of Justice personnel will be required to leave institution property;

[redacted]

E. Establishment of Command Center

[redacted]

[redacted]

IV. Period of Time Between Three Hours to Thirty Minutes Prior to the Execution

A. Pre-Execution Procedures

1. The Warden will ensure that all countdown procedures for required activities and actions are progressing.

2. Immediate action to complete any unfinished required procedures will be initiated.

3. The Warden will designate a recorder who will begin logging execution activities in the official execution log book commencing three hours prior to the scheduled execution. The log will reflect, at a minimum, the time each of the following events occurs:

a. Condemned individual removed from Inmate Holding Cell;

b. Condemned individual strapped to gurney;

c. Arrival of government/community witnesses;

d. Arrival of condemned individual's authorized witnesses;

e. Arrival of media witnesses;

f. Opening of drapes;

g. Last statement by condemned individual;

h. Reading of statement conveying inmate's sentence of death;

i. Upon Designated United States Marshal's approval, the execution process begins;

j. Signal by Executioner(s) that lethal substances have been administered;

k. Determination of condemned individual's death through the EKG readout by designated qualified person;

l. Announcement of death of condemned individual;

m. Closing of drapes;

n. Notification to outside media and demonstrators of condemned individual's death;

o. Removal and transportation of media witnesses to media center;

p. Removal of condemned individual's authorized witnesses;

q. Removal of government/community witnesses;

r. Restraint Team/Vigo County Coroner enter Execution Room to remove body;

s. Removal of body to Vigo County Coroner's vehicle;

t. Performance of any necessary cleaning chores;

u. Directive by Warden to secure Execution Facility.

B. Execution Room Staff Assemble

1. The Executioner(s) will be escorted into the Execution Facility and will inventory supplies and ensure that everything is ready.

[redacted]

3. All other Execution Room staff will be assembled on-site for final instructions at least forty-five minutes prior to the scheduled execution.

C. Contact with the Department of Justice Command Center

[redacted]

[redacted]

[redacted]

V. The Final Thirty Minutes Prior to the Execution

A. Final Sequence of Events: Preparation

1. Bringing the Condemned Individual to the Execution Room

At the appropriate time, the condemned individual will be:

a. removed from the Inmate Holding Cell by the Restraint Team;

b. strip-searched by the Restraint Team and then dressed in khaki pants, shirt, and slip-on shoes.

c. secured with restraints, if deemed appropriate by the Warden;

d. escorted to the Execution Room by the Restraint Team.

2. Restraint Team Procedures

In the Execution Room the ambulatory restraints, if any, will be removed and the condemned individual will be restrained to the Execution Table.

3. Admit Witnesses

a. Subsequent to appropriate search procedures, witnesses will be admitted to the witness rooms.

[redacted]

b. The government/community witnesses will then enter and will be escorted to their assigned area. The escorts will remain with the witnesses.

c. The authorized witnesses invited by the condemned individual will be admitted and escorted to their assigned area.

1. If any of the condemned individual's invited witnesses wish to be on-site, but not actually witness the execution, accommodations will be made for them by the Warden.

2. Escorts will remain with the condemned individual's witnesses. There will be a minimum of two escorts for each witness group.

d. The last witnesses to be admitted will be the news media representatives. The members of the news media selected to witness the execution will be escorted to their assigned area. Escorts will remain with the news media witnesses and ensure their separation from the other witnesses while at the Execution Facility. Media witnesses will not be permitted to interview or question staff or other witnesses while at the Execution Facility.

VI. Final Sequence of Events: Execution

A. Staff Witnesses

1. Staff participating in the preparation for the execution will exit the Execution Room but stand by in an adjacent area.

2. Staff members participating in and/or observing the execution will include the:

a. Designated United States Marshal;

b. Warden;

c. Executioner(s);

d. Other staff authorized by the Director of the BOP.

B. Countdown

1. Once the condemned individual has been secured to the table, staff inside the Execution Room will open the drapes covering the windows of the witness rooms.

2. The condemned individual will be asked if he/she has any last words or wishes to make a statement. The condemned individual will have been advised in advance that this statement should be reasonably brief.

3. At the conclusion of the remarks, or when a determination is made to proceed, the documentation deemed necessary to the execution process will be read. Once the Designated United States Marshal makes a final determination that the execution is to proceed, the executioner(s) will be directed to administer the lethal injection.

4. If the execution is ordered delayed [redacted] the Designated United States Marshal will instruct the Executioner(s) to step away from the execution equipment and will notify the condemned individual and all present that the execution has been stayed or delayed.

C. Determination of Death

1. After the lethal injection has been administered:

   a. The EKG will be monitored until apparent signs of life have ceased;

   b. The time of death will be announced prior to the drapes being closed.

2. The Designated United States Marshal will complete and sign the Return described in Section 26.2(b) of 28 C.F.R. and will file such document with the sentencing court.

CHAPTER 3: POST-EXECUTION CHECKLIST

I. General Provisions

A. Purpose of Chapter

The purpose of this chapter is to:

1. provide the procedures to be followed after the execution, of the condemned individual;

2. identify the responsibilities for tasks to be completed; and

3. provide for the transfer of the body of the condemned individual from the custody of the BOP.

B. Policy

It is the policy of the BOP that:

1. the condemned individual will be examined by a specified qualified person following the administration of the lethal substances to ensure that death has occurred;

2. When the qualified individual is satisfied that death has occurred, the time of death will be announced to the witnesses;

3. the witnesses to the execution will then be removed from the Execution Facility and returned to their individual staging areas so that they may leave the institution. News media witnesses will be removed to a secondary press location where they will participate in a press conference;

4. the body of the condemned individual will be surrendered to the Vigo County Coroner;

5. after removal of the body, the site will be cleaned and restored to its previous condition.

II. Removing Witnesses from the Execution Facility

A. After the pronouncement of death, the witnesses will be escorted from the facility in the following order:

1. news media witnesses;

2. condemned individual's authorized witnesses; and

3. government/community witnesses.

B. Each group of witnesses will be kept separate from the others and escorted to waiting vehicles to be driven to separate designated sites.

III. Removal of the Body of the Condemned Individual

A. After the witnesses have departed, the restraints will be removed from the condemned individual's body.

B. The Vigo County Coroner or designee will be escorted into the Execution Facility. The body will be removed by the Vigo County Coroner, who will place it in a coroner's vehicle for transportation.

IV. Site Clean-Up

A. Under the supervision of an individual designated by the Warden, staff will clean and secure the Execution Facility.

B. Institution staff will be trained in infectious disease preventive practices and utilize appropriate precautions in cleaning up the Execution Facility.

C. The Execution Facility will be locked and secured when the Warden is satisfied that clean-up has been completed.

V. Returning to Routine Operations

A. Following the execution, Department of Justice and BOP staff involved in the execution will be deactivated, as appropriate, under direction of the senior departmental, BOP and USMS staff on-site.

B. The Warden's designated public affairs representative will determine when to secure the media assembly site after the news conference is complete.

C. The Warden will bring the institution security back to routine operations as he/she sees fit.

CHAPTER 4: Command Center

I. General Provisions

A. Purpose of Chapter

The purpose of this chapter is to:

1. identify the role and function of the Command Center;

2. specify the individuals authorized to staff the Command Center; and

3. provide an inventory of the minimum resources required in the Command Center.

B. Policy

It is the policy of the BOP that:

1. the Bureau operate a local, emergency Command Center during the execution operation to:

a. coordinate security, transportation, crowd control, access and other processes;

b. provide policy and procedural advice, as needed, or upon request;

c. coordinate inter-agency functions; and

d. serve as an information processing and operations nerve center for the execution;

[redacted]

3. sufficient resources be available in the Command Center to permit staff there to function efficiently.

II. Location, Role and Function

A. The Command Center will be operational prior to the scheduled execution and maintained for the duration of the execution operation, in an area identified by the Warden.

B. The roles and functions of the Command Center include:

1. coordinating the various personnel, components and elements of the execution operation;

[redacted]

[redacted]

[redacted]

III. Command Center Staffing

A. Command Center staff should include the following positions:

[redacted]

B. The Command Center Director may include such other persons as may be needed, for the period of time required. During that time, an additional temporary pass will be issued to and worn by the person so admitted.

C. Access to the Command Center will be limited to persons specifically authorized by the Command Center Director or Warden.

IV. Radio Communication

A. The official radio frequency for communication with personnel involved in the execution process will be determined by the Warden.

B. Non-cellular telephones must be used for critical or confidential communications.

[redacted]

[redacted]

[redacted]

[redacted]

CHAPTER 5: CONTINGENCY PLANNING

I. General Provisions

A. Purpose of Chapter

The purpose of this chapter is to:

1. aid in the development of a predetermined contingency plan to assist staff in the management of the execution event and in responding to related emergency situations;

2. identify the role and function of staff needed to formulate and activate the plan, if needed; and

3. identify specific areas to stage staff and equipment. The location of witness processing will be pre-determined by the Warden on a case-by-case basis.

B. Policy

It is the policy of the BOP to:

1. prepare and test contingency plans;

2. identify all security measures needed to protect staff and inmates of an institution as well as BOP property; and

3. coordinate all resources to ensure the safety of the public, staff, and inmates.

II. Specific Procedures

A. An individual identified by the Warden will prepare contingency plans related to an emergency occasioned by the execution, such as an institution disturbance, hostage taking, outside demonstration, outside assault on the facility, etc. All plans will be reviewed and approved by the Warden and the Regional Director.

B. Plans will include provisions for:

[redacted]

[redacted]

[redacted]

C. Intelligence Operations

[redacted]

D. Staging Areas

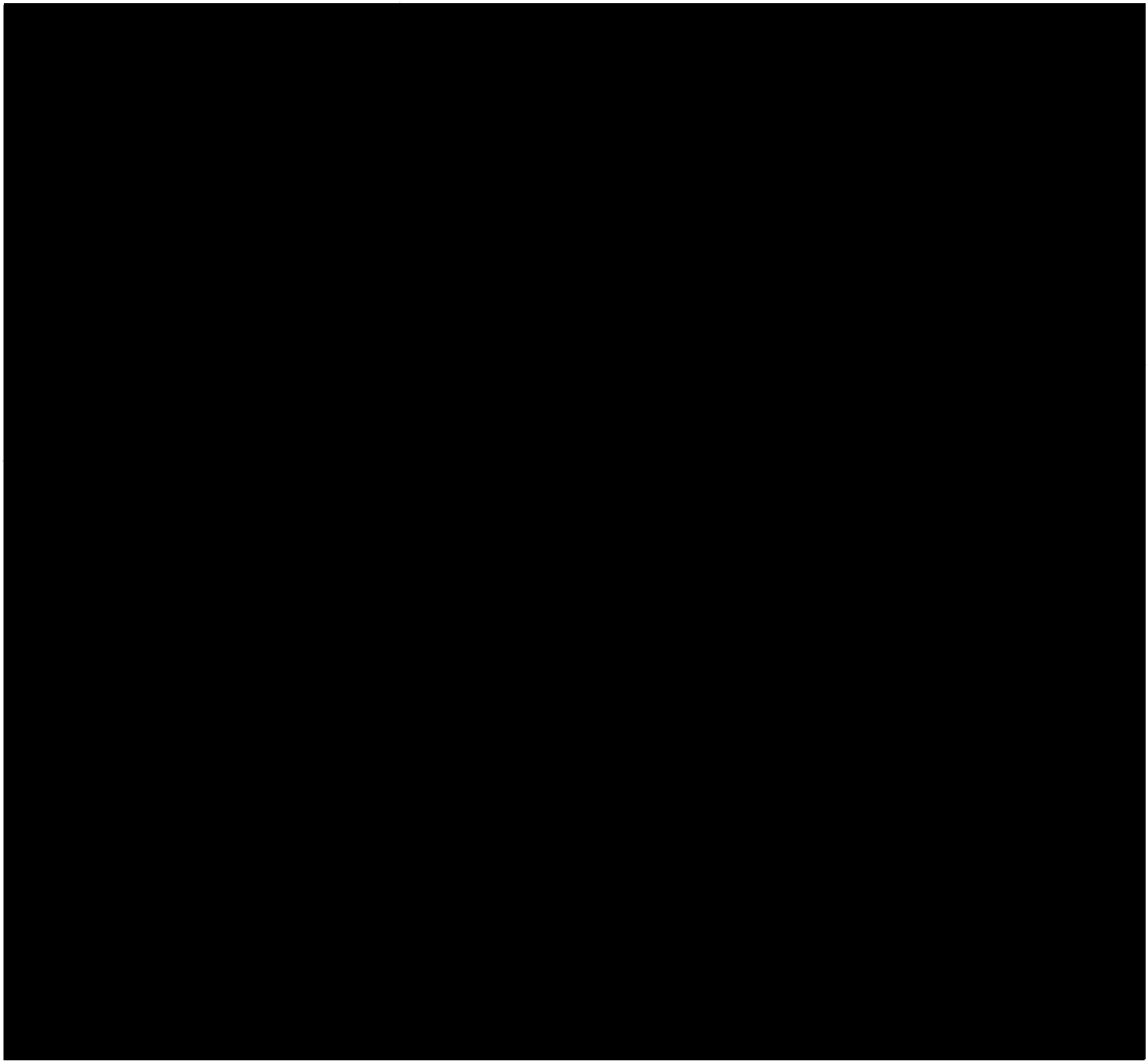
[redacted]

E. Tactical Deployment

[redacted]

[redacted]

III. Execution Witness Management



4. No pat or visual search of any witness will be conducted unless the Warden has reasonable suspicion

to believe the witness is concealing weapons, drugs, audio or visual recording devices, or any other item not expressly authorized and the witness agrees to be searched. If the witness refuses to be searched, he/she will not be permitted to serve as a witness.

5. Staff at each staging area will notify the Command Center when all execution witnesses are accounted for and processed.

6. Escorts will remain at their assigned staging areas until the Command Center directs them to transport the witnesses to the Execution Facility.

B. Transportation to the Execution Facility

[redacted]

3. Escorts will ensure that witness groups do not come into contact with each other.

4. Escorts will transport witnesses to the Execution Facility and notify the Command Center when each group of witnesses is secured in the assigned observation area.

5. Once each group is secured, the next group will be moved as directed by the Command Center.

6. The Command Center will be notified by the appropriate staff member when all groups are in place.

7. The Command Center, in turn, will notify the Warden or designee.

C. Transportation from the Facility

[redacted]

[redacted]

[redacted]

2. The groups will be returned to the staging areas by the escorts, who will ensure that no group comes in contact with another group.

3. Escorts will notify the Command Center as each group returns to the staging area.

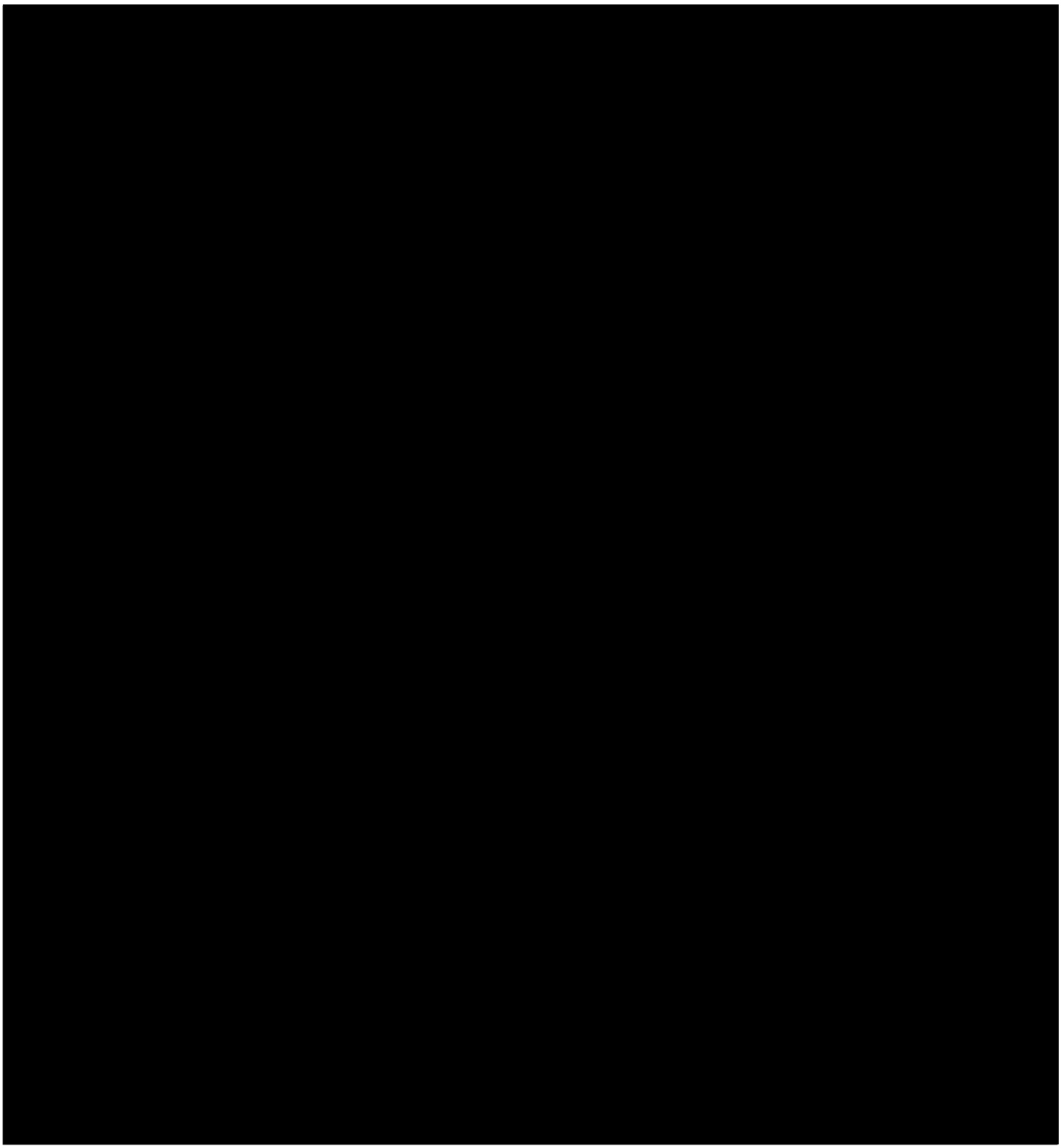
4. The Command Center will direct each move to expedite departures and also to prevent groups from encountering one another in the parking lot.

5. Media witnesses will be returned to the Media Center to have a press pool briefing as outlined in Chapter 6.

IV. Reservation Security Plan

[redacted]

[redacted]



3. The escort Lieutenant and escort teams will be available and will accompany execution witnesses.

[redacted]

[redacted]

CHAPTER 6: NEWS MEDIA PROCEDURES

I. General Provisions

A. Purpose of Chapter

This chapter describes the procedures and requirements for allowing representatives of the news media access to an inmate sentenced to death, as well as procedures for news media access to the execution. This chapter also provides procedures for releasing information relating to the execution.

B. Policy

The BOP recognizes the desirability of establishing procedures which afford the public information about its operations through the news media. In accordance with established policy, reasonable efforts will be made to accommodate representatives of the news media before, during, and after a scheduled execution. Media representatives will be treated in a fair and consistent manner in accordance with current policies and procedures of the BOP. The agency has the responsibility, however, to ensure the orderly and safe operation of its institutions, and therefore must regulate media access.

C. Roles

1. Representatives of the news media are those individuals described in Program Statement 1480.03, Contact with News Media, whose principal employment is to gather and report news.

2. The Warden will designate a specific staff member as the official representative to the news media regarding death penalty issues and the scheduled execution.

3. The BOP Assistant Director, Information, Policy and Public Affairs Division, will coordinate the release of information to the news media and assist the Warden in the selection of individual news media witnesses. The Department of Justice Office of Public Affairs will be kept informed of these matters.

II. Condemned Individual Interviews

A. Purpose

As stated in Program Statement 1480.03, Contact with News Media, it is not the BOP's intent to provide publicity for an inmate or special privileges for the news media, but rather to ensure a better informed public.

B. Limits

With this in mind, representatives of the news media may be permitted to conduct interviews with condemned individuals. Guidelines regarding the frequency and length of interviews, as well as accompanying security, will reflect BOP/institution policy and will be established by the Warden, who will take into account available resources.

C. Prohibition

Ordinarily, no media interviews will be permitted with the condemned individual once the execution date is within seven days.

III. Media Orientation

A. Definition

No later than eight days before a confirmed execution date, the institution will hold a Media Orientation to provide media representatives with information on the scheduled execution. No other press conference or Media Orientation regarding the execution will be scheduled or held until after the scheduled execution, except as provided below in subsection B. Every effort will be made by the Warden's representative to notify local, State, and national media representatives of the scheduled Media Orientation. Central Office Public Affairs staff will provide assistance to institution personnel in this area.

1. All persons, including media representatives, must have appropriate identification to enter the institution on any occasion. Media representatives must have appropriate press credentials. This requirement includes camerapersons, sound technicians, and reporters.

2. All individuals will be advised that they are subject to search of their person and equipment prior to entering and prior to leaving a BOP facility.

B. Updates Prior to the Execution

Following activation of the Media Center, the Warden's representative will provide the news media with regular briefings or updates of the execution process.

1. No later than eight hours prior to the scheduled execution, a Media Center will be activated. Telephone lines, tables, risers for cameras and outlets for electrical equipment and cameras will be available. Restroom facilities (and if possible, vending machines) will also be provided.

2. The Warden's designated representative will be present in the Media Center to provide regular announcements.

C. Media Orientation Releases

During the Media Orientation, the following information will be made available to members of the media:

1. General information regarding the scheduled execution and about the individual scheduled for execution.

2. Specific information regarding procedures to be followed by the media on the date of the scheduled execution.

3. Media representatives will be reminded that there are obvious security concerns about aircraft flying over Federal correctional facilities and therefore, their assistance and cooperation in this matter is expected.

4. Media representatives will be informed of how the press pool will be established (see paragraph IV D 2) and advised that if they are selected as press pool witnesses to the execution, they will agree prior to the execution to:

   a. sign the document designated as the Media Witness Press Pool Agreement (see Media Witness Press Pool Agreement, Appendix B);

   b. be subject to a metal detection scanning;

   c. not make any photographic, visual or audio recordings of the execution (each media witness will be provided only paper and a pencil or pen while in the execution witness area); and

d. return to the Media Center after the execution to answer questions of all other media represented concerning their observations during the execution.

5. After the Warden's representative, media pool witnesses and appropriate Department of Justice staff, if available, have addressed the media in the Media Center, the press briefing will be terminated and all media personnel will leave the Media Center.

IV. Media Center Operations

A. Requesting Authorization

1. After an execution date is set by the court/Director of the BOP, and no sooner than twenty days prior to the scheduled execution, news media representatives will be advised, in writing, by the Warden's designated representative that they may request, in writing, authorization to participate in the institution's Media Center activity in the hours preceding the scheduled execution (see Sample Letter to Media, Appendix C).

The requests, which must be in writing, should be received by the Warden no later than ten days prior to the execution. Requests must include names, social security numbers, and dates of birth for each representative of a media organization and his/her support staff. Only those media organizations submitting written requests, within the stated time frame, will be considered for participation in Media Center activities.

2. Requests for consideration may be granted by the Warden, provided they demonstrate that the requesting individual falls within the definition of "member of the press and broadcast media" set forth in BOP Program Statement 1480.03, Contact with News Media.

B. Possible Limitations

The number of media representatives may be limited by the Warden due to space and safety considerations, but care will be taken to include representatives from both the print and broadcast media.

C. Briefing Packets and Updates

1. Packets

Following activation of the Media Center, the Warden's representative will provide press briefing packets for

reporters in the Media Center. The contents of the press briefing packet will include, but not be limited to, releasable information on the condemned individual, pool reporters (once selected), the sequence of events, and the history of Federal executions.

2. Updates

Written updates generally will be distributed to the press on a regular basis following activation of the Media Center. Updates will include:

a. a summary of activities related to the execution and sequence of events; and

b. a summary, cleared by the Warden, of the condemned individual's activities during his/her final twenty-four hours.

D. News Media Witness Selection

1. Number in Attendance

The Warden will permit no more than 10 members of the media to witness the execution. The number of additional media representatives authorized to remain in the Media Center on the day of the execution may be limited, due to space and safety concerns.

2. Pool Selection Process

a. Press pool members will be selected by their peers at least three hours prior to the scheduled execution. Representatives from each of the following categories must be included:

(1) one local media source (located within the city or town of the institution);

(2) three television news programs of a station or network holding an FCC license (at least two being national broadcast stations);

(3) two media sources from the area where the crime was committed;

(4) one wire service;

(5) one radio station; and

(6) two print media organizations.

b. Press pool witnesses will be selected from qualified media representatives who have been admitted into the institution's Media Center and who have provided staff with proper identification. A list of media representatives will be compiled by the Warden's representative and furnished to the media for their review in the selection process.

3. Signed Agreement

Media selected as press pool witnesses will then be required to agree to:

a. act as a pool representative as described further in this chapter; and

b. abide by all established conditions, rules, and regulations while in attendance at the execution; to include allowing a metal detector scan of their person.

4. Supplemental Representatives

In the event the media are unable to identify witnesses in each of the above described categories, the Warden's designated representative may name other qualifying media representatives to attend, with a maximum of 10 being named.

E. Media Witnesses to the Execution

1. Search Process

Each media pool witness attending the execution will be scanned by a metal detector prior to admittance to the Execution Facility.

a. No pat or visual search of any media pool witness will be conducted unless the Warden has reasonable suspicion to believe the media representative is concealing weapons, drugs, audio or visual recording devices, or any other items not expressly authorized and the media

representative agrees to be searched. If the representative refuses to be searched, he/she will not be permitted to serve as a media witness.

1. Electronic or mechanical recording devices include, but are not limited to, still, moving picture or video tape cameras, tape recorders or similar devices, and radio/television broadcasting devices.

2. The representative will only be permitted paper and a pencil or pen as provided by institution staff.

2. Witness Briefing

The 10 selected members of the news media will be required to sign both the witness agreement (Appendix A) and the Media Witness Press Pool Agreement (Appendix B). They must also attend the pre-execution briefing at the Media Center. This briefing, conducted by a representative of the Warden, will provide specific information on the event and expectations regarding their conduct. This will include:

a. a review of approved materials that can be taken to the Execution Room;

b. search procedures;

c. escort procedures; and

d. the role of pool reporters.

3. Prohibition of Substitutes

No substitute media pool witness will be permitted after this briefing is conducted.

4. Segregation after the Search

After the search, all witnesses will be segregated and escorted to the Execution Facility. Media witnesses will not be permitted to have physical contact with any other persons during this time.

5. Excluding Witnesses

The Warden will not exclude any media witness duly selected in accordance with this chapter from attendance at the execution or cause a selected media witness to be removed from the media pool witness area unless the media witness:

a. refuses to submit to a reasonable search as outlined in these regulations;

b. faints, becomes ill, or requests to be allowed to leave during the execution;

c. causes a disturbance within the media pool witness area that disrupts the orderly progress of the execution as determined by the Warden's representative on site; or

d. fails to abide by the provisions of the Witness Agreement.

6. The Execution Process

The selected media pool witnesses will be escorted as a group to the execution location prior to the execution and will be allowed to remain there throughout the execution process. The Warden will designate a BOP Spokesperson to remain with the media pool witnesses throughout the process and to answer questions.

F. Death Announcement

Immediately following the execution and prior to the post-execution press pool briefing, a Warden's representative will read the following prepared statement to the press and demonstrators:

SAMPLE STATEMENT

(To be read at post execution press briefing and to any assembled members of the public.)

_____, Warden of _____,

reports that pursuant to the sentence of the United States

District Court in _____, _____
(Condemned Individual's Name)

has been executed by lethal injection.

_____ was pronounced dead at
(Condemned Individual's Name)

_____ on _____.
(Time) (Date)

G. Press Pool Post-Execution Briefing

All news media press pool witnesses will, after being returned from the execution to the Media Center, immediately brief other media representatives covering the event. The pool witnesses will provide an account of the execution and will endeavor to answer all questions asked of them by other media representatives. They will not report their observations regarding the execution to their respective news organizations until after the non-witness media representatives have had the benefit of the pool representatives' accounts of the execution.

H. Post Execution Press Conference

If deemed necessary and appropriate, representatives of the Department of Justice, USMS and BOP will answer questions from the assembled media for no more than 30 minutes after the press briefing.

V. The Execution Information Center

A. Responsibility

The Warden's representative will establish and operate an Execution Information Center.

B. Purpose

The Execution Information Center:

1. is a central processing point for all incoming media and public interest telephone calls pertaining to the scheduled execution;

2. allows the institution's staff to handle normal and routine business;

3. handles "crank" calls and bomb threats in accordance with BOP policy; and

4. establishes a log of calls for future reference, investigation and evaluation.

C. Location

1. The Execution Information Center will be located in an area identified by the Warden.

2. Only persons authorized by the Warden will be allowed in the Center's operational area. Center staff are responsible for keeping the area clear of unauthorized personnel.

D. Schedule

1. The Execution Information Center will commence operations approximately two working days prior to the scheduled execution. The Information Center will operate twelve hours a day on the days prior to the scheduled execution and for the eighteen hours immediately preceding the scheduled execution. The Center will remain in operation until approximately one hour after the execution.

2. The Warden's representative will arrange coverage of telephones, based on the volume of calls.

3. Staffing for the Execution Information Center will be coordinated by the Warden's representative.

E. Screening Calls

1. Types of Calls

a. Business Calls

Calls from BOP staff or other Federal agencies relating to the execution; or fromBOP staff relating to operational issues affected by the execution which may need to be forwarded to the Command Center.

b. Personal Calls

Calls intended for individuals (staff or witnesses) connected with the execution.

c. Inquiry Calls

Execution-related calls from the general public.

1. Staff will endeavor to answer every call in a professional, courteous and efficient manner.

2. If bomb threats are received, the staff member receiving the call will utilize established procedures. Bomb threats will be communicated to the Command Center immediately.

3. If possible, all "crank" calls and calls considered to be an emergency, should be recorded and traced.

CHAPTER 7: STAYS, COMMUTATIONS AND OTHER DELAYS

I. General Provisions

A. Purpose of Chapter

The purpose of this chapter is to:

1. cite the entities capable of causing execution stays, commutations, and other delays;

2. specify the manner of communicating such delays/commutations; and

3. provide the procedures for implementing the delay/commutation.

B. Policy

It is the policy of the BOP that:

1. procedures must be in place to receive and ensure proper handling of legal interruptions of the execution countdown;

2. staff understand their roles and the BOP's responsibilities in the event of such interruptions; and

3. contingency plans provide methods for responding to:

   a. temporary delays;

   b. lengthy delays; and

   c. commutations.

II. Presidential and Judicial Authority to Interrupt Execution

A. President

1. The United States Constitution confers upon the President the power to grant reprieves and pardons for offenses against the United States. This has been held to include the power to grant conditional pardons and commute sentences.

2. Neither Congress nor a State legislature can limit the President's power to pardon.

B. Courts

A Federal court of competent jurisdiction may issue a stay of execution or invalidate a sentence of death as a result of appellate or collateral proceedings.

III. Communication of Pardons, Stays, Commutations or Delays

A. Prior to Final Execution Countdown

If the BOP receives an order from a Federal court of competent jurisdiction or the President ordering a respite, reprieve, stay, commutation, pardon or other action which requires the suspension or termination of the execution:

1. the Attorney General's Office will be contacted for consultation; and

2. a decision will be made by the Director of the BOP concerning the status of planning and preparation for the execution.

B. During Final Execution Countdown

1. During the final twenty-four hours, the BOP and the USMS will maintain frequent contact with the Attorney General's Office through [redacted]

[redacted]

C. Final Clearance for Execution

At an appropriate time prior to the execution [redacted] the Designated United States Marshal will verify clearance to continue with the execution [redacted]

[redacted]

IV. Procedures to Implement Last-Minute Stays

A. Upon receiving a stay during the final countdown, the first effort will be to determine the probable length of the delay.

B. If the witnesses have not been moved from their staging areas, they will be held in those locations until further instructions are received from the Warden to proceed with or terminate the execution.

C. If witnesses are already at the Execution Facility and the condemned individual is restrained:

1. If the delay appears to be relatively lengthy, the condemned individual will be returned to the Holding Cell by the Restraint Team. The witnesses will be returned to their staging areas in the order listed. There they will await further information.

2. If the delay is likely to be relatively short in duration, the witnesses will remain in place. The drapes will be closed and the condemned individual will remain restrained on the table.

3. If the execution is indefinitely stayed, set for re-sentencing, commuted, or halted by pardon, the execution will be halted, and the condemned individual and witnesses will be immediately advised. Witnesses will be returned to their staging areas and the condemned individual returned to appropriate quarters in the institution.

Appendix A

MEMORANDUM OF AGREEMENT
BETWEEN
FEDERAL BUREAU OF PRISONS
AND WITNESS

This agreement is made between the Federal Bureau of Prisons and the following witness:

_____

In accordance with Title 28, Code of Federal Regulations, Section 26.4, the Federal Bureau of Prisons may allow you, as a witness, to be present at the execution. However, your presence at the execution is not a right and, in order to be entitled to be present, you will be required to agree to the following conditions:

1. You will not bring onto institution grounds anything constituting legal or illegal contraband under any applicable statute, regulation or policy, including, but not limited to, firearms, weapons, explosives, metal cutting tools, narcotic drugs, alcoholic beverages, or any item creating a threat to institution safety, security, or good order;

2. You agree to submit to a reasonable search for contraband and other searches as considered necessary by the Bureau of Prisons for entry into the institution;

3. You will conduct yourself in a lawful and orderly manner;

4. You will comply with all lawful directives of correctional personnel while on institution grounds;

5. You will not bring onto institution grounds any photographic or other visual or audio recording device; and

You have read, understand, and agree to the above. By signing this agreement, you agree to comply with its conditions and understand that failure to abide by them will result in your removal from institution grounds and could lead to prosecution for violation of Federal laws.

_____ _____
(Witness) (Date)

_____ _____
(Agency Representative) (Date)

Appendix B

MEDIA WITNESS PRESS POOL AGREEMENT

In consideration of having been selected as an official witness to the execution of _____ on _____, I, _____, hereby agree to act as a pool reporter and, not to interview non-media witnesses or Department of Justice staff at the Execution Facility. Following the execution, I agree to return immediately to the Media Center to brief my colleagues there regarding the execution and answer their questions. I also agree to file my story only after I have completed my responsibilities as a pool reporter.

NAME: _____
(Signature)

ORGANIZATION: _____

DATE: _____

_____
(BOP Staff Witness)

Appendix C

SAMPLE LETTER TO MEDIA
(Re: Media Center Operations)

In accordance with the provisions of 28 C.F.R., Part 26, Implementation of Death Sentences in Federal Cases,

_____ is scheduled to be executed .
(Condemned Individual's Name)

at _____ on _____.
(Institution) (Date)

No later than eight hours preceding the scheduled execution, a Media Center will be established at the _____ in
(Location)
Terre Haute, Indiana, and telephones will be available. Should you desire to cover the event from the Media Center, or if selected, be a media pool witness, please submit your written request to me, via fax or by mail, so that it is received in my office no later than _____.
(Date 10 days prior to execution)

The request must include your name, the names of all support staff (sound technician, cameraperson, etc.) who may accompany you on this day. Social security numbers and dates of birth for all participants, including yourself, must also be furnished in your letter so that appropriate security checks can be completed. You will be notified promptly if we have any concerns with your request. Space is limited and admittance to the Media Center will have to be on a first-come, first-accommodated basis.

Should you desire to be considered to be a media pool witness to the execution, you will also be required to sign agreements consenting to a search prior to entering the execution facility, and agreeing to abide by all relevant conditions, rules and regulations. Should you participate, your name is subject to being released to the media.

Please note that all media representatives will be required to sign a log and show proper press credentials in order to be admitted to the Media Center.

Sincerely,
Name
Title

ADMINISTRATIVE RECORD SUMMARY
BOP USE OF SINGLE DRUG PROTOCOL

Introduction

The Federal Bureau of Prisons ("BOP") is responsible for implementing federal death sentences. *See* 28 C.F.R. Part 26. These regulations require the sentence be implemented by "intravenous injection of a lethal substance or substances in a quantity sufficient to cause death, such substance or substances to be determined by the Director of the Federal Bureau of Prisons . . . ." *See* 28 C.F.R. § 26.3(a)(4).

The BOP carried out the executions of Timothy McVeigh (2001), Juan Garza (2001), and Louis Jones (2003). At that time, the BOP lethal injection protocol consisted of three drugs: sodium pentothal, pancuronium bromide, and potassium chloride. The BOP has since been unable to acquire sodium pentothal.

In *Baze v. Rees*, 553 U.S. 35 (2008), the Supreme Court upheld Kentucky's use (along with at least 30 other states) of a three-drug combination, including sodium pentothal, pancuronium bromide, and potassium chloride. While *Baze* provided clear approval of a specific protocol for states to carry out the death penalty, practical obstacles soon emerged as pharmaceutical companies began refusing to supply the drugs used to implement the death sentences. *See Glossip v. Gross*, 135 S.Ct. 2726, 2733 (2015). Specifically, the sole American manufacturer of sodium pentothal stopped producing the drug because of its use in the death penalty. *Id.* Unable to obtain sodium thiopental, states explored alternatives and adopted use of pentobarbital, which was used in all of the 43 executions carried out by the states in 2012. *Id.* at 2733 (citing the Death Penalty Information Center online site at www.deathpenaltyinfo.org). However, pentobarbital also became difficult to obtain as anti-death-penalty advocates lobbied manufacturers to stop selling it for use in executions. *Id.*

States are unwilling to discuss or reveal the identity of entities that supply their lethal injection drugs because those entities often stop supplying the drugs once their identity is disclosed. *See In re: Missouri Department of Corrections*, 839 F.3d 732, 736 (8th Cir. 2016). Further, many states have enacted legislation precluding disclosure of entities that supply drugs necessary to carry out an execution and/or the identity of individuals who participate in executions. *See e.g.* Ga. Code Ann. § 42-5-36 (Georgia Lethal Injection Secrecy Act); Tex. Code Ann. § 552.1081 and Tex. Code Crim. Proc. Art. 43.14(b); Ark. Code Ann. § 5-4-617; Miss. Code Ann. § 99-19-51; Mo. Rev. Stat. § 546.720; Ohio Rev. Code Ann. § 2949.221; Okla. Stat. Ann. Title 22, § 1015; Tenn. Code Ann. § 10-7-504; S. D. Codified Laws § 23A-27A-31.2; and Va. Code Ann. § 53.1-234.

As sodium pentothal became unavailable, the BOP explored alternative drugs. The BOP benchmarked with state practices, reviewed case law, consulted with medical professionals, and reviewed available professional literature in this area. As a result of this review, the BOP has determined that a single-drug protocol, using pentobarbital, would be adopted as the execution protocol.

Benchmark with States

BOP personnel visited several state execution sites and reviewed state lethal injection protocols. The state lethal injection protocols were viewed on the corresponding state department of corrections' web sites and/or the Death Penalty Information Center website.

After the availability of sodium pentothal declined, states developed alternative drug combinations that replaced sodium pentothal with pentobarbital. *Glossip*, 135 S.Ct. at 2733. Some states incorporated pentobarbital as a one-drug protocol, and some states used pentobarbital in a three-drug protocol.

However, the availability of pentobarbital declined and states implemented other protocols. Due to challenges with availability of sodium pentothal and pentobarbital, several states have changed their protocols or adopted more than one lethal injection protocol to overcome shifting availability of various drugs. For example:

- In 2017, the State of Nevada adopted a three-drug execution protocol that includes fentanyl, diazepam, and cisatracurium. In June 2018, Nevada revised the protocol and replaced diazepam with midazolam, reportedly because Nevada's inventory of diazepam expired.
- From 2011 to 2013, Florida executed 10 individuals using a three-drug protocol wherein pentobarbital was the first drug administered. However, pentobarbital became unavailable for use in executions. In October 2013, Florida became the first state to substitute midazolam for pentobarbital as part of a three-drug protocol. *Glossip*, 135 S.Ct. at 2734. Florida executed 13 individuals using a lethal injection protocol with midazolam as the first drug without any reported problems. *Arthur v. Alabama Department of Corrections*, 840 F.3d 1268, 1304 (11th Cir. 2016). However, Florida encountered difficulties acquiring midazolam and in January 2017, Florida adopted a new three-drug protocol because it was unable to acquire midazolam. In that new protocol, Florida substituted etomidate for midazolam as the first drug, followed by rocuronium bromide and potassium acetate. The Florida Supreme Court upheld the use of etomidate as part of the lethal injection protocol. *Asay v. State of Florida*, 224 So.3d 695 (Fla. 2017). Florida has executed two individuals using that protocol.

Fourteen states have used pentobarbital in their lethal injection protocol, either as part of a three-drug combination or as a single-drug method. Georgia, Idaho, Missouri, South Dakota, and Texas administer a single-drug pentobarbital protocol. Both Missouri and Texas have extensive experience using the single-drug pentobarbital method, executing 20 and 78 inmates, respectively, since approximately 2012. Since 2010, pentobarbital was used as part of a single or three-drug combination in 208 executions. Of the ten executions in 2019, as of June 24, 2019, five used a single-drug pentobarbital protocol. https://deathpenaltyinfo.org/executions/lethal-injection/state-by-state-lethal-injection-protocols

Anticipating that the BOP would encounter the same obstacles that the states have encountered in obtaining pentobarbital, it also considered other lethal injection protocols. One alternative

protocol considered consists of three drugs: midazolam, sufentanil citrate, and potassium chloride.

The BOP determined that a one-drug protocol is preferred for several reasons. First, there are complications inherent in obtaining multiple drugs (availability obstacles) and navigating the respective expiration dates. Second, acquiring and storing one drug is administratively more efficient. Third, administering one drug reduces the risk of errors during administration, and eliminates the need to orchestrate the pace and sequence of administering multiple drugs and IV line management.

Professional Medical Expert Consultation

The BOP consulted with two medical experts to review whether the BOP's proposed pentobarbital protocol will produce a humane death. Both concluded that the protocol would produce a humane death.

Publically available expert testimony was also reviewed by the BOP. First, in January 2017, the expert addressed Ohio's lethal injection protocol, which entails midazolam, pancuronium bromide, and potassium chloride. Second, in February 2017, the expert provided testimony addressing Missouri's one drug lethal injection of pentobarbital.

In the Missouri case, the expert testified for the state on the efficacy of pentobarbital, and secondarily the use of nitrogen gas. When asked which option is better, the expert testified, "I don't offer an opinion about one being better than the other." The reason advanced was that medical ethics prevent him from so opining. Similarly, the inmate's expert declined to offer an opinion in that regard.

In the Missouri case, the inmate's attorney explored the expert's prior testimony regarding the efficacy of midazolam in the context of Ohio's 3-drug protocol. The inmate's attorney asked questions about the effects of each drug without directly asking which is better (e.g., the 3-drug protocol using midazolam vs pentobarbital). The expert testified that both are effective at producing unconsciousness (the intended effect), and then stated that pentobarbital achieves deeper levels of unconsciousness than midazolam.

In sum, the expert's prior testimony opined that both pentobarbital and midazolam in their respective protocols work to have the intended effect in this setting. He also testified that the properties of pentobarbital achieve a "deeper level" of unconsciousness than midazolam.

Review of After Action Report

The BOP reviewed the after action report of the widely publicized Oklahoma execution in 2015 involving state inmate Clayton Locket, which used a three drug protocol using midazolam, a paralytic agent, and then potassium chloride. As summarized by the Supreme Court in *Glossip*, 135 S.Ct. at 2734-35, that investigation concluded that the viability of the IV access point was the single greatest factor that contributed to the difficulty in administering the execution drugs.

Although various media outlets have reported complications with lethal injection executions, none of those executions appear to have resulted from the use of single-drug pentobarbital. This consideration included review of information provided by Death Penalty Information Center, *Botched Executions*, https://deathpenaltyinfo.org/some-examples-post-furman-botched-executions?scid=8&did=478.

Review of Case Law

The BOP reviewed case law addressing lethal injection protocols. Courts have held that the use of pentobarbital in executions does not violate the Eighth Amendment. *See, e.g.*, *Ladd v. Livingston*, 777 F.3d 286 (5th Cir. 2015); *Zink v. Lombardi*, 783 F.3d 1089, 1102 (8th Cir. 2015); *Jackson v. Danberg*, 656 F.3d 157 (3d Cir. 2011); *DeYoung v. Owens*, 646 F.3d 1319 (11th Cir. 2011); and *Pavatt v. Jones*, 627 F.3d 1336 (10th Cir. 2010). *See also Bucklew*, 139 S.Ct. at 1129-1132 (finding that death row inmate challenging Missouri's method of execution using a single-drug pentobarbital protocol failed to show a feasible and readily implemented alternative method of execution that would significantly reduce a substantial risk of severe pain).

Challenges to state lethal injection protocols frequently propose a single dose of pentobarbital rather than a three-drug protocol. *See, e.g.*, *McGehee v. Hutchinson*, 854 F.3d 488 (8th Cir. 2017); *In re Missouri Department of Corrections*, 839 F.3d 732 (2016); *Arthur v. Commissioner, Alabama Department of* Corrections, 840 F.3d 1268 (11th Cir. 2016); *In re Ohio Execution Protocol*, 860 F.3d 881, 890-91 (6th Cir. 2017); and *Glossip*, 135 S.Ct. at 2738. The common argument is that use of pentobarbital is an alternative method that would significantly reduce the substantial risk of pain from the challenged method. Two U.S. Supreme Court Justices dissented from denial of certirorari in two cases where the Petitioners' argued that state lethal injection protocols violated the Eighth Amendment. In both cases, the dissenting opinions indicated that the proposed alternative of a single-drug protocol consisting of pentobarbital did not carry the risks of the protocols being challenged. *See Zagorski v. Parker*, 139 S.Ct. 11 (2018) (challenge to the Tennessee lethal injection protocol consisting of midazolam, vecuronium bromide, and potassium chloride); and *Arthur v. Dunn*, 137 S.Ct. 725 (2017) (challenge to the Alabama lethal injection protocol consisting of midazolam, vecuronium bromide, and potassium chloride).

Based on review of case law, it is evident that use of pentobarbital is litigation tested, and courts across the country have held that the use of pentobarbital in executions does not violate the Eighth Amendment. Further, inmates and their advocates frequently cite to pentobarbital as a method that would significantly reduce the substantial risk of pain compared to the challenged method.

Source for Pentobarbital

The BOP has a viable source for obtaining pentobarbital. The manufacturer is properly registered as a bulk manufacturer of the active pharmaceutical ingredient ("API") for pentobarbital. The API was subjected to quality assurance testing, further supporting the reliability and qualification of this manufacturer.

The BOP has secured a compounding pharmacy to store the API and to convert the API into injectable form as needed. The BOP conferred with DEA to ensure the compounding pharmacy is properly registered. The compounding pharmacy has performed its own testing and the drug further passed quality assurance testing conducted by two independent laboratories.

The BOP confirmed with DEA that the BOP facility in Terre Haute, Indiana, meets the regulatory requirements for storage and handling of pentobarbital.

ATTACHMENTS

BENCHMARK

- Lethal Injection Protocol from:
  - Georgia
  - Idaho
  - Missouri
  - South Dakota
  - Texas

- State-by-state lethal injection summary from the Death Penalty Information Center website, https://deathpenaltyinfo.org/lethal-injection
- Internal talking points summarizing:
  - The State of Florida lethal injection protocol evolution
  - States that currently or previously used pentobarbital, and aggregated data.

CASE LAW

- *Bucklew v. Precythe*, 139 S.Ct. 1112 (2019)
- *Zagorski v. Parker*, 139 S.Ct. 11 (2018)
- *Arthur v. Dunn*, 137 S.Ct. 725 (2017)
- *Glossip v. Gross,* 135 S.Ct. 2726 (2015)
- *Baze v. Rees*, 553 U.S. 35 (2008)
- *Ladd v. Livingston,* 777 F.3d 286 (5th Cir. 2015)
- *Zink v. Lombardi*, 783 F.3d 1089 (8th Cir. 2015)
- *Jackson v. Danberg,* 656 F.3d 157 (3d Cir. 2011)
- *DeYoung v. Owens*, 646 F.3d 1319 (11th Cir. 2011)
- *Pavatt v. Jones*, 627 F.3d 1336 (10th Cir. 2010)
- *Price v. Commissioner, Alabama Dep't of Corrections*, 920 F.3d 1317 (11th Cir.2019)
- *Arthur v. Commissioner, Alabama Dep't of Corrections*, 840 F.3d 1268 (11th Cir. 2016)
- *In Re: Ohio Execution Protocol*, 860 F.3d 881 (6th Cir. 2017)
- *McGehee v. Hutchinson*, 854 F.3d 488 (8th Cir. 2017)

MEDICAL EXPERT DEPOSITIONS/REPORTS

- Rule 26(a)(2) Expert Report Declaration of Joseph F. Antoginini, M.D. (in the case of *Bucklew v. Lombardi*, 2016 WL 11258099 (W.D.Mo.))
- Expert Deposition of Joseph Antoginini, M.D. (2017 WL 9471457 (W.D. Mo.))
- Expert Report of Craig W. Lindsley, Ph.D., dated May 26, 2017
- Transcript of Preliminary Injunction Hearing dated January 5, 2017, in *In re: Ohio Execution Protocol Litigation*, in the U.S. District Court for the Southern District of Ohio.

JOURNALS, MEDIA, AND REPORTS

- Deborah W. Denno, *Lethal Injection Chaos Post-Baze*, 102 GEO. L.J. 1331, 1382 (2014)
- Hospira, Press Release, Hospira Statement Regarding Pentothal (sodium thiopental) Market Exit (Jan. 21, 2011).
- CNN article - *Death row inmate executed using pentobarbital in lethal injection*, December 16, 2010, *available at* http://www.cnn.com/2010/CRIME/12/16/oklahoma.execution
- Death Penalty Information Center, *Botched Executions*, https://deathpenaltyinfo.org/some-examples-post-furman-botched-executions?scid=8&did=478
- Oklahoma Department of Public Safety Report: The Execution of Clayton D. Lockett

BUREAU OF PRISONS AND DEPARTMENT OF JUSTICE CORRESPONDENCE

- November 27, 2017, memorandum from Director Mark S. Inch to the department (addressing proposed one-drug protocol).
- March 7, 2018, memorandum from Director Mark S. Inch to the department (addressing use of fentanyl).
- Addendum to BOP Execution Protocol (one drug pentobarbital).
- Draft memorandum from Acting Director to the department addressing anticipated adoption of one-drug protocol.
- Letter from various State Attorneys General dated January 25, 2011, to Attorney General Eric Holder, and the response letter from Attorney General Eric Holder dated March 4, 2011.
- Op. Off. Legal Counsel Volume 43 (May 3, 2019).

A Communication From The Chief Legal Officers Of The Following States
Alabama * Colorado * Delaware * Florida * Idaho * Mississippi * Missouri * Nevada * Oregon * Tennessee * Utah * Washington * Wyoming

January 25, 2011

Attorney General Eric Holder
Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

Dear Attorney General Holder:

The majority of jurisdictions in the United States that include the death penalty as an authorized punishment in certain cases, including the Federal Government, provide for lethal injection as the prescribed method of execution. In a majority of those capital-crime jurisdictions, again including the Federal Government, it is the only prescribed method of execution. We, the Attorneys General of the States listed below, seek your assistance in resolving an issue concerning the procurement of one of the prescribed medications used in lethal injection protocols.

The protocol used by most of the jurisdictions employing lethal injection includes the drug sodium thiopental, an ultra-short-acting barbiturate. Sodium thiopental is in very short supply worldwide and, for various reasons, essentially unavailable on the open market. For those jurisdictions that have the drug available, their supplies are very small – measured in a handful of doses. The result is that many jurisdictions shortly will be unable to perform executions in cases where appeals have been exhausted and Governors have signed death warrants.

Therefore, we solicit your assistance in either identifying an appropriate source for sodium thiopental or making supplies held by the Federal Government available to the States. We also request an opportunity to discuss this important matter with you.

We look forward to hearing from you.

Sincerely,

John Kroger
Oregon Attorney General

Luther Strange
Alabama Attorney General

John Suthers
Colorado Attorney General

Pam Bondi
Florida Attorney General

Jim Hood
Mississippi Attorney General

Catherine Cortez Masto
Nevada Attorney General

Mark Shurtleff
Utah Attorney General

Bruce Salzburg
Wyoming Attorney General

Joseph Biden III
Delaware Attorney General

Lawrence Wasden
Idaho Attorney General

Chris Koster
Missouri Attorney General

Robert Cooper
Tennessee Attorney General

Rob McKenna
Washington Attorney General

Office of the Attorney General
Washington, D.C. 20530

March 4, 2011

Mr. James McPherson
Executive Director
National Association of Attorneys General
2030 M Street, NW
Washington, DC 20036

Dear Mr. McPherson:

This letter responds to the January 25, 2011 letter from various State Attorneys General concerning the difficulties related to procurement of sodium thiopental for use in lethal injections.[1] The lack of availability of sodium thiopental is a serious concern that the Federal Government is currently analyzing.

At the present time, the Federal Government does not have any reserves of sodium thiopental for lethal injections and is therefore facing the same dilemma as many States. The relevant Federal officials tasked with implementing the Federal death penalty have undertaken a review of this matter. They are looking at all applicable options to determine the best course of action for effectively discharging our legal responsibilities, as well as any necessary changes to current Federal death penalty procedures. Bureau of Prisons General Counsel Kathleen Kenney is coordinating our efforts to resolve this issue and is available to discuss it with you; she can be reached at 202-307-3062.

I appreciate and share your concerns about this matter, but I am optimistic that workable alternatives are available that will allow us to carry out our duties.

Sincerely,

Eric H. Holder, Jr.
Attorney General

[1] The January 25 letter was sent by the Attorneys General of Alabama, Colorado, Delaware, Florida, Idaho, Mississippi, Missouri, Nevada, Oregon, Tennessee, Utah, Washington, and Wyoming.

(Slip Opinion)

Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions

May 3, 2019

Articles intended for use in executions carried out by a State or the federal government cannot be regulated as "drugs" or "devices" under the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration therefore lacks jurisdiction to regulate articles intended for that use.

MEMORANDUM OPINION FOR THE ATTORNEY GENERAL

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., grants the Food and Drug Administration ("FDA") the authority to regulate all "drugs" and "devices," which include any "articles (other than food) intended to affect the structure or any function of the body," as well as any components of such articles. *Id*. § 321(g)(1)(C)–(D), (h)(3). Your office has asked us whether FDA has authority to regulate articles used in historically accepted methods of execution. Some of those articles—like electric chairs and gas chambers—exist for the sole purpose of effectuating capital punishment. Others—like substances used in lethal-injection protocols and firearms used by firing squads—have other intended uses.

FDA has not historically exercised jurisdiction over articles intended to carry out a lawful sentence of capital punishment. In connection with challenges to FDA's regulatory inaction, the federal courts have addressed when the agency may lawfully decline to enforce the FDCA against such articles. *See, e.g.*, *Heckler v. Chaney*, 470 U.S. 821 (1985); *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013). Yet they have not squarely addressed whether FDA has administrative jurisdiction in the first place. Congress has repeatedly authorized the death penalty on the assumption that there are lawful means to carry it out, but the regulation of such articles under the FDCA would effectively require their prohibition because they could hardly be found "safe and effective" for such an intended use. *See FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 137–39 (2000). Consistent with the agency's practice in this area for several decades before 2017, we thus conclude that, when an article's intended use is to

effectuate capital punishment by a State or the federal government, it is not subject to regulation under the FDCA.[1]

I.

The FDCA was first enacted in 1938. Act of June 25, 1938, ch. 675, 52 Stat. 1040. Then, as well as now, the United States and several States authorized the imposition of capital punishment for the most serious offenses. From the time of the FDCA's enactment until very recently, FDA had never claimed authority over the methods by which the federal and state governments carry out executions. That is in no small part because one of the FDCA's fundamental purposes is to ensure that drugs and devices marketed in interstate commerce are safe and effective for their intended uses—a goal that markedly conflicts with the purpose of an execution. In this Part, we summarize the regulatory structure of the FDCA and the history of its intersection with capital punishment.

A.

The FDCA authorizes FDA to regulate drugs and devices. The FDCA defines "drug" to mean:

> (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
>
> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
>
> (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
>
> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C. § 321(g)(1) (paragraph breaks added). Congress has made only superficial changes to this definition since 1938. *Compare* Act of June 25, 1938, § 201(g), 52 Stat. at 1041.

[1] In reaching this conclusion, we have solicited and considered the views of FDA and of the Office of the Associate Attorney General.

The FDCA defines "device" as any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" that does not "achieve its primary intended purposes through chemical action within or on the body"; is not "dependent upon being metabolized for the achievement" of those purposes; and is:

> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals.

21 U.S.C. § 321(h) (paragraph breaks added). The definition of "device" also includes "any component, part, or accessory" of such articles. *Id*.[2]

As the statutory definitions indicate, whether FDA may regulate an article as a "drug" or "device" often depends not just on that article's effect on a human or animal body, but also on whether that effect is intended. *Id*. § 321(g)(1), (h). An article may be a "drug" or "device" for some uses but not for others, depending on the manufacturer's or distributor's intent. For instance, FDA regulates "medical gases," but not chemically identical industrial gases. As FDA has explained, "industrial gases . . . are not drugs" because manufacturers and distributors of industrial gases do not intend their products to treat disease or other conditions, or to otherwise affect the structure or function of the body. Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements, 71 Fed. Reg. 18,039, 18,044 (Apr. 10, 2006); *see* 21 C.F.R. §§ 201.161, 211.94(e). In a similar vein, FDA considers hot tubs, saunas, and treadmills as "devices" only when they are "intended for medical purposes." Physical Medicine Devices; General Provisions and Classification of 82 Devices, 48 Fed. Reg. 53,032, 53,034, 53,044, 53,051–52

[2] Initially, the FDCA defined "device" as "instruments, apparatus, and contrivances, including their components, parts, and accessories" if they were "intended" either "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" or "to affect the structure or any function of the body of man or other animals." Act of June 25, 1938, § 201(h), 52 Stat. at 1041. In 1976, Congress expanded the definition of "device" to its current scope. Medical Device Amendments of 1976, Pub. L. No. 94-295, sec. 3(a)(1)(A), § 201(h), 90 Stat. 539, 575.

(Nov. 23, 1983); *see* 21 C.F.R. §§ 890.5100, 890.5250, 890.5380. Thus, powered treadmills intended "to redevelop muscles or restore motion to joints" are "devices," but those sold solely for recreational purposes are not. 48 Fed. Reg. at 53,044, 53,052; 21 C.F.R. § 890.5380. Likewise, FDA considers tape recordings as "devices" when they are "intended for use in the mitigation, treatment, and cure of disease and other medical conditions" (as in hypnotherapy), but not when they are intended "for behavior modification, self-improvement, habit correction, learning techniques, and simple relaxation." FDA, Compliance Policy Guide § 335.300.

Many of the FDCA's prohibitions are keyed to a product's intended use. The FDCA prohibits distribution of a "new drug" that FDA has not approved as safe and effective for its intended use. *See* 21 U.S.C. § 355(a), (d)(1), (d)(5); *United States v. Caronia*, 703 F.3d 149, 152–53 (2d Cir. 2012). Similarly, the FDCA prohibits distribution of certain devices that present "a potential unreasonable risk of illness or injury," unless FDA has approved them as safe and effective for their intended uses. 21 U.S.C. § 360c(a)(1)(C); *see id.* §§ 331(a), 351(f)(1), 360e(a), (d)(2)(A)–(B). The FDCA also bars distribution of "misbranded" drugs and devices, including those whose labeling lacks adequate directions for their intended uses, *id.* § 352(f)(1), or adequate warnings against unsafe dosages or methods of administration for those uses, *id.* § 352(f)(2). Finally, the FDCA provides that FDA "shall" block the importation of drugs and devices that appear to be unapproved for their intended use or misbranded. *Id.* § 381(a)(3).

Even if FDA has approved an article for one intended use, it still may not be imported, sold, or distributed for another, unapproved use. *See Wash. Legal Found. v. Henney*, 202 F.3d 331, 332–33 (D.C. Cir. 2000). FDA's regulations define the "intended use" of a drug or device with reference to "the objective intent of the persons legally responsible for the labeling" of the article. 21 C.F.R. §§ 201.128 (drugs), 801.4 (devices). That intent "is determined by such persons' expressions" or from "the circumstances surrounding the distribution of the article." *Id.* §§ 201.128, 801.4. The regulations emphasize that "[t]he intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer." *Id.* §§ 201.128, 801.4. "[F]or example, a packer, distributor, or seller [may] intend[] an article for different uses than those intended by the person from whom he received the" drug or device, in which case "such packer, distributor, or seller is required to supply adequate

labeling in accordance with the new intended uses." *Id*. §§ 201.128, 801.4. Likewise, a manufacturer could lawfully distribute an article intending that it be used for an approved purpose, and then later violate the FDCA by distributing the same article intending that it be used for a different, unapproved purpose.

As a general matter, FDA does not regulate the practice of medicine, which includes "off-label" prescribing—that is, when physicians prescribe FDA-approved drugs or devices for non-FDA-approved uses.[3] As the Supreme Court has explained in the context of medical devices, "'off-label' usage . . . (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *see also Caronia*, 703 F.3d at 153. Thus, while the FDCA bars a manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses.

B.

Capital punishment in the United States predates the Republic. For most of the Nation's history, the federal government and the States employed the gallows. Starting in the late nineteenth century, States began using the electric chair and, to a lesser degree, the gas chamber. At least since Thomas Edison's New Jersey laboratory supplied parts for New York's first electric chair in 1890, prison authorities have used interstate suppliers to procure articles necessary for executions.[4] Today, every

[3] *See* Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 1994) ("'[O]nce a [drug] product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens o[f] patient populations that are not included in approved labeling.'") (quoting 12 FDA Drug Bulletin 5 (Apr. 1982)); *see also* 21 U.S.C. § 396.

[4] *See* Stuart Banner, *The Death Penalty: An American History* 183, 197 (2002) (describing New York's purchase of electric-chair components, and Nevada's purchase of hydrocyanic acid for use in the gas chamber from a California source); Scott Christianson, *The Last Gasp: The Rise and Fall of the American Gas Chamber* 6 (2010) (explaining that Eaton Metal Products in Colorado built gas chambers for most of the States that used them); Carol J. Williams, *Maker of Anesthetic Used in Executions is Discontinuing Drug*,

method of execution appears to involve some component that traveled in interstate or foreign commerce.

Beginning in the late 1970s, many States and the federal government adopted lethal injection as the preferred method of execution. Those executions generally used sodium thiopental, a widely administrered surgical anaesthetic. Although patients typically received a dose of around 300 milligrams of sodium thiopental during surgical procedures, the dose in a lethal injection was anywhere from "seven to sixteen times higher." Mark Dershwitz & Thomas K. Henthorn, *The Pharmacokinetics and Pharmacodynamics of Thiopental as Used in Lethal Injection*, 35 Fordham Urb. L.J. 931, 932 (2008); *see also Glossip v. Gross*, 135 S. Ct. 2726, 2742 (2015) (noting that the dose of midazolam in Oklahoma's more recent execution protocol "is many times higher than a normal therapeutic dose").

In 1980, death-row inmates petitioned FDA to seize lethal-injection substances from several States, arguing that, although the substances were approved for other uses, their use in executions would violate the FDCA's prohibitions against the distribution of unapproved new drugs and misbranded drugs. FDA denied the petition, reasoning that it lacked authority to regulate States' use of FDA-approved drugs in capital punishment. FDA also stated that, even if it had such authority, it would decline to regulate in its enforcement discretion. When the issue reached the Supreme Court, the United States argued more broadly that FDA lacked jurisdiction over articles intended for use in capital punishment. *See Heckler*, 470 U.S. 821; Br. for Pet'r at 13–14, 44–46, *Heckler v. Chaney*, 470 U.S. 821 (1985) (No. 83-1878) ("*Heckler* Pet'r Br."). The Court found it "implausible . . . that the FDA is required to exercise its enforcement power to ensure that States only use drugs that are 'safe and effective' for human execution." 470 U.S. at 827. Rather than "address the thorny question of the FDA's jurisdiction," however, the Court held that FDA's exercise of enforcement discretion is not subject to judicial review. *Id*. at 828.

L.A. Times (Jan. 22, 2011), http://articles.latimes.com/2011/jan/22/local/la-me-execution-drug-20110122 (discussing California's use of sodium thiopental produced in North Carolina); Deborah W. Denno, *Getting to Death: Are Executions Constitutional?*, 82 Iowa L. Rev. 319, 354 & n.207 (1997) (explaining that the sole commercial suppliers of electric-chair equipment were in Massachusetts and Arkansas).

In 2009, the sole American manufacturer of sodium thiopental ceased production. *See Glossip*, 135 S. Ct. at 2733. Since then, several States have imported sodium thiopental from foreign suppliers. *Cook*, 733 F.3d at 4. In 2012, however, the U.S. District Court for the District of Columbia held that, although FDA has unreviewable discretion when enforcing the FDCA's domestic prohibitions, FDA's discretion is more limited with respect to the Act's importation provisions. The court issued a permanent injunction requiring FDA to block the importation of sodium thiopental on the grounds that it was unapproved and misbranded. *See Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff'd*, *Cook*, 733 F.3d 1. Neither the parties nor the district court, however, addressed the government's previous argument in *Heckler* that FDA lacks jurisdiction over articles intended for use in capital punishment. *See Beaty*, 853 F. Supp. 2d at 34. Following the *Beaty* injunction, FDA expressly stated in a letter ruling, apparently for the first time, that it had jurisdiction over a substance intended for that use, though, significantly, the State seeking the ruling had conceded the point. *See* Letter from Todd W. Cato, Director, Southwest Import District Office at 5 (Apr. 20, 2017).

As of December 31, 2016, there were over 2,750 inmates with state death sentences. Elizabeth Davis & Tracy L. Snell, Bureau of Justice Statistics, U.S. Dep't of Justice, *Capital Punishment, 2016*, at 3 tbl.1 (2018). And there are now approximately 62 civilian prisoners with federal death sentences. *See* Federal Bureau of Prisons, *Statistics: Sentences Imposed*, https://www.bop.gov/about/statistics/statistics_inmate_sentences.jsp (last updated Apr. 13, 2019). In response to difficulties in obtaining appropriate substances for lethal injection, some States are considering turning to different methods of execution, including the electric chair and nitrogen gas. Tom Barton, *SC Senators Resurrect Bill to Bring Back the Electric Chair, Add Firing Squad*, The State (Jan. 30, 2019), https://www.thestate.com/news/politics-government/article225312765.html; Denise Grady & Jan Hoffman, *States Turn to an Unproven Method of Execution: Nitrogen Gas*, N.Y. Times (May 7, 2018), https://www.nytimes.com/2018/05/07/health/death-penalty-nitrogen-executions.html.

II.

With this background in mind, we turn to whether FDA may regulate articles intended for use in capital punishment. The Supreme Court recognized some time ago that "Congress fully intended that the [FDCA]'s

coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow." *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969). Nevertheless, in *Brown & Williamson*, the Court recognized one limitation to such coverage in the context of reviewing FDA's authority to regulate tobacco products.

In *Brown & Williamson*, the Court considered whether FDA had properly determined that tobacco products as customarily marketed could be regulated as "drugs" or "devices" under the FDCA. FDA had conducted a rulemaking in which it concluded that the definitional phrase, "intended to affect the structure or any function of the body," is "broad in scope and encompass[es] a range of products wider than those ordinarily thought of as drugs or medical devices." Analysis Regarding the Food and Drug Administration's Jurisdiction over Nicotine-Containing Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453, 41,463 (Aug. 11, 1995); Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619, 44,658 (Aug. 28, 1996). FDA deemed nicotine to be regulable as a "drug" because it was "intended" to have "psychoactive, or mood-altering, effects on the brain" that foster addiction, stimulate and depress the nervous system, and suppress appetite, thus mirroring the effects of tranquilizers, stimulants, weight-loss drugs, and other articles long subject to FDA jurisdiction. 61 Fed. Reg. at 44,631–32.

The Supreme Court rejected FDA's conclusion, holding that the FDCA's jurisdictional provisions must be read in the context of the entire statute, and of later-enacted laws, to ensure "a symmetrical and coherent regulatory scheme." *Brown & Williamson*, 529 U.S. at 133. "Viewing the FDCA as a whole," the Court concluded that it would "contravene[] the clear intent of Congress" to treat tobacco products as subject to FDA regulation. *Id*. at 132, 133. Were tobacco products regulated as "drugs" or "devices," the FDCA would prohibit their sale, because they could not be "safe" or "effective" for their intended use. *Id*. at 134–37. Yet such "a ban would contradict Congress's clear intent as expressed in its more recent, tobacco-specific legislation," which reflected the "collective premise . . . that cigarettes and smokeless tobacco will continue to be sold in the United States." *Id*. at 137, 139, 143–56. Furthermore, Congress had enacted this tobacco-specific legislation "against the background of the FDA repeatedly and consistently asserting that it lacks jurisdiction under the FDCA to regulate tobacco products as customarily marketed." *Id*. at 155–

56. The Court concluded: "The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit." *Id*. at 143.[5]

Congress subsequently ratified the Court's conclusion in the Tobacco Control Act, 21 U.S.C. § 387 *et seq*., which confirmed that tobacco products as customarily marketed are not regulable as "drugs" or "devices" under the FDCA. *See id*. § 321(rr)(1)–(2). At the same time, Congress granted FDA the authority to impose other regulations on tobacco products. *See id*. § 387a(a) ("Tobacco products . . . shall be regulated . . . under this subchapter and shall not be subject to the [drug-and-device] provisions of subchapter V."); *Sottera, Inc. v. FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010).

Under *Brown & Williamson*, FDA lacks jurisdiction to regulate articles intended for a use not traditionally regulated by FDA, when those articles cannot be safe and effective for such intended use, and Congress has otherwise made clear its expectation that at least some of those articles shall remain lawful and available for that use. *See Sottera*, 627 F.3d at 896 (interpreting *Brown & Williamson*); *see also Massachusetts v. EPA*, 549 U.S. 497, 530–31 (2007) (explaining that *Brown & Williamson* rested on "the unlikel[ihood] that Congress meant to ban tobacco products" and "an unbroken series of congressional enactments that made sense only if adopted against the backdrop of the FDA's consistent and repeated statements" disclaiming jurisdiction (internal quotation marks omitted)); *Verizon v. FCC*, 740 F.3d 623, 638 (D.C. Cir. 2014) (similar).

III.

Applying *Brown & Williamson*, we conclude that the FDCA does not allow FDA to regulate an article intended for use in capital punishment in the United States. The FDCA's regulatory framework for "drugs" and

[5] The *Brown & Williamson* Court declined to give the agency deference under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc*., 467 U.S. 837 (1984), because "Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion." 529 U.S. at 160; *see also King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (similarly concluding that "[w]hether [tax] credits are available on Federal [Health Insurance] Exchanges is . . . a question of deep 'economic and political significance'" that Congress did not implicitly delegate to the agency) (quoting *Brown & Williamson*, 529 U.S. at 160)).

"devices" cannot sensibly be applied to such articles. If the FDCA applied to electric chairs, gallows, gas chambers, firearms used in firing squads, and substances used in lethal-injection protocols, the statute would effectively ban those articles. Yet the Constitution and laws of the United States presuppose the continued availability of capital punishment for the most heinous federal and state crimes. FDA did not expressly assert the authority to regulate articles intended for use in executions at any time before 2017, and we believe that such an assertion cannot be reconciled with the FDCA and other federal law.

A.

Articles used in capital punishment do literally "affect the structure or any function of the body" by causing all bodily functions to cease. 21 U.S.C. § 321(g)(1)(C), (h)(3). Hanging, gas asphyxiation, a firing squad, lethal injection, and electrocution are all intended to achieve the same effect: they cause death. When a prison official seeks to purchase an article essential to one of these methods of execution, the seller will often know that the item will be used in an execution and is thus "intended" to affect the structure or any function of the body. *Id*.; *see* 21 C.F.R. § 201.128 (a drug's "intended use" can "be shown by the circumstances surrounding the distribution of the article"); *id*. § 801.4 (same for devices); *cf*. *United States v*. *Kaminski*, 501 F.3d 655, 671 (6th Cir. 2007) (concluding that egg powders were "drugs" because defendants "distributed them to consumers for the express purpose of treating and/or preventing diseases" as evidenced by, among other things, "the methods of sale and distribution").

Nevertheless, *Brown & Williamson* prevents us from interpreting the FDCA in a manner that would depart from its "symmetrical and coherent regulatory scheme," 529 U.S. at 133, and interpreting the FDCA to authorize regulation of articles intended for use in executions would do exactly that. *See also Weyerhaeuser Co*. *v*. *U.S. Fish & Wildlife Serv*., 139 S. Ct. 361, 368 (2018) ("[S]tatutory language cannot be construed in a vacuum . . . so we must also consider [the term] in its statutory context." (internal quotation marks and citation omitted)). If such articles were regulated as "drugs" or "devices," the FDCA would effectively ban them and FDA could seek fines or prosecutions against those involved in their sale or distribution. The FDCA "generally requires the FDA to prevent the marketing of any drug or device where the potential for inflicting death or

physical injury is not offset by the possibility of therapeutic benefit." *Brown & Williamson*, 529 U.S. at 134 (internal quotation marks omitted). In the case of tobacco products, their short-term physiological effects were greatly outweighed by their demonstrated carcinogenic qualities. *Id*. at 134–35. Thus, if tobacco products had been regulated as "drugs" or "devices," the FDCA would have effectively rendered them unlawful. *Id*. at 135–37.

The same conclusion follows here, because the articles used in capital punishment are intended to cause death—for some articles that is their sole purpose. Under the FDCA, a "new drug" may not go to market unless FDA determines, based on "adequate and well-controlled investigations," that the substance is "safe" and "effective[]" for the "use . . . prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d)(1), (5); *see also* 21 C.F.R. § 314.50(d)(5). To approve a substance for use in a lethal-injection protocol, then, FDA would have to find that clinical-trial data established that the substance was "safe" for executions—that is, that the harm inflicted by the product would be "offset by the possibility of therapeutic benefit" to the inmate. *Brown & Williamson*, 529 U.S. at 134. It would not be sufficient to show that the substance is safer or more effective than other means of execution. *Brown & Williamson* dismissed such an interpretation of "safety" as involving a "qualitatively different inquiry" from that required by the FDCA. *Id*. at 140. Instead, FDA must find "that the *product itself* is safe as used by consumers." *Id*. But there is no way products intended to carry out capital punishment could ever satisfy that test, under which "a drug is unsafe if its potential for inflicting death . . . is not offset by the possibility of therapeutic benefit." *United States v. Rutherford*, 442 U.S. 544, 556 (1979).

The same would be true if electric chairs, gallows, or firing squads' firearms were regulated as "devices." Those articles would require premarket approval because they "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II). And FDA could approve them only if the applicant provided "reasonable assurance" that they were "safe" and "effective" for the intended use of carrying out capital punishment, *id*. § 360e(d)(1)(A), (2)(A)–(B), after "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," *id*. § 360c(a)(2)(C). Again, FDA

could not possibly approve "devices" that are intended to effectuate executions as "safe" and "effective."[6]

Nor would it matter whether an article intended for use in capital punishment was designed solely for that purpose or had other, FDA-approved uses.[7] Either way, whenever manufacturers or distributors intended that an article be used in capital punishment, the FDCA would prohibit distributing it for that use. For example, FDA has approved midazolam for use as a sedative and anesthetic in certain procedures. But if a manufacturer or distributor of midazolam sold it to prison officials specifically for use in capital punishment, the drug's "intended use" would be different from any approved use. *See* 21 C.F.R. § 201.128. A drug's labeling must bear adequate directions for use for all of its intended uses; otherwise it is misbranded. *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.128. Accordingly, the manufacturer or distributor would violate the FDCA's new drug prohibition where the product's labeling suggested its use in capital punishment. Drugs intended for use in lethal injection that were FDA-approved only for other uses would also be misbranded because their FDA-approved labeling would, by definition, lack adequate warnings against unsafe dosages or methods of administration for use in capital punishment. *See* 21 U.S.C. § 352(f)(2).[8] In sum, if articles intended for

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[6] Applications to market drugs and devices both require the submission of well-controlled clinical investigations. 21 U.S.C. §§ 355(d), 360c(a)(2), (3)(A)–(B); 21 C.F.R. § 860.7(c). Given that the articles at issue here are intended to cause death during lawful executions, it is difficult to envision how the articles could be studied in clinical investigations involving humans.

[7] The FDCA's practice-of-medicine exception does not extend to articles used in executions. That exception applies only when an article is "prescribe[d] or administer[ed]" to treat a "condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396 (devices); *see* James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 77–78 (1998) (discussing history behind section 396, which shows it was enacted to extend to devices the practice-of-medicine exception that already applied to drugs).

[8] The law-enforcement exception in 21 C.F.R. § 201.125 exempts a drug from the requirement in section 502(f)(1) of the FDCA that labeling include "adequate directions for use." 21 U.S.C. § 352(f)(1). That exception, however, does not extend to section 502(f)(2), which requires "adequate warnings . . . against unsafe dosage or methods or duration of administration." *Id.* § 352(f)(2). Thus, even if executions qualified as an excepted law-enforcement use, substances used in executions would be misbranded under subsection (f)(2).

use in capital punishment were regulated as "drugs" or "devices," then the FDCA would prohibit them altogether.

In the past, FDA has avoided such regulatory consequences by declining to regulate the domestic sale and distribution of articles intended for use in executions as a matter of enforcement discretion. But the D.C. Circuit recently upheld a district court order enjoining FDA from permitting the importation of foreign-manufactured sodium thiopental, on the grounds that it was misbranded and unapproved. *Cook*, 733 F.3d 1. And the question now is whether FDA's regulatory authority encompasses articles intended for use in lethal injection or other methods of capital punishment, not whether FDA may use its enforcement discretion to alleviate the regulatory consequences. FDA equally had discretion not to enforce the FDCA against domestic tobacco sales that, in FDA's view, would have violated the FDCA's prohibitions on misbranding or unapproved new drugs or devices. What mattered in *Brown & Williamson* was that the FDCA would have rendered the sale of tobacco products per se unlawful, not that FDA could have tempered that ban by selectively sparing particular manufacturers from civil and criminal penalties. *See, e.g.*, 529 U.S. at 136 ("[T]he Act admits no remedial discretion once it is evident that the device is misbranded."). The prospect that articles intended for use in capital punishment could be sold or distributed at FDA's sufferance does not alter the fact that the FDCA, by its terms, would effectively require a ban of such articles if they were regulated under the FDCA as "drugs" or "devices."

B.

Even if the FDCA could be interpreted to authorize regulation of articles intended for use in executions without requiring them to be banned, any attempt to do so would create serious tension with other provisions of the Act. We do not conclude that, in order for FDA to have jurisdiction over an article as a "drug" or "device," every drug- or device-related provision of the FDCA must apply neatly to the article's intended use. But the sheer number of FDCA provisions here that would make no sense as applied reinforces the conclusion that FDA lacks jurisdiction over articles intended for use in capital punishment. For example, with respect to articles intended for use in capital punishment, FDA could not assess "[t]he seriousness of the disease or condition that is to be treated with the drug" or "[t]he expected benefit of the drug with respect to such disease

or condition." 21 U.S.C. § 355-1(a)(1)(B)–(C). Execution drugs address no "condition" suffered by, and produce no "benefit" for, the end user; instead, they exclusively inflict harm upon that user. For the same reason, when reviewing a new drug application for an article intended for use in capital punishment, FDA could not provide for review of scientific disputes by a "panel[] of experts" that includes members with "expertise in *the particular disease or condition* for which the drug . . . is proposed to be indicated." *Id.* § 355(n)(1), (3)(D) (emphasis added); *see also id.* § 360bbb-1; 8 C.F.R. § 10.75(b)(2). In the context of an execution, there is no applicable "disease or condition."

Further, with respect to articles intended for use in capital punishment, "patient experience data"—which includes "information about patients' experiences with a disease or condition," such as "patient preferences with respect to treatment of such disease or condition"—would never be available. 21 U.S.C. § 360bbb-8c(b)(1), (c)(2). Other FDCA provisions treat death as a serious side effect that triggers mandatory reporting and FDA oversight. *See, e.g.*, *id.* § 355(k)(3)(C)(i)(II) (requiring drug manufacturers to "report[] . . . on all serious adverse drug experiences," including death); 21 C.F.R. § 314.80 (detailing exhaustive reporting requirements for each "adverse drug experience," including those resulting in death). These provisions cannot sensibly be read to allow an article's intended use to be the causing of death in an execution.

Other provisions presuppose that an approved device may not be intended to effectuate an execution. A manufacturer's application for FDA approval "shall include" a "description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure," 21 U.S.C. § 360e-1(a)(2)(A), which suggests that a device must be intended to *improve* a patient's circumstances. FDA must also submit any new device to a panel of experts with "adequate expertise . . . to assess . . . the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose." *Id.* § 360c(b)(1), (5)(B)(i)(I). But again, it would make no sense to apply those provisions to articles for use in executions, which are not intended to produce any benefit for the end user.

Congress has treated certain articles intended to cause death as falling outside FDA's jurisdiction. For instance, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") expressly gives the Environmental Protection Agency rather than FDA jurisdiction over "pesticides," which include "any substance . . . intended for preventing, destroying, repelling,

or mitigating any pest" but exclude "any article that is a 'new animal drug' within the meaning" of the FDCA. 7 U.S.C. § 136(u). FIFRA thus suggests that Congress generally views substances intended to harm or kill pests (such as mosquitos and rats, *see id*. § 136(t)) as outside FDA's jurisdiction.

Over the years, FDA has disclaimed jurisdiction over several other articles intended to kill or harm humans or animals. In 1969, for instance, FDA's Chief Counsel testified that even though "pistols and bullets are intended to affect the function or structure of the body in the same way" as mace, the agency "concluded that the products could not properly be classified as drugs under the definition" in the FDCA. *Public Sale of Protective Chemical Sprays: Hearings Before the Consumer Subcomm. of the S. Comm. on Commerce*, 91st Cong. 37 (1969) (statement of William Goodrich). FDA reiterated that position when asserting jurisdiction over tobacco products in 1996, explaining that it "has never construed the structure-function provision to include products such as guns, airbags, and chemical sprays," despite their intended effects on the structure or function of the body. 61 Fed. Reg. at 44,684. That same rationale extends to articles intended for use in executions.[9]

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[9] Since 1977, FDA has asserted jurisdiction over articles intended for animal euthanasia. FDA first asserted jurisdiction over Beuthanasia-D. *See United States v. Articles of Drug Beuthanasia-D Regular*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,265 (D. Neb. Aug. 1, 1979). A district court agreed that FDA had jurisdiction, both because Beuthanasia-D's two active ingredients were listed in the United States Pharmacopoeia (a different component of the FDCA's definition of "drug"), *id*. ¶ 39,129 (citing 21 U.S.C. § 321(g)(1)(A) (1972)), and because "euthanasia—the cessation of all bodily functions— . . . constitute[s] an effect on the function, if not the structure, of the animal's body," *id*. ¶ 39,130 (citing 21 U.S.C. § 321(g)(1)(C) (1972)). In 1980, FDA issued a two-paragraph guidance statement, opining that "products intended for animal euthanasia . . . conform to the definition of a drug" under the FDCA "since they are clearly intended to affect the function of the body by inducing death." FDA, Compliance Policy Guide § 650.100 (Oct. 1, 1980). FDA's guidance in this area predates *Brown & Williamson*, and no court has revisited the matter. Although it may be difficult to view animal-euthanasia articles as "safe" for their intended use (at least where such articles are used on healthy but unwanted animals), FDA has regulated such articles since 1977; it has approved five applications for these articles; its regulation does not raise constitutional concerns; and we are aware of no legislation that suggests FDA's assertion of jurisdiction over articles intended for animal euthanasia is contrary to the intent of Congress. Additionally, animal euthanasia has long been an accepted part of veterinary practice, whereas capital punishment has not been a part of medical practice. Therefore, whether or not animal euthanasia may be distinguishable from executions, we do not view FDA's practice of regulating the former

C.

The FDCA cannot be read as authorizing FDA to effectively ban capital punishment, because that reading would contravene or render moot a host of federal statutes that presuppose the lawfulness of capital punishment. In *Brown & Williamson*, the Court held that FDA was not authorized to prohibit tobacco products because Congress had repeatedly confirmed that such products would remain available. That reasoning applies equally well to articles intended for use in capital punishment. The Constitution and numerous federal statutes presuppose that capital punishment will remain available and that the federal government will defer to States over methods of execution. Interpreting the FDCA to bar the importation, sale, and distribution of articles intended for use in executions would conflict with that settled understanding. By contrast, the conclusion that articles intended for use in executions cannot be regulated under the FDCA would be consistent with how FDA has traditionally exercised its authority; and it would avoid the serious federalism concerns that would arise from a contrary interpretation.

1.

As the Supreme Court recently observed, the Constitution expressly "allows capital punishment." *Bucklew v. Precythe*, 139 S. Ct. 1112, 1122 (2019). Indeed, "the Fifth Amendment, added to the Constitution at the same time as the Eighth, expressly contemplates that a defendant may be tried for a 'capital' crime and 'deprived of life' as a penalty, so long as proper procedures are followed." *Id*. Federal law, accordingly, has authorized the imposition of the death penalty since 1790, when the First Congress mandated that several federal crimes, including treason and murder on federal land, be punished by death. Act of Apr. 30, 1790, ch. 9, §§ 1, 3, 33, 1 Stat. 112, 112, 113, 119. By 1938, federal statutes authorized the death penalty for dozens of offenses. And, in the decades since the FDCA's enactment, Congress has acted numerous times to make additional federal crimes punishable by death.[10] In providing that the

as sufficient to overcome the force of the arguments against FDA's authority to regulate the latter.

[10] *See, e.g.*, Act of June 8, 1940, ch. 286, 54 Stat. 255, 255–56 (authorizing capital punishment if anyone is killed by the willful derailment of any train in interstate commerce); Uniform Code of Military Justice, Act of May 5, 1950, ch. 169, 64 Stat. 107,

death penalty is an available punishment for dozens of federal crimes, Congress has presupposed there would be a lawful means for carrying out such a sentence.

From 1790 until 1937, federal law prescribed hanging as the method of execution. Act of Apr. 30, 1790, § 33, 1 Stat. at 119; *Andres v. United States*, 333 U.S. 740, 745 n.6 (1948). Congress then mandated that each federal execution be carried out in "the manner prescribed by the laws of the State within which the sentence is imposed," or, if that State did not have the death penalty, in accordance with the laws of another State designated by the sentencing court. Act of June 19, 1937, ch. 367, 50 Stat. 304, 304 (repealed 1984). At the time, nearly 30 States were using cyanide gas or the electric chair, but the States adopted at least six different methods of execution between then and the early 1980s. *See* Deborah A. Denno, *Getting to Death: Are Executions Constitutional?*, 82 Iowa L. Rev. 319, 439–64 (1997). After that provision was repealed in 1984, federal regulations required the government to propose to the sentencing court that any death sentence be carried out by lethal injection. 28 C.F.R. § 26.2(a)(2). Unless the court ordered otherwise, they required the Director of the Federal Bureau of Prisons to "determine[]" which "substance or substances" to use. *Id*. § 26.3(a)(4).

Today, capital sentences imposed under the Federal Death Penalty Act of 1994 are again required to be implemented "in the manner prescribed by" either (i) "the law of the State in which the sentence is imposed," or (ii) if that State does not have the death penalty, the law of another State designated by the sentencing court. 18 U.S.C. § 3596(a). The Army's executions are by "intravenous administration of a lethal substance, or substances, in a quantity sufficient to cause death." Army Regulation 190-55, U.S. Army Corrections System: Procedures for Military Executions § 3-1, -2 (Jan. 17, 2006).

135–40 (articles 85, 90, 94, 99, 100, 101, 102, 104, 106, 110, 113, 118, and 120, establishing 13 military offenses punishable by death); Organized Crime Control Act of 1970, Pub. L. No. 91-452, sec. 1102, § 844(d), 84 Stat. 922, 957 (authorizing capital punishment if death results from the use of explosives to maliciously destroy government property); Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, § 7001(a), 102 Stat. 4181, 4387–88 (codified at 21 U.S.C. § 848(e)) (authorizing capital punishment for intentional killing while engaging in criminal enterprises or drug felonies); Federal Death Penalty Act of 1994, Pub. L. No. 103-322, §§ 60001–60026, 108 Stat. 1796, 1959–82 (codifying procedures for federal death sentences and authorizing capital punishment for 60 offenses under 13 existing and 28 new federal statutes).

This extensive backdrop of legislative and regulatory action precludes any suggestion that the FDCA prohibits the importation, sale, or distribution of articles intended for use in executions; to the contrary, these statutory and regulatory schemes unambiguously assume the continued availability of such articles. Before and after the FDCA's enactment, Congress extended the federal death penalty and required the federal government to adopt States' preferences as to methods of execution. Such provisions would be nonsensical if the FDCA had rendered it a crime to distribute in interstate commerce, including through importation (*see* 21 U.S.C. § 321(b)), the very articles that States and the federal government need to effectuate capital sentences. By expressly recognizing States' discretion to select methods of execution (subject to constitutional limits), Congress precluded any role for FDA in supplanting States' judgments about those methods.

2.

In addition, as in *Brown & Williamson*, "[t]he consistency of the FDA's prior position" concerning the absence of regulatory jurisdiction over methods of execution, coupled with a corresponding history of nonenforcement, "provides important context" for interpreting federal death-penalty legislation postdating the FDCA. 529 U.S. at 157. Just as FDA "asserted authority to regulate tobacco products as customarily marketed" only late in its history, *id*. at 146, FDA does not appear to have asserted jurisdiction to regulate articles intended for use in executions before 2017.

Between 1981 and 1985, FDA directly addressed its jurisdiction in the proceedings associated with *Heckler*, 470 U.S. 821. The challenge in *Heckler* involved state lethal-injection protocols, which required the unapproved use of drugs that were FDA-approved for other purposes. Although the *Heckler* Court found it "implausible . . . that the FDA is required to exercise its enforcement power to ensure that States only use drugs that are 'safe and effective' for human execution," *id*. at 827, the Court ultimately declined to resolve the "thorny question of the FDA's jurisdiction" in that circumstance, *id*. at 828. Instead, the Court held that FDA's decision not to enforce the FDCA was unreviewable. *Id*. at 837–38. Even so, we find instructive FDA's own statements about its jurisdiction in the Supreme Court and in the underlying administrative proceeding.

In 1981, FDA rejected a petition from death-row inmates asking FDA to adopt a procedure for the seizure and condemnation of drugs destined or held for use in executions. *See* Letter for David E. Kendall, from Arthur Hull Hayes, Commissioner of Food and Drugs at 1 (July 7, 1981) ("*Heckler* Petition Response"). The inmates contended that the States' acquisition of FDA-approved drugs for capital punishment constituted misbranding because the drugs lacked adequate directions or warnings for that use. *Id*. at 1–2. FDA denied the petition in the first instance because "the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction." *Id*. at 2. FDA concluded that the States' off-label use of FDA-approved drugs in lethal-injection protocols was sufficiently analogous to the practice of medicine, including physicians' lawful off-label use of FDA-approved drugs, to fall outside the FDCA's ambit. *Id*. at 3–4. But FDA also emphasized that its lack of jurisdiction flowed from "a consideration of the proper role of the Federal Government with respect to the conduct of State criminal justice systems." *Id*. at 2. FDA further recognized that, "[b]ecause . . . the [FDCA] does not provide us with authority to declare unlawful the use by State governments of drugs for lethal injection," concerns about the safety of lethal-injection protocols would "more appropriately [be] addressed to the State legislatures." *Id*. at 4.[11]

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[11] FDA did contend that, "[u]nder the Supremacy Clause," "a State could not legitimize the unlawful shipment of an unapproved new drug in interstate commerce or prevent its misbranding after shipment in interstate commerce by authorizing its use," including for purposes of execution. *Heckler* Petition Response at 3. But that reflected a general observation that state law cannot trump the FDCA's provisions to the extent they apply to a given drug or device, or effectively immunize prior conduct that violated the FDCA by approving a product's use at a later time. The government's opening brief in the Supreme Court also represented in a footnote that "[t]his case concerns the FDA's authority to regulate the states' *use* of drugs, lawfully in interstate commerce, for the unapproved purpose of causing death, and not the *marketing* of drugs for an unapproved use." *Heckler* Pet'r Br. at 45–46 n.34; *accord* Reply Br. at 8, *Heckler v. Chaney*, 470 U.S. 821 (1985) (No. 83-1878) ("*Heckler* Reply Br.") ("FDA lacks jurisdiction over the use of approved drugs by state authorities for capital punishment purposes."). The brief asserted that an FDCA violation would occur "if a drug were marketed for the purpose of causing death without being approved for that use," but it noted that no one was alleged to have "directly or indirectly promote[d] the use of the drugs at issue" for executions. *Heckler* Pet'r Br. at 45–46 n.34. Those statements did not reserve FDA jurisdiction over unapproved articles used in executions because the government's briefs categorically disclaimed FDA jurisdiction over any method of execution. *See infra* notes 12–13 and accompanying text.

In the resulting litigation, the D.C. Circuit divided over whether FDA had jurisdiction over drugs intended for use in executions. *See Chaney v. Heckler*, 718 F.2d 1174 (D.C. Cir. 1983), *rev'd*, 470 U.S. 821 (1985). The majority rejected FDA's conclusions that administering capital punishment fell within the FDCA's "practice of medicine" exception or, in the alternative, that actions taken by prison officials did not qualify as misbranding under the Act. *See id*. at 1179, 1181. Then-Judge Scalia, in dissent, recognized the incongruity in treating "a law designed to protect consumers against drugs that are unsafe or ineffective for their represented use" as "mandating federal supervision of the manner of state executions." *Id*. at 1192 (Scalia, J., dissenting). He would have held that FDA lacked jurisdiction because the drugs were not "held for sale" in interstate commerce. *Id*. at 1199–1200. Because FDA did not press the point, neither opinion addressed whether "the unapproved use of drugs for lethal injection is outside the general jurisdictional provisions of the Act"—that is, whether drugs intended for use in lethal injection are subject to regulation under the FDCA. *Id*. at 1179.

In the Supreme Court, the government contended that FDA categorically lacked jurisdiction over articles used in capital punishment, and that FDA had denied the inmates' petition because it had concluded "that it lacked authority under the FDCA to regulate the states' use of lethal injections for capital punishment." *Heckler* Pet'r Br. at 13; *see id*. at 4 (similar). The government repeatedly asserted that "Congress did not intend the FDA to regulate capital punishment," *id*. at 45, and emphasized that the assessment of lethal injections would be "far removed from [FDA's] mission of protecting the consuming public from unsafe and improperly labeled drugs," *id*. at 10; *see id*. at 45 (similar).[12] The government concluded that FDA jurisdiction over the unapproved use of FDA-

[12] *See also Heckler* Reply Br. at 8 ("[T]here is not a scintilla of evidence that Congress intended for the FDCA to regulate capital punishment."); *id*. at 11 ("The FDA has no experience or particular expertise in making a comparative assessment of different methods of capital punishment, nor does it have a congressional mandate to venture into this field."); *Heckler* Pet'r Br. at 13 ("[T]here is not a hint in the legislative history that Congress had any intention to regulate the methods used by states in carrying out lawful death sentences."); *id*. at 44 ("Neither the court of appeals nor respondents have produced a shred of evidence that Congress wanted the FDA to regulate the methods of capital punishment used by the states."); *id*. at 46 ("[T]here is absolutely no evidence that Congress intended to regulate the use of drugs or devices, pursuant to a lawful court order, for the purpose of capital punishment.").

approved drugs in executions "would lead to the absurd result of requiring the FDA to regulate such traditional means of capital punishment as the gas chamber, electric chair, and gallows." *Heckler* Reply Br. at 8.[13]

Although *Heckler* did not resolve the question of the agency's jurisdiction, *see* 470 U.S. at 837–38, for more than three decades thereafter, FDA continued to avoid regulating drugs intended for use in capital punishment. In 2011, FDA explained that "[r]eviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA's explicit public health role," and that as a matter of "longstanding policy," FDA would "continue to defer to law enforcement on all matters involving lethal injection." E-mail for Nathan Koppel, from Shelly Burgess, FDA Public Affairs Specialist (Jan. 4, 2011), Doc. 13-3, *Beaty v. FDA*, No. 11-cv-289 (D.D.C. Apr. 20, 2011).

In 2012, a group of death-row inmates sued FDA, alleging that it had violated the FDCA by allowing shipments of a misbranded and unapproved new drug from an unregistered foreign establishment to enter the United States. The U.S. District Court for the District of Columbia held that, unlike in the domestic context where FDA has unreviewable discretion when enforcing violations, the statutory scheme for imports under 21 U.S.C. § 381(a) is different, and the court enjoined FDA from permitting entry of foreign-manufactured sodium thiopental, on the grounds that it was unapproved and misbranded. *Beaty*, 853 F. Supp. 2d at 37–41. The D.C. Circuit affirmed the injunction. *Beaty* and *Cook*, however, turned solely on whether FDA could exercise enforcement discretion over the imported sodium thiopental. Although the district court assumed that "thiopental is both 'misbranded' and an unapproved 'new drug' under the FDCA," *id*. at 34 n.2, neither the district court, nor the D.C. Circuit, addressed the broader question of FDA's jurisdiction.

Following the *Beaty* injunction, in 2015, FDA blocked Texas's attempt to import sodium thiopental for use in capital punishment. FDA's Southwest Import District Office detained and then refused the shipment on the

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[13] *See also Heckler* Pet'r Br. at 13–14 (if FDA had jurisdiction over FDA-approved lethal-injection drugs, then the FDCA would also "encompass many of the paraphernalia traditionally used for executions, such as the gallows and the electric chair," and would presumably oblige FDA "to regulate the use of these devices as well"); *id*. at 44 ("the state and federal governments regularly used" the electric chair and gallows in 1938, and "there is no indication that any member of Congress even considered the possibility that enactment of the FDCA might affect these practices").

grounds that the drug was misbranded and unapproved. *See* Letter from Todd W. Cato, Director, Southwest Import District Office at 1–2 (Apr. 20, 2017). FDA's 2017 notice of final action appears to be the first instance in which FDA expressly asserted jurisdiction over a substance intended for use in capital punishment. Even then, Texas conceded that sodium thiopental "is a drug within the meaning of the [FDCA]," *id*. at 5, and FDA's decision was based upon the premise that "FDA is bound by the terms of the order issued by the District Court" in *Beaty*, *id*. at 2; *see also id*. at 6–7, 23, 24.

An agency may, of course, change its interpretation of an ambiguous statute when the new interpretation falls within the permissible scope of the agency's discretion and the agency shows "that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009); *see Brown & Williamson*, 529 U.S. at 156–57. But for nearly 80 years after the FDCA's enactment, FDA had never asserted jurisdiction over articles intended for use in capital punishment, notwithstanding thousands of cases that would have implicated FDA's enforcement discretion under such a theory. During that period, States carried out approximately 3,700 executions, and the federal government carried out approximately 192 civilian or military executions, employing a range of methods (hanging, the electric chair, firing squads, gas chambers, and lethal injections).[14] FDA did not regulate the method of execution in any of those instances or assert the authority to do so.

3.

Even if there were genuine ambiguity about whether FDA has jurisdiction over articles intended for use in capital punishment, serious constitutional concerns would arise if FDA could regulate and take enforcement action against (including seizing and destroying) such articles. *See Jennings v. Rodriguez*, 138 S. Ct. 830, 842 (2018) ("When a serious doubt is raised about the constitutionality of an Act of Congress, it is a cardinal principle that this Court will first ascertain whether a construction of the

[14] *See Glossip*, 135 S. Ct. at 2732; Bureau of Justice Statistics, U.S. Dep't of Justice, *Publications & Products: Executions*, https://www.bjs.gov/index.cfm?ty=pbtp&tid=182&iid=1 (last visited Apr. 29, 2019); M. Watt Espy & John Ortiz Smykla, *Executions in the United States, 1608-2002: The ESPY File*, Inter-university Consortium for Political and Social Research (July 20, 2016), https://www.icpsr.umich.edu/icpsrweb/NACJD/studies/8451.

statute is fairly possible by which the question may be avoided." (internal quotation marks omitted)). As the Supreme Court recently explained, "because it is settled that capital punishment is constitutional, [i]t necessarily follows that there must be a [constitutional] means of carrying it out." *Glossip*, 135 S. Ct. at 2732–33 (internal quotation marks omitted); *see Bucklew*, 139 S. Ct. at 1122–23 (similar). It would present a serious intrusion on state sovereignty if Congress sought, under the guise of drug-safety regulation, to bar States from effectuating otherwise-lawful death sentences.

The Supreme Court requires an unambiguous statement of congressional intent before it will construe a federal statute as effecting a significant intrusion into an area of traditional state responsibility. Courts must "be certain of Congress' intent before finding that federal law overrides the usual constitutional balance of federal and state powers." *Bond v. United States*, 572 U.S. 844, 858 (2014) (internal quotation marks omitted). When States choose to impose and effectuate death sentences, they are engaged in "the punishment of local criminal activity," which is the "clearest example of traditional state authority." *Id.*[15]

So long as a State employs a method of execution that comports with the Fourteenth Amendment's incorporation of the Eighth Amendment's Cruel and Unusual Punishments Clause, "the Constitution affords a 'measure of deference to a State's choice of execution procedures.'" *Bucklew*, 139 S. Ct. at 1125 (quoting *Baze*, 553 U.S. at 51 n.2). Thus, *In re Kemmler*, 136 U.S. 436 (1890), held that the New York statute requiring execution by electrocution was "within the legitimate sphere of the legislative power of the State." *Id.* at 449. And the plurality opinion in *Baze v. Rees*, 553 U.S. 35 (2008), explained that "[o]ur society has . . .

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[15] *See also Danforth v. Minnesota*, 552 U.S. 264, 280 (2008) (referring to "[t]he fundamental interest in federalism that allows individual States to define crimes, punishments, rules of evidence, and rules of criminal and civil procedure in a variety of different ways—so long as they do not violate the Federal Constitution"); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) ("A basic principle of federalism is that . . . each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction."); *Ewing v. California*, 538 U.S. 11, 24 (2003) (plurality opinion) ("Though three strikes laws may be relatively new, our tradition of deferring to state legislatures in making and implementing such important policy decisions is longstanding."); *Patterson v. New York*, 432 U.S. 197, 201 (1977) ("[W]e should not lightly construe the Constitution so as to intrude upon the administration of justice by the individual States.").

steadily moved to more humane methods of carrying out capital punishment" because state legislatures have taken "the steps they deem appropriate, in light of new developments, to ensure humane capital punishment." *Id*. at 62 (opinion of Roberts, C.J.); *accord Glossip*, 135 S. Ct. at 2731–32 (similar). The Court has never endorsed an Eighth Amendment standard that would "transform [federal] courts into boards of inquiry charged with determining 'best practices' for executions," because that "would substantially intrude on the role of state legislatures in implementing their execution procedures." *Baze*, 553 U.S. at 51 (opinion of Roberts, C.J.).

The FDCA does not reflect any clear statement of congressional intent to regulate the States' administration of capital punishment. Had Congress sought to enable FDA to prohibit articles that States have chosen to use for executions, it would have said so explicitly. But Congress did no such thing. The FDCA's definitions of "drug" and "device" are broad, but breadth alone fails to manifest the intent needed to alter federal-state relations so dramatically with respect to capital punishment. *See, e.g.*, *Bond*, 572 U.S. at 860 ("insist[ing] on a clear indication that Congress meant to reach purely local crimes [in a statute implementing a chemical-weapons treaty] before interpreting the statute's expansive language in a way that intrudes on [States'] police power"). This principle of federalism provides further support for the conclusion that the FDCA should not be read to regulate—and therefore, effectively prohibit—the States' administration of capital punishment.

D.

We emphasize the narrowness of our conclusion that articles intended for use in capital punishment may not be regulated under the FDCA. We are not concluding that the FDCA covers only "drugs" or "devices" that have a medical or therapeutic purpose. For example, FDA has consistently regulated other products that affect the structure or function of the human body for an aesthetic, rather than medical or therapeutic, purpose (e.g., implants to augment breasts, dermal fillers to correct wrinkles, and silicone injections to augment buttocks and breasts). Likewise, FDA has long regulated drugs with non-therapeutic or recreational uses, including narcotics, street drugs, and their alternatives. *See, e.g.*, FDA, *Guidance for Industry: Street Drug Alternatives* (Mar. 2000), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/

ucm070343.pdf. Unlike with tobacco products or articles intended for use in capital punishment, however, federal statutes evince no "collective premise" that drugs intended to be used in achieving a recreational high "will continue to be sold in the United States." *Brown & Williamson*, 529 U.S. at 139. To the contrary, the manufacture and distribution of recreational drugs is already highly restricted by other federal statutes, such as the Controlled Substances Act. *See* 21 U.S.C. § 812.

Nor do we address whether FDA has jurisdiction over drugs intended for use in physician-assisted suicide. In marked contrast with capital punishment and tobacco products, at the time of the FDCA's enactment, there was not—so far as we are aware—any history of federal or state laws authorizing human euthanasia. As with recreational drugs, there is no congressional determination that human-euthanasia drugs remain lawfully on the market, nor has FDA historically disclaimed jurisdiction over them. *Cf. Brown & Williamson*, 529 U.S. at 137–53. Accordingly, human-euthanasia drugs lack the historical backdrop that weighs heavily against FDA jurisdiction over capital punishment.

We further note that a contrary conclusion regarding articles intended for use in capital punishment could sweep well beyond execution-related articles. If FDA had jurisdiction over such articles simply because they are "intended to affect the structure or any function of the body," 21 U.S.C. § 321(g)(1)(C), (h)(3), such reasoning would likely mean that FDA also had jurisdiction in a host of other areas that have long been considered well beyond its purview. Any type of firearm, when used for hunting or by the military or law enforcement, is intended to affect the structure or function of the body by killing or disabling a person or animal. But FDA has never sought to regulate firearms when they are intended to be used for hunting, police operations, or military purposes, and such an implausible interpretation of the FDCA would raise serious constitutional questions of its own.

Finally, there is nothing unusual about our conclusion that articles intended for use in capital punishment fall outside FDA's jurisdiction, even though the same articles could be subject to regulation when intended for other uses. For example, as noted above, FDA has classified articles such as hot tubs, saunas, and treadmills as devices for some purposes, but not for others. *See supra* pp. 3–4. Therefore, finding that substances fall outside FDA's jurisdiction when they are intended for use in capital punishment does not bear upon FDA's potential jurisdiction over other intended uses of the same substances.

IV.

We conclude that articles intended for use in capital punishment by a State or the federal government cannot be regulated as "drugs" or "devices" under the FDCA. FDA accordingly lacks jurisdiction to regulate such articles for that intended use.

STEVEN A. ENGEL
Assistant Attorney General
Office of Legal Counsel

ADDENDUM TO BOP EXECUTION PROTOCOL
FEDERAL DEATH SENTENCE IMPLEMENTATION PROCEDURES
EFFECTIVE TBA

A. Federal death sentences are implemented by an intravenous injection of a lethal substance or substances in a quantity sufficient to cause death, such substance or substances to be determined by the Director, Federal Bureau of Prisons (BOP) and to be administered by qualified personnel selected by the Warden and acting at the direction of the United States Marshal. 28 CFR 26.3. The procedures utilized by the BOP to implement federal death sentences shall be as follows unless modified at the discretion of the Director or his/her designee, as necessary to (1) comply with specific judicial orders; (2) based on the recommendation of on-site medical personnel utilizing their clinical judgment; or (3) as may be required by other circumstances.

B. The identities of personnel considered for and/or selected to perform death sentence related functions, any documentation establishing their qualifications and the identities of personnel participating in federal judicial executions or training for such judicial executions shall be protected from disclosure to the fullest extent permitted by law.

C. The lethal substance to be utilized in federal lethal injections shall be propofol.

D. Not less than fourteen (14) days prior to a scheduled execution, the Director or designee, in conjunction with the United States Marshal Service, shall make a final selection of qualified personnel to serve as the executioner(s) and their alternates. See BOP Execution Protocol, Chap. 1, §§ III (F) and IV (B) & (E). Qualified personnel includes currently licensed physicians, nurses, EMTs, Paramedics, Phlebotomists, other medically trained personnel, including those trained in the United States Military having at least one year professional experience and other personnel with necessary training and experience in a specific execution related function. Non-medically licensed or certified qualified personnel shall participate in a minimum of ten (10) execution rehearsals a year and shall have participated in at least two (2) execution rehearsals prior to participating in an actual execution. Any documentation establishing the qualifications, including training, of such personnel shall be maintained by the Director or designee.

E. The Director or designee shall appoint a senior level Bureau employee to assist the United States Marshal in implementing the federal death sentence. The Director or designee shall appoint an additional senior level Bureau employee to supervise the activities of personnel preparing and administering the lethal substances.

ADDENDUM TO BOP EXECUTION PROTOCOL
FEDERAL DEATH SENTENCE IMPLEMENTATION PROCEDURES
EFFECTIVE TBA

F. The lethal substances shall be prepared by qualified personnel in the following manner unless otherwise directed by the Director, or designee, on the recommendation of medical personnel. The lethal substances shall be placed into three sets of numbered and labeled syringes. One of the sets of syringes is used in the implementation of the death sentence and two sets are available as a backup.

G. Approximately thirty (30) minutes prior to the scheduled implementation of the death sentence, the condemned individual will be escorted into the execution room. The condemned individual will be restrained to the execution table. The leads of a cardiac monitor will be attached by qualified personnel. A suitable venous access line or lines will be inserted and inspected by qualified personnel and a slow rate flow of normal saline solution begun.

H. Lethal substances shall be administered intravenously. The Director or designee shall determine the method of venous access (1) based on the training and experience of personnel establishing the intravenous access; (2) to comply with specific orders of federal courts; or (3) based upon a recommendation from qualified personnel.

A set of syringes will consist of:

Syringe #1 contains 500 milligrams of propofol,
Syringe #2 contains 500 milligrams of propofol,
Syringe #3 contains 500 milligrams of propofol,
Syringe #4 contains 500 milligrams of propofol and
Syringe #5 contains 60 mL of saline flush.

Each syringe will be administered in the order set forth above when directed by supervisory personnel.

If peripheral venous access is utilized, two separate lines shall be inserted in separate locations and determined to be patent by qualified personnel. A flow of saline shall be started in each line and administered at a slow rate to keep the line open. One line will be used to administer the lethal substances and the second will be reserved in the event of the failure of the first line. Any failure of a venous access line shall be immediately reported to the Director or designee.

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B. The identities of personnel considered for and/or selected to perform death sentence related functions, any documentation establishing their qualifications and the identities of personnel participating in federal judicial executions or training for such judicial executions shall be protected from disclosure to the fullest extent permitted by law.

C. The lethal substances to be utilized in federal lethal injections shall be midazolam, sufentanil citrate and potassium chloride.

D. Not less than fourteen (14) days prior to a scheduled execution, the Director or designee, in conjunction with the United States Marshal Service, shall make a final selection of qualified personnel to serve as the executioner(s) and their alternates. See BOP Execution Protocol, Chap. 1, §§ III (F) and IV (B) & (E). Qualified personnel includes currently licensed physicians, nurses, EMTs, Paramedics, Phlebotomists, other medically trained personnel, including those trained in the United States Military having at least one year professional experience and other personnel with necessary training and experience in a specific execution related function. Non-medically licensed or certified qualified personnel shall participate in a minimum of ten (10) execution rehearsals a year and shall have participated in at least two (2) execution rehearsals prior to participating in an actual execution. Any documentation establishing the qualifications, including training, of such personnel shall be maintained by the Director or designee.

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H. Lethal substances shall be administered intravenously. The Director or designee shall determine the method of venous access (1) based on the training and experience of personnel establishing the intravenous access; (2) to comply with specific orders of federal courts; or (3) based upon a recommendation from qualified personnel.

A set of syringes will consist of:

Syringe #1 contains 250 milligrams of midazolam,
Syringe #2 contains 250 milligrams of midazolam,
Syringe #3 contains 60 mL of saline flush,
Syringe #4 contains 2500 micrograms of sufentanil citrate,
Syringe #5 contains 60 mL of saline flush,
Syringe #6 contains 120 mEq of potassium chloride,
Syringe #7 contains 120 mEq of potassium chloride and
Syringe #8 contains 60 mL of saline flush.

Each syringe will be administered in the order set forth above when directed by supervisory personnel.

If peripheral venous access is utilized, two separate lines shall be inserted in separate locations and determined to be patent by qualified personnel. A flow of saline shall be started in each line and administered at a slow rate to keep the line open. One line will be used to administer the lethal substances and the second will be reserved in the event of the failure of the first line. Any failure of a venous access line shall be immediately reported to the Director or designee.

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C. The lethal substances to be utilized in federal lethal injections shall be Midazolam and Hydromorphone.

D. Not less than fourteen (14) days prior to a scheduled execution, the Director or designee, in conjunction with the United States Marshal Service, shall make a final selection of qualified personnel to serve as the executioner(s) and their alternates. See BOP Execution Protocol, Chap. 1 §§ III (F) and IV (B) & (E). Qualified personnel includes currently licensed physicians, nurses, EMTs, Paramedics, Phlebotomists, other medically trained personnel, including those trained in the United States Military having at least one year professional experience and other personnel with necessary training and experience in a specific execution related function. Non medically licensed or certified qualified personnel shall participate in a minimum of ten (10) execution rehearsals a year and shall have participated in at least two (2) execution rehearsals prior to participating in an actual execution. Any documentation establishing the qualifications, including training, of such personnel shall be maintained by the Director or designee.

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[redacted]

Certified Reference Material CRM

[redacted]

CERTIFIED WEIGHT REPORT

Part Number: [redacted]
Lot Number:
Description: Pentobarbital

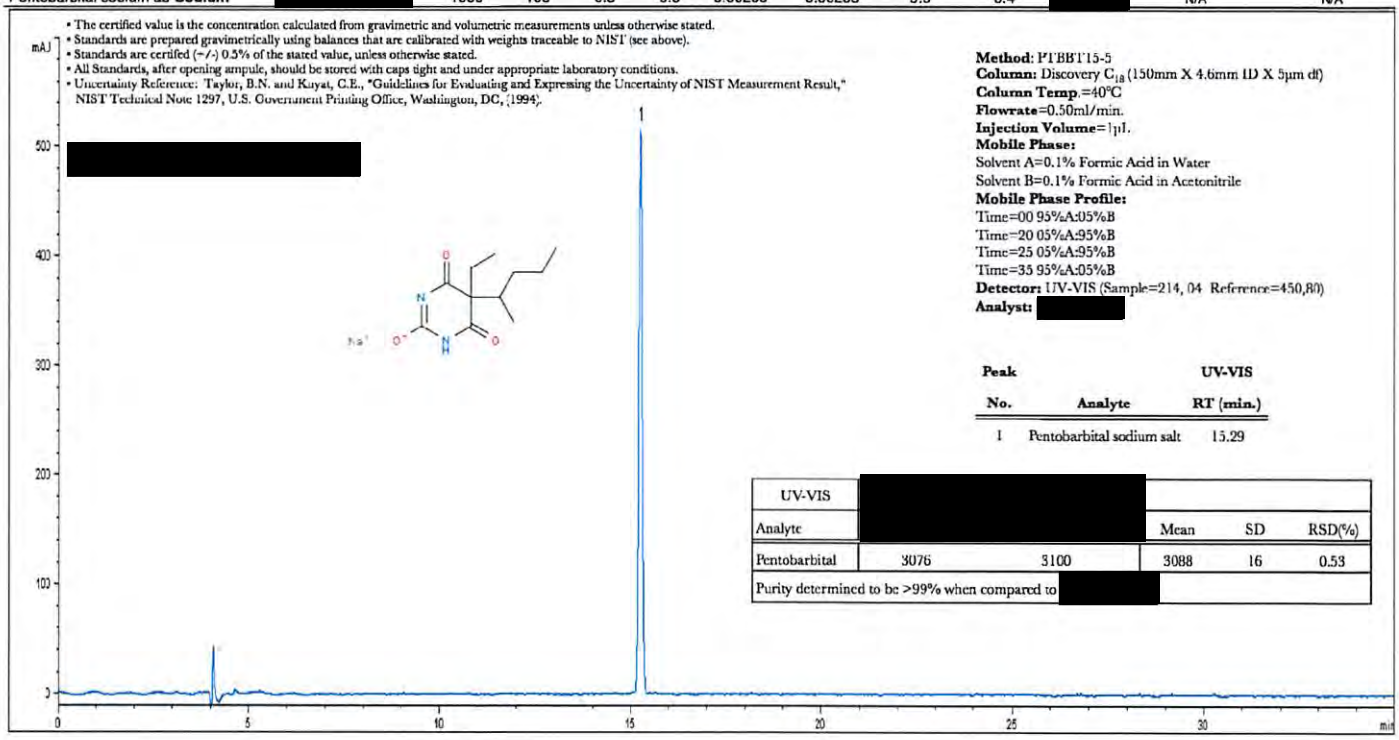
Expiration Date: 101923
Recommended Storage: Freezer (0 °C)
Nominal Concentration (µg/mL): 1000
NIST Test ID#: [redacted] [redacted] Balance Uncertainty
Weight(s) shown below were combined and diluted to (mL): 25.0 0.001 Flask Uncertainty

Solvent: Methanol **Lot#** [redacted]

[redacted]
Formulated By: [redacted] DATE
[redacted]
Reviewed By: [redacted] DATE

Compound	RM#	Lot Number	Nominal Conc (µg/mL)	Purity (%)	Uncertainty Purity (%)	Assay (%)	Target Weight (g)	Actual Weight (g)	Actual Conc(µg/mL)	Expanded Uncertainty (+/-) (µg/mL)	SDS Information (Solvent Safety Info. On Attached pg.) CAS#	OSHA PEL (TWA)	LD50
1. Pentobarbital sodium salt	[redacted]		1000	100	0.5	90.7	0.02755	0.02756	1000.4	10.6	[redacted]	N/A	N/A
2. Pentobarbital sodium as **Sodium**			1000	100	0.5	9.3	0.00255	0.00255	9.5	0.4		N/A	N/A

- The certified value is the concentration calculated from gravimetric and volumetric measurements unless otherwise stated.
- Standards are prepared gravimetrically using balances that are calibrated with weights traceable to NIST (see above).
- Standards are certified (+/-) 0.5% of the stated value, unless otherwise stated.
- All Standards, after opening ampule, should be stored with caps tight and under appropriate laboratory conditions.
- Uncertainty Reference: Taylor, B.N. and Kuyat, C.E., "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Result," NIST Technical Note 1297, U.S. Government Printing Office, Washington, DC, (1994).



Method: PTBBT15-5
Column: Discovery C_{18} (150mm X 4.6mm ID X 5µm df)
Column Temp.=40°C
Flowrate=0.50ml/min.
Injection Volume=1µL
Mobile Phase:
Solvent A=0.1% Formic Acid in Water
Solvent B=0.1% Formic Acid in Acetonitrile
Mobile Phase Profile:
Time=00 95%A:05%B
Time=20 05%A:95%B
Time=25 05%A:95%B
Time=35 95%A:05%B
Detector: UV-VIS (Sample=214, 04 Reference=450,80)
Analyst: [redacted]

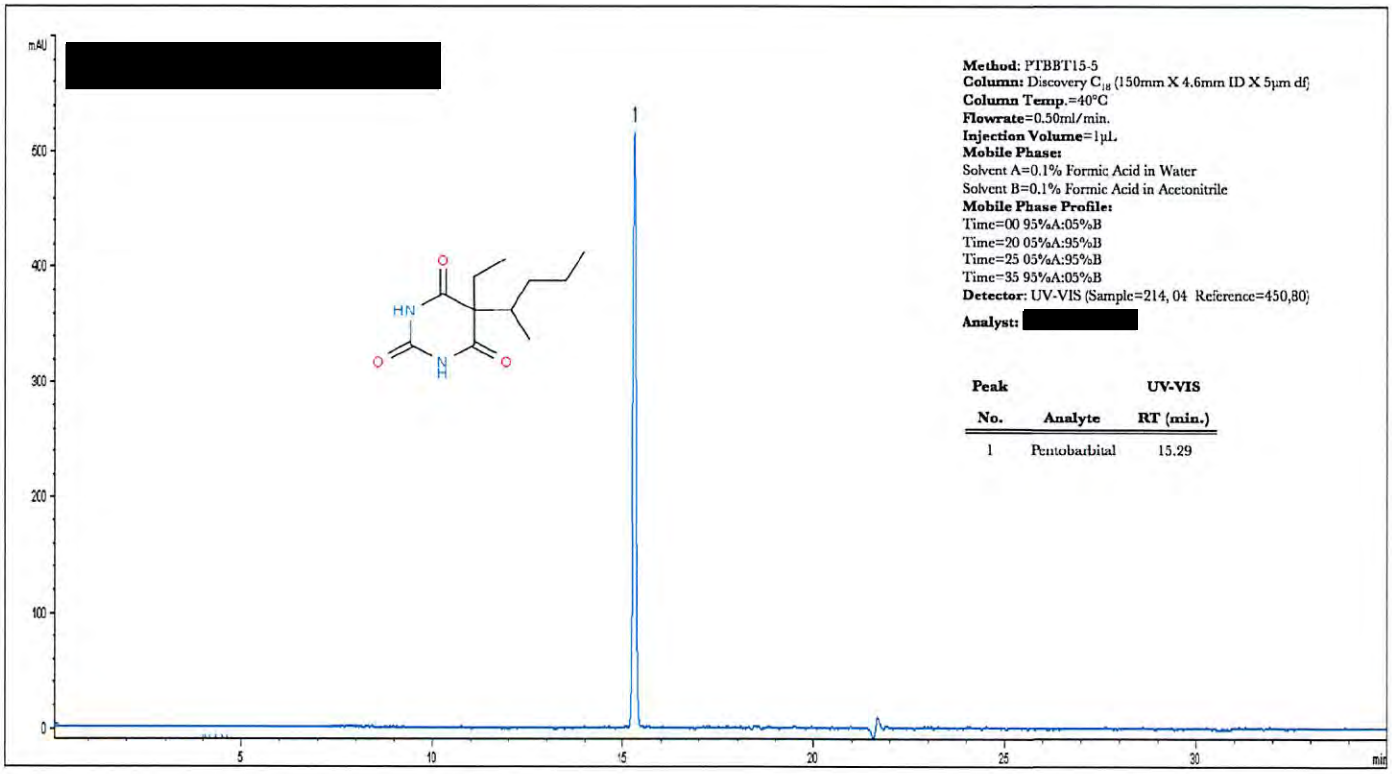
Peak No.	Analyte	UV-VIS RT (min.)
1	Pentobarbital sodium salt	15.29

UV-VIS	[redacted]				
Analyte			Mean	SD	RSD(%)
Pentobarbital	3076	3100	3088	16	0.53
Purity determined to be >99% when compared to [redacted]					

[redacted]

Certified Reference Material CRM

[redacted]



[redacted]

Method: PTBBT15-5
Column: Discovery C_{18} (150mm X 4.6mm ID X 5µm df)
Column Temp.=40°C
Flowrate=0.50ml/min.
Injection Volume=1µL
Mobile Phase:
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Solvent B=0.1% Formic Acid in Acetonitrile
Mobile Phase Profile:
Time=00 95%A:05%B
Time=20 05%A:95%B
Time=25 05%A:95%B
Time=35 95%A:05%B
Detector: UV-VIS (Sample=214, 04 Reference=450,80)
Analyst: [redacted]

Peak No.	Analyte	UV-VIS RT (min.)
1	Pentobarbital	15.29

[redacted]

Certified Reference Material CRM

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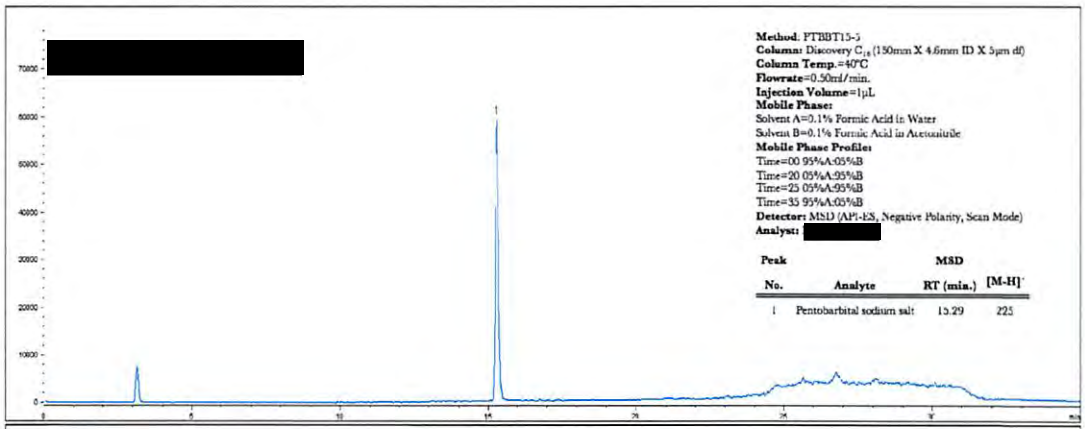
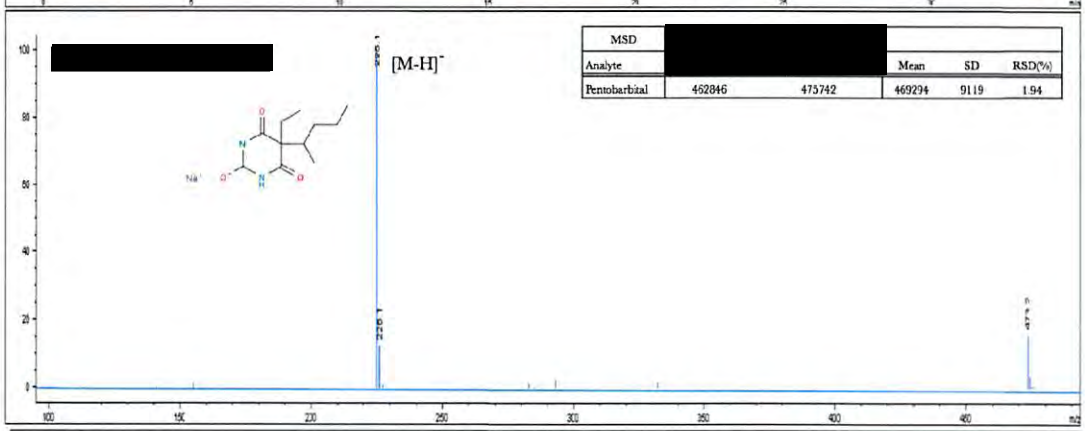
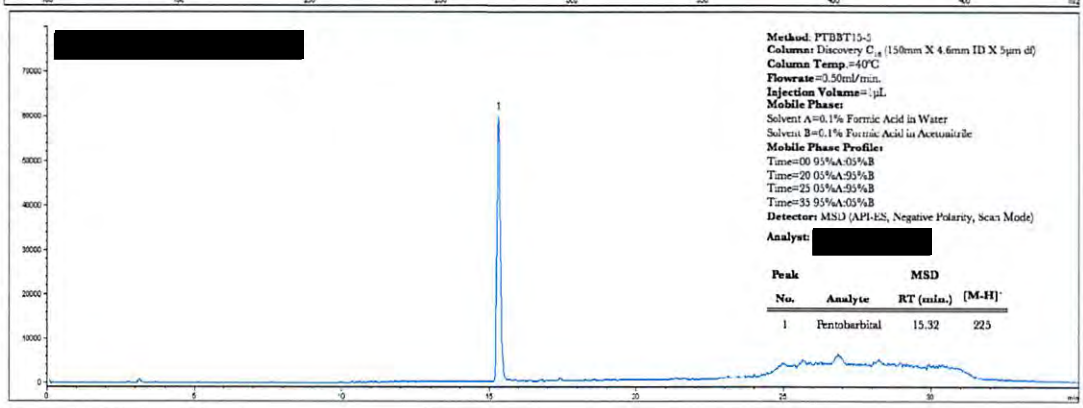
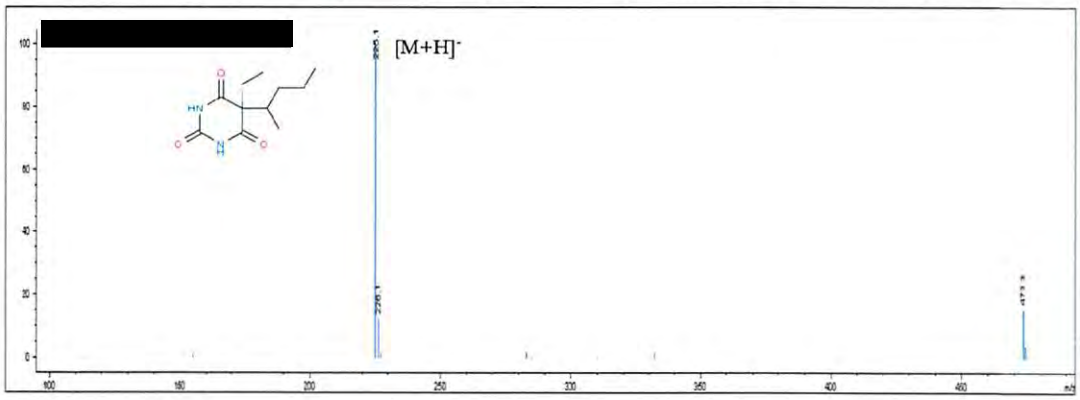


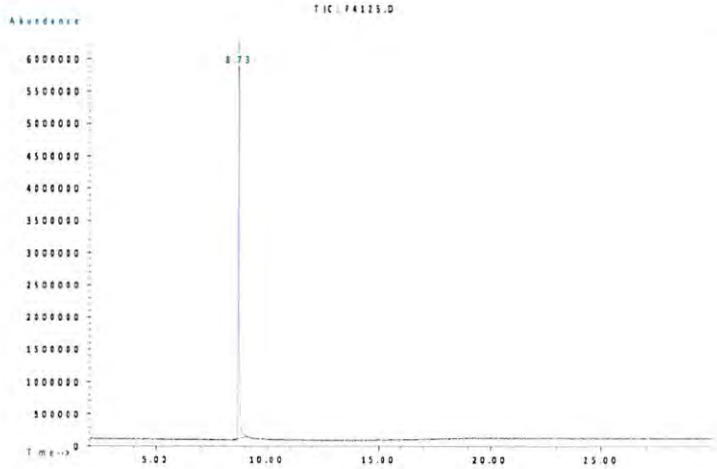


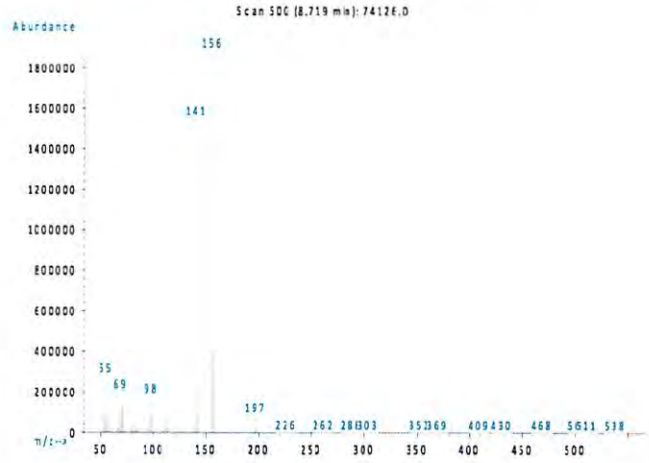




[redacted] **Certified Reference Material CRM** [redacted]

Method GC8MS7: Column: SPB-5 (30m X 0.25mm ID X 0.25µm film thickness), Temp 1 = 150°C (4 min.), Temp 2 = 300°C (13 min.), Rate = 10°C/min., Injector B= 225°C, Detector B = 300°C. Split Ratio = 100:1, Sample Rate=2. Analysis performed by [redacted]





[redacted] **Certified Reference Material CRM** [redacted]

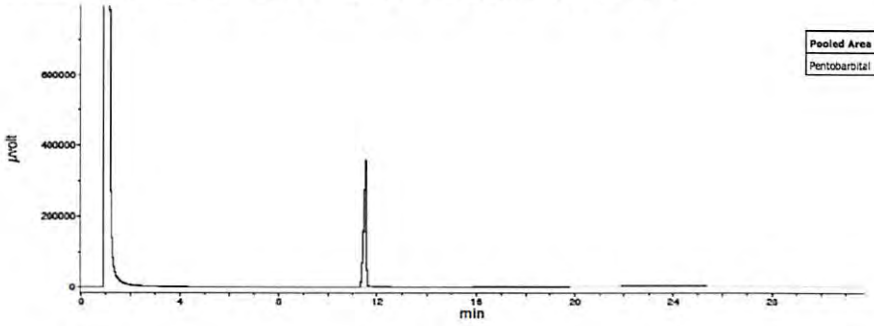
Run 20, [redacted] [1000µg/mL in MeOH]"

Run Length: 31.68 min, 19005 points at 10 points/second.
Created: Thu, Oct 18, 2018 at 1:20:32 PM.
Sampled: Sequence "101218-GC9-GCM3", Method "GC9-GC3M".
Analyzed using Method "GC9-GC3M [2]".

Comments
GC9-GC3M Analysis by [redacted]
Column ID SPB-5 30 meter x 0.53mm x 1.5um Film Thickness
Flow rates; Total Flow = 300 ml/min, Helium (carrier) = 6.5 mL, Helium (make-up) = 25 mL, Hydrogen (detector) = 30 mL, Air (detector) =360 mL
Oven Temp 1 = 150°C (4 min), Rate = 8°C/min, Oven Temp 2 = 290°C (13.5 min), Total Run Time = 35 Minutes.
Injector Temp = 200°C, FID Temp = 300°C, FID Signal = eDaq Channel 1.
Gas Chromatograph = HP 5890, Auto Sampler = HP 7673, Standard Injection = 2.0 uL, Range = 2

Name	FID RT (min.)
Pentobarbital	11.55

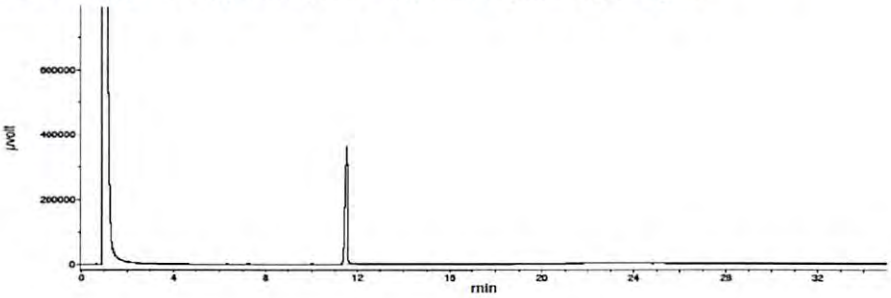
Pooled Area	[redacted]		Average	Stdev	(%) RSD
Pentobarbital	2415768	2508639	2462203	65670	2.67



Run 22, [redacted] [1000µg/mL in MeOH]

Run Length: 35.00 min, 20999 points at 10 points/second.
Created: Thu, Oct 18, 2018 at 2:17:05 PM.
Sampled: Sequence "101218-GC9-GCM3", Method "GC9-GC3M".
Analyzed using Method "GC9-GC3M [2]".

Comments
GC9-GC3M Analysis by [redacted]
Column ID SPB-5 30 meter x 0.53mm x 1.5um Film Thickness
Flow rates; Total Flow = 300 ml/min, Helium (carrier) = 6.5 mL, Helium (make-up) = 25 mL, Hydrogen (detector) = 30 mL, Air (detector) =360 mL
Oven Temp 1 = 150°C (4 min), Rate = 8°C/min, Oven Temp 2 = 290°C (13.5 min), Total Run Time = 35 Minutes.
Injector Temp = 200°C, FID Temp = 300°C, FID Signal = eDaq Channel 1.
Gas Chromatograph = HP 5890, Auto Sampler = HP 7673, Standard Injection = 2.0 uL, Range = 2



[redacted]

Certified Reference Material CRM

[redacted]

Sodium ug/mL

Theoretical Na ug/mL 92.54
Analyzed Na ug/mL 87.02
% Rec 94.04

RM [redacted]
Na 248.26
Na % 22.98
9.256

File Name : [redacted]
Method : TRACE4M3.M
Acq Time : Oct 19 18 04:30 pm
Sample Name : [redacted]
Sample Type : Sample
Comments :
Dilution : 1.00
Operator Name: [redacted]
Acq Mode : Spectrum
Cal Title : Si
Cal Type : External Calibration Method (Unweighted)
Last Calib : Oct 19 18 04:43 pm
Bkg File : --------
Interference Correction : ON
Blank File : --------

Element	Mass	IS	Counts		Conc.		RSD(%)	Time(sec)	Rep
	6		405.6871	P	---		---	---	-
Li	7	45	30.05444	P	-0.01979	ug/l	67.05	0.3	3
Be	9	45	0.1412439	P	0.009953	ug/l	82.45	0.3	3
B	11	45	37.68733	P	6.544	ug/l	8.83	0.3	3
Na	23	45	11,935.64	A	435.1	ug/l	1.56	0.3	3
Mg	24	45	5.704952	P	0.2195	ug/l	9.17	0.3	3
Al	27	45	30.42864	P	0.8808	ug/l	19.48	0.3	3
Si	29	45	103.4431	P	56.63	ug/l	13.02	0.3	3
P	31	45	15.95492	P	-0.2739	ug/l	138.30	0.3	3
S	34	45	109.5500	P	-601.2	ug/l	12.06	0.3	3
K	39	45	4,267.396	P	-0.6721	ug/l	366.61	0.3	3
Ca	43	45	0.5298764	P	6.886	ug/l	15.95	0.3	3
Ca	44	45	13.61490	P	4.220	ug/l	3.87	0.3	3
Sc	45		167,194.1	P	1,017	ug/l	2.34	0.3	3
Ti	47	45	0.4290841	P	0.1427	ug/l	39.73	0.3	3
V	51	45	24.97066	P	0.4552	ug/l	22.74	0.3	3
(V)	52	45	77.24907	P	1.774	ug/l	22.11	0.3	3
Cr	53	45	1.094301	P	0.2197	ug/l	18.54	0.3	3
Mn	55	45	2.392268	P	0.01123	ug/l	47.76	0.3	3
Fe	56	45	1,194,362	P	---		---	---	-
Fe	57	45	20.38318	P	-2.586	ug/l	41.88	0.3	3
Co	59	45	0.9955027	P	0.003814	ug/l	81.15	0.3	3
Ni	60	45	0.2752530	P	0.01219	ug/l	52.14	0.3	3
Cu	63	45	3.014495	P	0.2438	ug/l	6.52	0.3	3
Zn	66	45	1.300341	P	0.3687	ug/l	18.24	0.3	3
Ga	69		33.33426	P	---		---	---	-
	71		10.66690	P	---		---	---	-
As	75	45	4.392135E-5	P	0.02811	ug/l	59.94	0.3	3
(As)	77	115	32.66748	P	---		---	---	-
	78	115	3,444.636	P	---		---	---	-
Se	82	115	0.2558027	P	-0.02231	ug/l	436.17	0.3	3
Sr	88	115	1.738569	P	0.01739	ug/l	9.84	0.3	3
Y	89	115	41.00100	P	---		---	---	-
Zr	90	115	16,328.67	P	---		---	---	-
Mo	95	115	3.362646	P	0.3235	ug/l	6.78	0.3	3
Rh	103	115	9.666906	P	---		---	---	-
Pd	105	115	55.00150	P	---		---	---	-
(Cd)	106	115	0.6847240	P	1.432	ug/l	18.55	0.3	3
Ag	107	115	3.008497	P	0.1022	ug/l	10.08	0.3	3
(Cd)	108	115	1.980917	P	0.9021	ug/l	53.74	0.3	3
Cd	111	115	0.2577754	P	0.03677	ug/l	107.78	0.3	3
In	115		115,802.9	P	979.8	ug/l	1.47	0.3	3
Sn	118	115	1.474114	P	0.1093	ug/l	32.74	0.3	3
Sb	121	115	1.465382	P	0.08935	ug/l	28.29	0.3	3
Cs	133	115	77.33560	P	---		---	---	-
Ba	137	115	0.4150361	P	0.03259	ug/l	31.67	0.3	3
Pr	141		192,422.7	P	989.8	ug/l	2.28	0.3	3
Tb	159		10.00023	P	---		---	---	-
Ho	165		143,474.0	P	985.5	ug/l	2.57	0.3	3
W	182	165	171.3395	P	---		---	---	-
Pt	195	165	48.66785	P	---		---	---	-
Au	197	165	606.0406	P	---		---	---	-
Hg	202	165	1.396972	P	0.5290	ug/l	10.95	0.3	3
Tl	205	209	2.061851	P	0.01372	ug/l	20.28	0.3	3
Pb	206	209	46.69563	P	1.161	ug/l	1.97	0.3	3
Pb	207	209	10.81195	P	1.225	ug/l	1.40	0.3	3
Pb	208	209	24.77976	P	1.181	ug/l	4.13	0.3	3
Bi	209		81,979.22	P	980.9	ug/l	1.67	0.3	3
U	238	209	1,812.615	P	---		---	---	-

End of Report

Fri Oct 19 16:43:55 2018

Part # [redacted] Lot # [redacted]

Printed: 8/27/2019, 11:06:23
AM

[redacted]

Certificate Of Analysis

CLIENT: [redacted]

[redacted] [redacted]

LOT #: [redacted]

DESCRIPTION: Pentobarbital Sodium

DATE RECEIVED: 10/26/2018

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: One amber container w/ 1g of powder in a clear bag

Test	Test Method	Limits	Results	Date Tested
Identification B (HPLC - Retention Time)	USP 41	Conforms to USP Specifications	Conforms	11/06/2018
Loss on Drying <731>	USP 41	NMT 3.5%	1.6%	11/06/2018
Related Compounds (HPLC) <621>	USP 41	see**Note	Fail	11/06/2018
Assay (HPLC) <621>	USP 41	98.0% - 102.0%	99.6%	11/06/2018

Assay: on the dried basis.

**Note: USP 41, Pentobarbital Sodium, Related compounds Results: 6-Imino-5-ethyl-5-(1-methyl-butyl)barbituric acid = 0.005%, limit: NMT 0.2%; 5-Ethyl-5-(1-ethyl-propyl)barbituric acid = 0.259%, limit: 0.1%; 5-Ethyl-5-(1,3-dimethylbutyl)barbituric acid = not detected, limit: NMT 0.3%. NMT 0.1% of unknown impurity; unknown impurity = 0.028%, unknown impurity = 0.003%, unknown impurity = 0.006%. Total impurities = 0.3%, limit: NMT 0.5%.

[redacted]

11/19/2018

Date Reported

Results reported above relate only to the sample that was tested.

[redacted]

[redacted]

Certificate of Analysis

Client: Bureau of Prisons [redacted]

[redacted] **Product ID:** N/A
Lot Number: [redacted]
Description: Pentobarbital Sodium powder – 1 g

Test	Results	Limits	Test Method	Date Tested
Identification B (HPLC – Retention Time)	Conforms	Conforms to USP Specifications	USP 41	11/06/2018
Loss on Drying <731>	1.6%	NMT 3.5%	USP 41	11/06/2018
Related Compounds (HPLC) <621>	Fail	See Below	USP 41	11/06/2018
6-Imino-5-ethyl-5-(1methyl-butyl)barbituric acid	0.005%	NMT 0.2%		
5-Ethyl-5-(1-ethylpropyl)barbituric acid	0.259%	0.1%		
5-Ethyl-5-(1,3dimethylbutyl)barbituric acid	Not Detected	NMT 0.3%		
Unknown Impurities	0.028% 0.003% 0.006%	NMT 0.1%		
Total Impurities	0.3%	NMT 0.5%		
Assay (HPLC) <621>	99.6%	98.0% - 102.0%	USP 41	11/06/2018

Respectfully,

[redacted]

12/06/2018
Date Reported

[redacted]

Certified Reference Material CRM

[redacted]

Part Number: [redacted]
Lot Number:
Description: Pentobarbital sodium salt

Expiration Date: 020124
Recommended Storage: Refrigerate (4 °C)
Mass(g): 10.0
NIST Test ID#: [redacted] [redacted] Balance Uncertainty

[redacted]

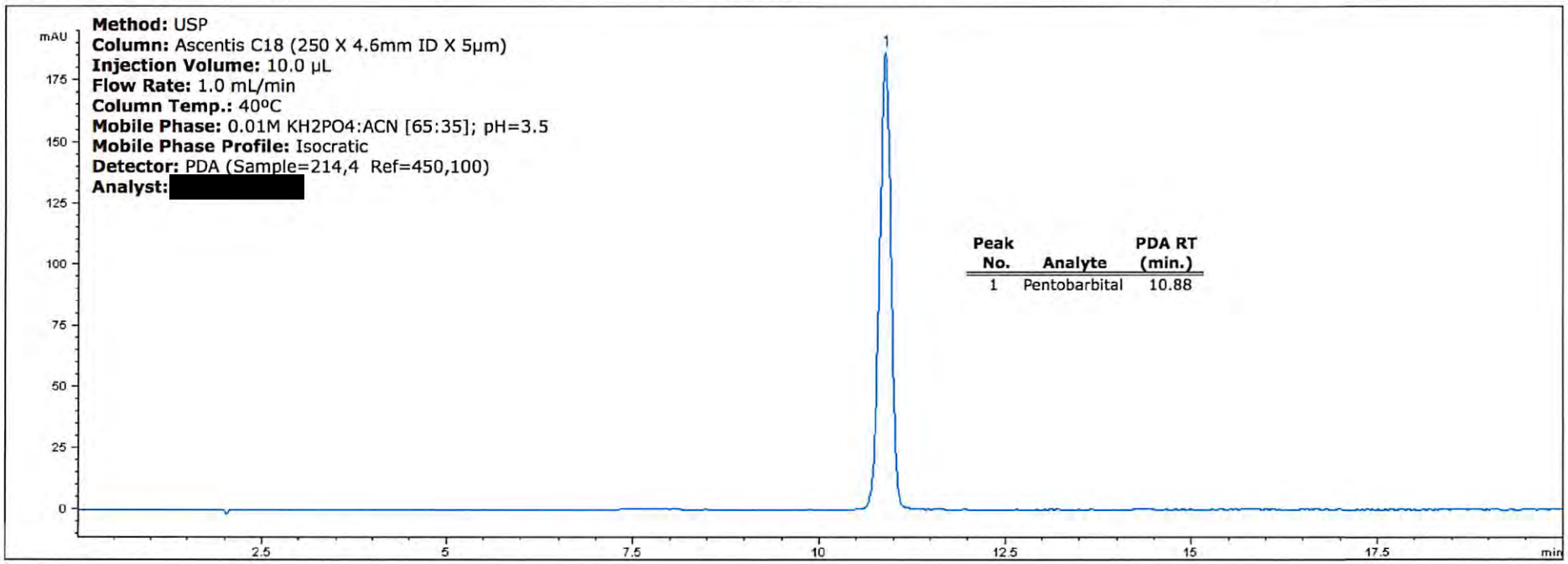
Formulated By: [redacted] DATE

[redacted]

Reviewed By: [redacted] DATE

SDS Information
(Solvent Safety Info. On Attached pg.)

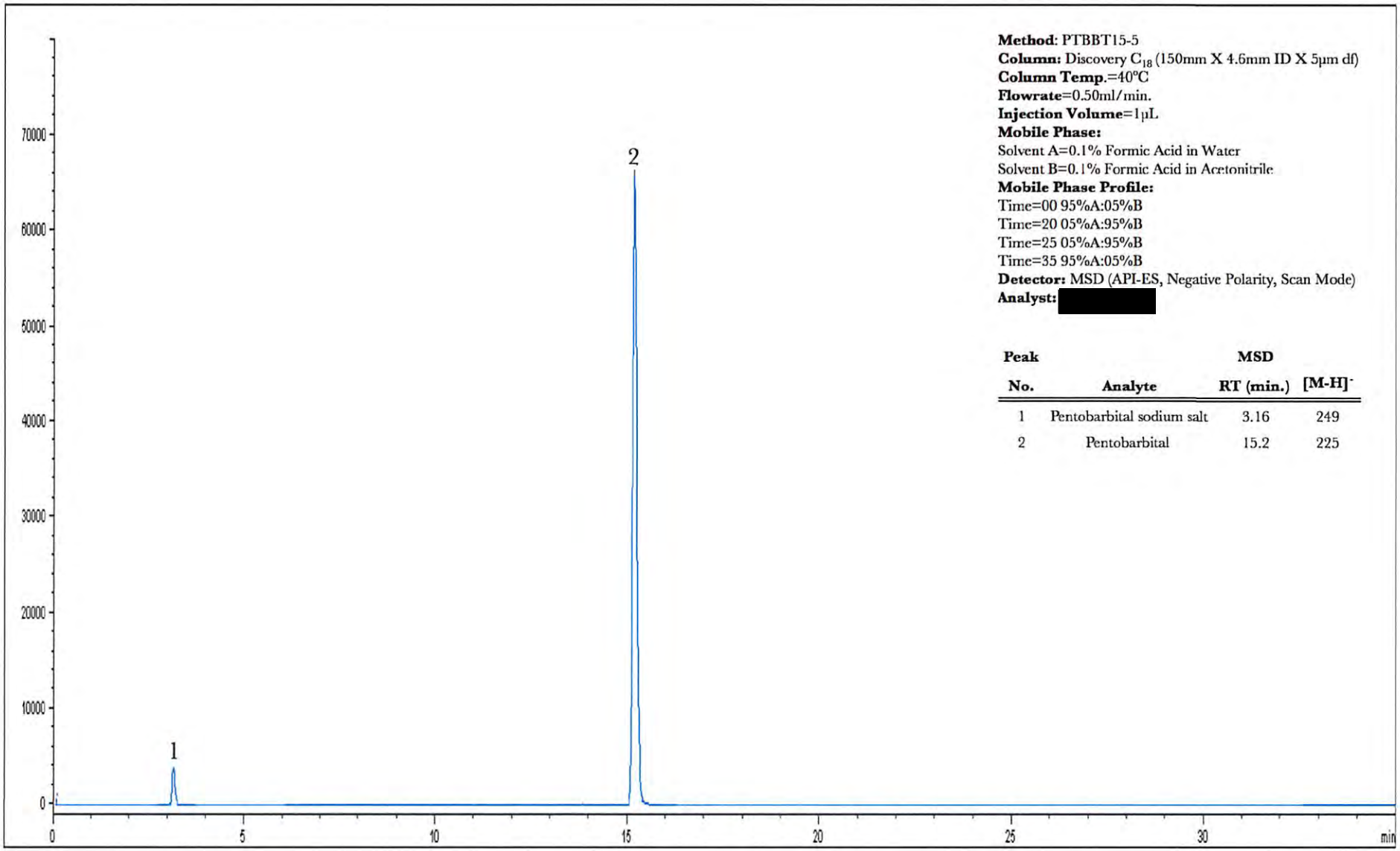
Compound	RM#	Lot Number	Purity (%)	Uncertainty Purity (%)	Assay (%)	Target Weight (g)	Actual Weight (g)	CAS#	OSHA PEL (TWA)	LD50
1. Pentobarbital sodium salt	[redacted]		100	0.5	90.7	10.0000	10.7500	[redacted]	N/A	N/A



[redacted]

Certified Reference Material CRM

[redacted]



Method: PTBBT15-5
Column: Discovery C_{18} (150mm X 4.6mm ID X 5µm df)
Column Temp.=40°C
Flowrate=0.50ml/min.
Injection Volume=1µL
Mobile Phase:
Solvent A=0.1% Formic Acid in Water
Solvent B=0.1% Formic Acid in Acetonitrile
Mobile Phase Profile:
Time=00 95%A:05%B
Time=20 05%A:95%B
Time=25 05%A:95%B
Time=35 95%A:05%B
Detector: MSD (API-ES, Negative Polarity, Scan Mode)
Analyst: [redacted]

Peak No.	Analyte	MSD RT (min.)	MSD [M-H]⁻
1	Pentobarbital sodium salt	3.16	249
2	Pentobarbital	15.2	225

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium Powder

Test / Specification	Results	Test Method	Date Tested
Completeness of Solution Conforms / does not conform	Conforms	USP <41>	02/21/2019
pH <791> 9.8 – 11.0	10.3	USP <41>	02/21/2019
Loss on Drying <731> NMT 3.5%	1.0%	USP <41>	02/21/2019
Related Compounds (HPLC) <621> See ** note	Pass	USP <41>	02/21/2019
Assay (HPLC) <621> 97.0% - 102.0%	101.2%	USP <41>	02/21/2019

**Note: USP 41, Pentobarbital Sodium, related compounds results: 6-Imino-5-ethyl-5-(1-methyl-butyl)barbituric acid = not detected, limit: NMT 0.2%; 5-ethyl-5-(1-ethyl-propyl)barbituric acid = not detected, limit: 0.1%; 5-ethyl-5-(1,3-dimethylbutyl) barbituric acid = 0.005%, limit: NMT 0.3%. NMT 0.1% of unknown impurity; unknown impurity = 0.009%, unknown impurity = 0.02%, unknown impurity = 0.004%. Total impurities = 0.04%, limit: NMT 0.5%.

Respectfully,

[redacted]

[redacted]

Certificate Of Analysis

CLIENT: [redacted]

[redacted] **#:** [redacted]

LOT #: [redacted]

DESCRIPTION: Pentobarbital Sodium

DATE RECEIVED: 02/08/2019

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: One amber container w/ 3.14g of powder in a clear bag

Test	Test Method	Limits	Results	Date Tested
Completeness of Solution	USP 41	Conforms to USP Specifications	Conforms	02/21/2019
pH <791>	USP 41	9.8 - 11.0	10.3	02/21/2019
Loss on Drying <731>	USP 41	NMT 3.5%	1.0%	02/21/2019
Related Compounds (HPLC) <621>	USP 41	See *Note	Pass	02/21/2019
Assay (HPLC) <621>	USP 41	97.0% - 102.0%	101.2%	02/21/2019

Assay: On dried basis.

*Note: Per USP 41, Pentobarbital Sodium Related Compounds Limits: 6-Imino-5-ethyl-5-(1-methyl-butyl)barbituric acid NMT 0.2%, 5-ethyl-5-(1-ethyl-propyl)barbituric acid NMT 0.1%, 5-ethyl-5-(1,3-dimethylbutyl)barbituric acid NMT 0.3%, Unknown Impurities NMT 0.1%, Total Impurities NMT 0.5%. Results: 6-Imino-5-ethyl-5-(1-methyl-butyl)barbituric acid (RRT~0.39) = Not Detected, Unknown Impurity (RRT=0.64) = 0.009%, Unknown Impurity (RRT=0.73) = 0.02%, 5-ethyl-5-(1-ethyl-propyl)barbituric acid (RRT~0.93) = Not Detected, Unknown Impurity (RRT=1.40) = 0.004%, 5-ethyl-5-(1,3-dimethylbutyl)barbituric acid (RRT=1.47) = 0.005%,, Total Impurities=0.04%.

[redacted]

02/22/2019

Date Reported

Results reported above relate only to the sample that was tested.

[redacted]

[redacted]

Certified Reference Material CRM

[redacted]

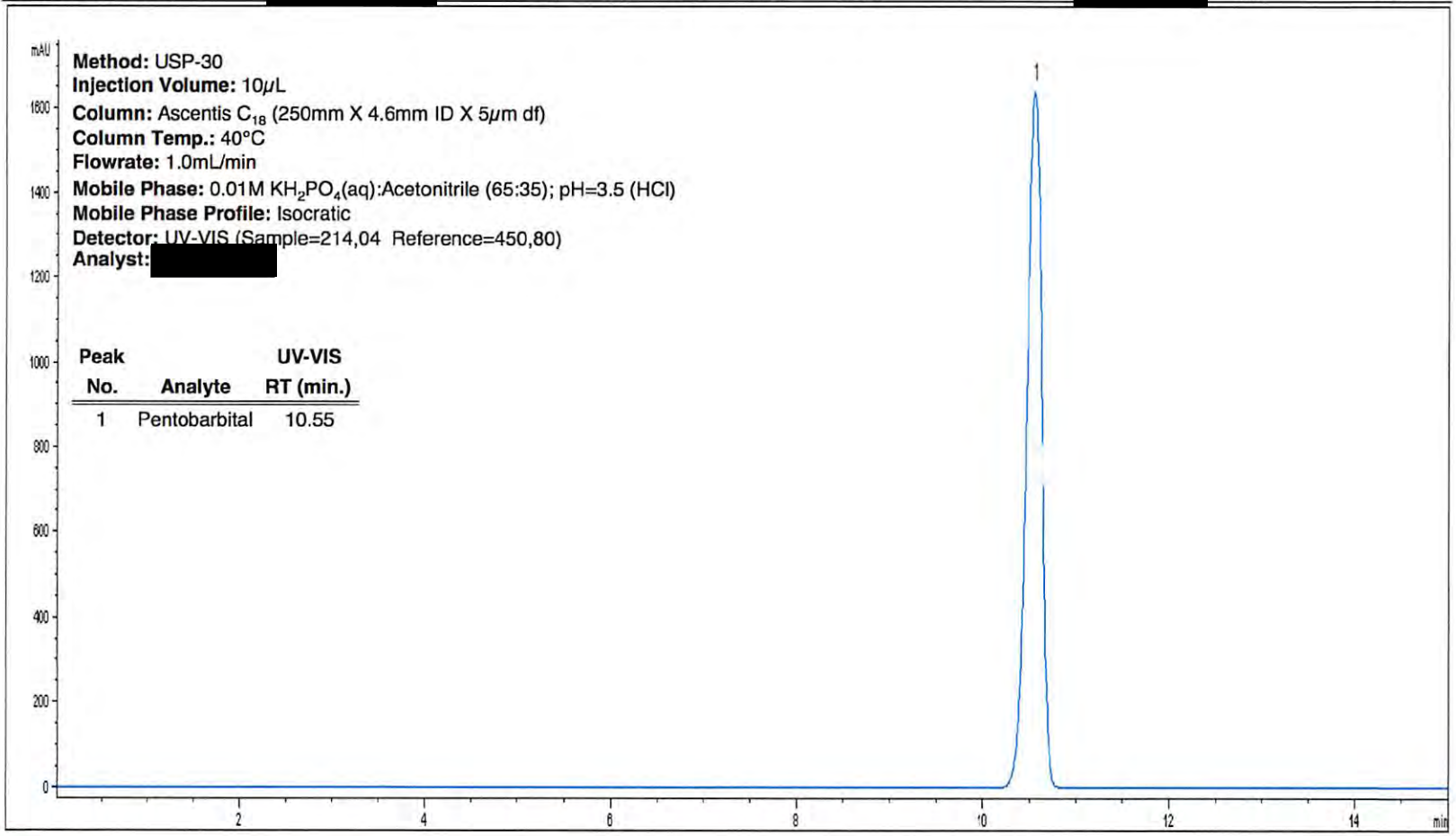
CERTIFIED WEIGHT REPORT

Part Number: [redacted]
Lot Number:
Description: Pentobarbital sodium salt

Expiration Date: 032224
Recommended Storage: Refrigerate (4 °C)
Mass(g): 150.0
NIST Test ID#: [redacted] [redacted] Balance Uncertainty

[redacted]
Formulated By: [redacted] DATE
[redacted]
Reviewed By: [redacted] DATE

Compound	RM#	Lot Number	Purity (%)	Uncertainty Purity (%)	Assay (%)	Target Weight (g)	Actual Weight (g)	SDS Information (Solvent Safety Info. On Attached pg.) CAS#	OSHA PEL (TWA)	LD50
1. Pentobarbital sodium salt	[redacted]		100	0.5	90.7	150.00	151.43	[redacted]	N/A	N/A



Peak No.	Analyte	UV-VIS RT (min.)
1	Pentobarbital	10.55

[redacted]

[redacted] PENTOBARBITAL SODIUM 50 MG/ML INJECTABLE

2019-328 Method Validation [redacted]

[redacted]

[redacted]

Quotation for Testing Services

Method Validation Quote 2019-328

04/05/2019

[redacted]

Dear [redacted]

[redacted] is committed to providing the best service and the highest quality testing services in the industry. We are fully cGMP compliant, registered with the FDA and DEA licensed. We maintain compliance with the various regulatory bodies with which we are engaged and required by law.

Please review this provided quotation and initial Appendix B: Method Development, Appendix D: Deliverables and Payment Terms, and sign Appendix E: Approval and Expiration.

Please let us know if you have any questions about this proposal or any of [redacted] wide range of pharmaceutical industry services.

Best Regards,

[redacted]

[redacted]

[redacted]

Pentobarbital - Method Validation for PENTOBARBITAL SODIUM 50 MG/ML INJECTABLE 2019-328

Appendix A: Pre-production/Validation Components and Definitions

Sterility Method Validation/Suitability USP<71> - *REQUIRED FOR REGULATORY COMPLIANCE*

Please match your product type (injectable or ophthalmic/non-injectable) and fill volume appropriate to the row and follow to the appropriate batch size. The Batch Size conveyed in this document is the amount requested. You may proceed with your current maximum batch size (and risk repeating Method Suitability if you increase production); however, the infinite batch size is recommended (and highlighted). This will ensure your formulation does not need revalidation due to an increase in production size. Per USP, ophthalmic/non-injectables are treated as injectables when single dose. **A total volume of 480mL (10 vials) is needed to meet batch size volume requirements. Chart listed below is based on three times the amount for routine testing.**

Nominal Container Size (in mLs)	50.00
Maximum Batch Size	40

Nominal Container Volume (Injectable)	Actual Max Batch Size (Increasing Batch Size requires new Method Suitability)	Batch Size 1-100 Containers	Batch Size 101-500 Containers	Batch Size 501-1000 Containers	Infinite Batch Size	Number of Containers Required
mL-100mL	40	12			>1000	60

Nominal Container Volume (Ophthalmic or Non-Injectable)	Actual Max Batch Size (Increasing Batch Size requires new Method Suitability)	Batch Size 1-200 Containers	Batch Size 201-500 Containers		Infinite Batch Size	Number of Containers Required
>2mL	40	6			>200	30

This is required for all USP <71> sterility testing. This test will ensure that interfering factors in the formulation do not impede growth and cause false negatives. If this testing is not completed before initiating the study, the outcome could nullify the study. An increase in batch size during compounding could require this validation to be repeated.

[redacted]

[redacted]

Appendix B: Method Development

Pre-Development Work		
Research and Feasibility		Waived
Set-Up and Supplies (If applicable)[1]		$0.00
Protocol Development		$1,000.00
Microbiology Method Suitability Work		
Description of Work	**Requested**	**Cost**
USP <71> Method Suitability	Accepted	$ 600.00
Potency Method Development Package[2]		
Description of Work	**Requested**	**Cost**
Linearity, Accuracy, and Precision	Accepted	$ 4,400.00
Range	Accepted	Waived
Robustness	Recommended	$ 600.00
Ruggedness	Recommended	$ 600.00
Forced Degradation Pathways: Acid/Base Hydrolysis, Oxidation, Light, Heat	Accepted	$ 1,800.00
Specificity	Accepted	Waived
Intermediate Precision	Recommended	$ 500.00
In Vial Sample Stability	Declined	$ -
USP Equivalency	Declined	$ -
Feasibility and Protocol Development Subtotal		**$ 1,000.00**
Method Development Cost Subtotal		**$ 8,500.00**

[1]In the event there is a cost, the cost will be described and provided to the Client. A separate quote may be required to capture total supply cost.

The method development process at [redacted]s based on USP <1225> and ICH guidelines. The items priced above is based upon initial conversations with Client and by requested testing.

[2]The method developed will contain the following method validation criteria: Accuracy, Precision, Ruggedness, Specificity, Linearity, and robust in regards to the Client's provided formulations and products. The method will be designed on the Client's specific formulation and will be stability indicating at this time. Additional criteria and testing may be discussed and performed based on Client's approval. In the event the Client wishes to add or change the listed development work provided, [redacted] will issue a Scope Change Form to capture changes as detailed in Appendix C.

The expected completion time is 15 – 20 business days upon receipt of materials. Timeline and Milestones will be developed upon signature of quotation.

Estimated Routine Potency Testing Price: $165.00 per test.

Final price provided will be finalized dependent on final execution and completion of the validated method. Price is representative of Silver pricing SLA and does not reflect discounts or price reductions.

Customer Initial and Date:_____

[redacted]

[redacted]

Appendix C: Definitions and Line Item Price Description

Method Validation – the process by which it is established, by laboratory studies, that the performance characteristics of the method meets the requirements for the intended analytical applications.

Accuracy - the closeness of test results obtained by that method to the true value. The accuracy of an analytical method should be established across the optimal testing range based on commonly used pharmaceutical dosages.

Relative Accuracy – the relationship between measured relative potency and known relative potency. The most common approach for demonstrating relative accuracy is via a dilutional linearity study; accomplished by diluting material of known potency to a range of target potencies.

Precision – the degree of agreement among individual test results when the method is applied repeatedly to multiple samplings of a homogeneous sample. The precision of an analytical method is usually expressed as the standard deviation (coefficient of variation) of a series of measurements.

System Suitability – if measurements are susceptible to variations in analytical conditions, these should be suitably controlled, or a precautionary statement should be included in the test method.

Specificity – the ability to assess unequivocally the analyte in the presence of components that may be expected to be present, such as impurities, degradation products and matrix components. Assay specificity will provide an exact result, which allows an accurate statement on the content or potency of the analyte in the sample. Specificity includes forced degradation work as appropriate based on analyte and type of chromatographic testing performed.

Detection Limit – the lowest amount of analyte in a sample that can be detected, but not necessarily quantitated under the experimental conditions. Also called LOD.

Quantitation Limit – a characteristic of quantitative assays for low levels of compounds in sample matrices. It is the lowest amount of an analyte in a sample that can be determined with acceptable precision and accuracy under the stated conditions. Also called LOQ.

Linearity – the ability of an analytical method to elicit test results that are directly, or by a well-defined mathematical transformation, proportional to the concentration of analyte in samples within a given range.

Range – the interval between the upper and lower levels of analyte that have been demonstrated to be determined with a suitable level of precision, accuracy and linearity using the method as written.

Ruggedness – the degree of reproducibility if test results obtained by the analysis of the same samples under a variety of conditions, such as different laboratories, different analysts, different instruments, different lots of reagents etc.

Robustness – the measure of a methods capacity to remain unaffected by small but deliberate variations in method parameters. Robustness provides an indication of a methods reliability during normal usage.

Selectivity – The ability of an analytical method to differentiate and quantify an analyte in the presence of other components in the sample. Potential interfering substances include endogenous matrix components, metabolites, and decomposition products.

Vial and Sample Stability - This design of experiment is for trending and informational purposes in the event a result is found to be outside of the specification and an investigation has been initiated. This will provide information into how long your formulation

USP Equivalency/Secondary Verification - This testing will be used to ensure that the Core Method and Validation Extension created is validated against a secondary. Testing performed will be performed via the USP Monograph (See attachment provided). Additional quotation and scope of works needed.

Unknown Peak or Degradant Identification - This testing is recommended if compounding from raw powder is performed or degradation and additional unknown peaks are presented within the chromatography. Additional quotation and scope of work is need

[redacted]

[redacted]

Appendix D: Deliverables and Payment Terms

1. **Deliverables**
   - 1.1. Upon receipt of this signed quote, [redacted] will order necessary standards, supplies, equipment.
   - 1.2. Upon signature of this quote, [redacted] project management team will provide a project protocol and project timeline that will include key achievement dates and estimated project timeline for this Quoted Scope of Work.
   - 1.3. Client is responsible for providing sufficient sample material(s) to perform all requested testing as outlined per the Quoted Scope of Work provided in this quote.
   - 1.4. Upon receipt of supplies and Client samples, development and work towards the completion of the Quoted Scope of Work will commence.
   - 1.5. In the event the Timeline changes or Scope of Work changes by either the Client or [redacted] Project Scope Change Document will be supplied outlining the agreed upon changes for documentation purposes. Project Scope Change Document will address description of the issue, proposed change(s), benefits of the change, and potential negative impact if no change is made.
   - 1.6. Changes in Quoted Scope of Work may require amendments to charges and agreed upon test schedule. Additional charges will be issued in the form of an amended Quote requiring Client signed approval prior to the commencement of work associated with the Project Scope Change Document.
   - 1.7. [redacted] commits to providing timely responses to inquiries as well as alerting the Client to any delays in testing or failure to meet any specification.
   - 1.8. In the event an issue arises that will delay or impact the work provided in the Quoted Scope of Work, a [redacted] Issue Management Document will be supplied to document resolution. Issue Management Document will address the following: Description of the Issue, Remediation or Action Plan to Resolve the issue, Impact Assessment, and Proposed Resolution.
   - 1.9. Upon completion of the agreed upon Quoted Scope of Work, the Client will have access to the method data along with a comprehensive method summary.

2. **Payment Terms**
   - 2.1. Client will be invoiced for this Quoted Scope of Work in three installments per the following: (1) 60% of the quoted amount upon signature of this Quote, (2) 20% of the quoted amount upon completion and approval of the project protocol, (3) the remaining 20% of the quoted amount upon completion of the method summary report.
   - 2.2. The pricing is valid for 30 days from the date of quotation.

3. **Cancellation**
   - 3.1. Written notification for cancellation of any portion of this quote and study is required. Cancellation of an in-process study could be subject to a $500 cancellation fee and any fees associated with work completed prior to cancellation notice.

Customer Initial and Date:_____

[redacted]

Appendix E: Approval and Expiration

Client Approval
Signature:
Date:

This quote and its contents are confidential and proprietary to [redacted] and may not be disclosed or shared without the express written permission of [redacted] management. Approval of quote is required before testing will begin. Signature verifies understanding and acceptance of quote.

[redacted] commitment to completing the attached quotation per the terms and pricing outline is contingent on the following:

- The quote must be signed and returned within 30 days of the quote date (cover page);
- An expired signed quote can be submitted back to [redacted] to be reissued.

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[redacted]

LABORATORY REPORT

Sample:Pentobarbital Sodium Injection

Conc.:50mg/mL
Lot #:[redacted]
Sample ID #[redacted]
Date Rec'd:04/09/2019

Storage Loc: RT

Chemistry Tests:	***Date***	***Reported***	***Measured***	***Potency***
Pentobarbital Sodium	04/18/2019	50.0 mg/mL	49.2 mg/mL	98.4 %
pH*	04/19/2019		9.66 pH Unit	

Microbiology Tests:	***Date***	***Measured***	***Result***
Scan RDI	04/10/2019		Pass
Bacterial Endotoxins	04/11/2019	<1.00 EU/mL	Pass -
Scan RDI Suitability Test	04/11/2019		Pass -
USP <788> Particulate Count	04/12/2019		Pass -

Notes:

Bacterial Endotoxins: Endotoxins are measured using USP<85> Turbidimetric procedure, with an inhibition / enhancement test performed on each sample.

Potency: Potency is determined via USP <621> HPLC, USP<851> Spectrophotometry, and/or specific monograph testing procedures.

Respectfully submitted,

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable

365 Day Study at ICH Room Temperature Conditions and 180 Days at ICH Elevated Temperature Conditions

Protocol 2019[redacted]

[redacted]

[redacted]

[redacted]

Customer Signature/Date: [redacted]

[redacted] Project Manager Signature/Date: [redacted] 05/08/19

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable

365 Day Study at ICH Room Temperature Conditions and 180 Days at ICH Elevated Temperature Conditions

Protocol 2019-[redacted]

[redacted]

Customer Signature/Date: _____

[redacted] **Project Manager Signature/Date:** _____

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019[redacted]

1. Table of Contents

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019-[redacted]

2. Specification and Sample Submission Calibration

2.1. As part of the Protocol approval process this section is intentionally left blank until [redacted] Project Manager signs off on the study.

2.2. To ensure proper preparation and receipt of the stability study, [redacted] Project Manager will review for submission assurance that everything is correctly uploaded to [redacted] including calibrating the submission to reflect the specifications set within the agreed upon Protocol.

	Specification Check	[redacted] Initials/Date
Sample Built onto [redacted]		
Actives to be tested Checked		
Potency Specification Checked		
Endotoxin Limit Calculated Checked		
pH Specification Checked		
Particulate Matter Specification Checked		
Storage Conditions Checked		
Lots to be tested Checked		

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019[redacted]

3. Scope

3.1. This study will be performed on 1 lot of compounded drug product, Pentobarbital Sodium 50mg/mL Injectable, and will be stored at [redacted] using ICH room temperature conditions, 25°C ± 2°C/RH 60%± 5% for 365 days and elevated temperature conditions 40°C ± 2°C/RH 75%± 5% for 180 days. The sample required, 1 lot of Pentobarbital Sodium 50mg/mL Injectable, [redacted] and the above-mentioned material will be provided to [redacted] to complete this study and any testing that is required prior to execution of the study. The product will be shipped at conditions considered acceptable by [redacted] to ensure the stability of the study submission while in route. Adherence to Customer Responsibilities Section is required for accurate execution. This protocol is written to directly reflect a signed quotation.

- 3.1.1. Sample: Pentobarbital Sodium 50mg/mL Injectable
- 3.1.2. Storage Conditions: ICH room temperature conditions, 25°C ± 2°C/RH 60%± 5% and ICH elevated temperature 40°C ± 2°C/RH 75%± 5%
- 3.1.3. Total Duration of Study: 365 Days
- 3.1.4. See Sample Compounding and Experimental Design for Study Design
- 3.1.5. Potency Limits per USP monograph for Pentobarbital Sodium Injection, 92.0 -108.0%

3.2. Prior to initiation of the study [redacted] will ensure that all equipment calibrations are current and that all test methods used are validated.

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019-[redacted]

4. Definitions

4.1. BUD – Beyond Use Date

4.2. ICH – The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

4.3. USP- United States Pharmacopeia

4.4. HPLC- High Pressure Liquid Chromatography

4.5. UHPLC- Ultra High Pressure Liquid Chromatography

4.6. CV- Coefficient of Variance

4.7. PPC- Positive Product Control

4.8. DTI- Drug Testing Information

[redacted]

[redacted]

5. Responsibilities

5.1. Client Responsibilities

5.1.1. A representative from [redacted] is responsible for the thorough review of this protocol, including but not limited to sample amounts provided, testing required and storage conditions. A signature is required and verifies the accuracy and completeness of the study protocol. If a signed copy is not received by [redacted] before the study is shipped, errors in sample allocation and testing regiment may occur.

5.1.2. The Client is responsible for providing a formulation/ batch record.

5.1.3. The Client is responsible for ensuring that this protocol number and the quote number are included in the sample comments.

5.1.4. The Client is responsible for submitting any samples associated with this protocol on the website and for adding BUD at the end of the lot number(s). The theoretical maximum batch size will be entered when submitting samples. The customer will inform [redacted] when samples are being submitted and provide lot number(s) before shipping.

5.2. [redacted] Responsibilities

5.2.1. Approved deviations will be summarized in the final report if results or testing scheduled is impacted.

5.2.2. A [redacted] Representative is responsible for developing the protocol and submitting the protocol for review. The [redacted] Representative is also responsible for the accuracy and thoroughness of the protocol.

5.2.3. Analyst: The analyst is responsible for strict adherence to this protocol. The analyst is also responsible for placing the final results on the website and submitting the data to Quality.

5.2.4. Technical Quality Control: Technical Quality Control is responsible for verifying adherence to this protocol. They are also responsible for reviewing the collected data and comparing the results to acceptance criteria.

5.2.5. Quality Control Department: Quality Control Department is responsible for reviewing all the submitted data, paperwork, documents, attachments, and DTI. The review should determine completeness and adherence to all relative SOP's and existing protocols.

5.2.6. A [redacted] Representative is responsible for a comprehensive review of this protocol before implementation into the production stage of the project. After signatory acceptance and sample submission, changes to the protocol must be agreed upon by both parties.

[redacted]

[redacted]

6. Materials and Equipment

6.1. Testing Apparatuses (All items listed may not be applicable)

6.1.1. An LC is a HPLC/UHPLC capable of performing the testing described herein and equipped with the appropriate detector and will utilize software that accurately records data.

6.1.2. A balance capable of accurate weighing

6.1.3. Class A glassware or currently calibrated mechanical pipettes, where required, will be utilized

6.1.4. Mettler Toledo pH meter (± 0.2 pH units) or equivalent

6.1.5. A Particle Measuring System Inc. Liquilaz Laser Particle Counter connected to a Particle Measuring System Inc. Model Number LS-200 Liquid Sampler or equivalent and will utilize software that accurately records data.

6.1.6. Biotek ELx 808 endotoxin reader or equivalent and will utilize software that accurately records data.

6.2. Reagents

6.2.1. All reagents, prepared or purchased, will be properly maintained and verified to be within expiration date.

6.3. Expendables

6.3.1. All expendables consumed have been verified to have no negative impact on the testing procedures utilized.

6.4. Standard Materials

6.4.1. All standard materials utilized have been reviewed for accuracy, properly maintained, verified to be within expiration date, and documented to have successfully executed the method for which it is being utilized.

[redacted]

[redacted]

Pentobarpital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarpital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019-[redacted]

7. Sample Storage and Handling

7.1. Sample Storage

7.1.1. Samples will be stored at ICH room temperature conditions, 25°C ± 2°C/RH 60%± 5% and elevated temperature 40°C ± 2°C/RH 75%± 5%. The conditions in the storage area will be monitored electronically for the duration of the study.

7.1.2. Sample will be stored for 365 days at ICH room temperature conditions and ICH elevated temperature conditions for 180 days.

7.2. Sample Handling

7.2.1. Samples will be removed from the storage area at the designated time points by a [redacted] representative. Samples will be obtained by the appropriate testing areas at each time point.

7.2.2. Samples may be required to equilibrate to room temperature before testing.

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019-[redacted]

8. Pre-Production Tasks Required (informational only)

8.1. This protocol is executed under the premise that applicable validations below have been completed before the study is started. The validation dates will be recorded in the final the report. In the event the customer requests that validation work is performed concurrently with the study, the quotation for validation work associated with this compound will serve as the guideline for completion dates. Any study that does not have validation work completed before the starting is considered at risk. In this case, the final report will capture the validation work not complete and the potential impact to the study.

8.2. Potency Validation Extension (Specificity including sample precision)– This testing is required for chromatographic analyses that require assurance that excipients and/or other actives do not interfere with accuracy of the measured active peak. In circumstances where Validation Extension has not been performed a list of required materials will be provided by [redacted] If this testing is not completed before initiating the study, the outcome could nullify the study.

8.2.1. To be executed prior to testing the first time point

8.2.2. Sample amounts not included in Sample Compounding and Experimental Design

8.3. USP <71> Sterility Method Validation/Suitability – This is required for all USP <71> sterility testing. This test will ensure that interfering factors in the formulation do not impede growth and cause false negatives. In circumstances where Method Suitability has not been performed 3 times the number of containers required for sterility testing in Sample Compounding and Experimental Design will be required by [redacted] this does not have to be the same lot as the study. If this testing is not completed before initiating the study, the outcome could nullify the study.

8.3.1. To be executed prior to testing the first time point

8.3.2. Sample amounts not included in Sample Compounding and Experimental Design

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019-[redacted]

9. Sample Compounding and Experimental Design

9.1. Retain Samples and Disposal: Any additional samples will be stored at the same conditions as requested for the study (defined as Retain in the table below). Any remaining samples will be stored and disposed of per current SOP requirements. Samples can be retained longer if specifically requested.

9.2. Retesting Protocol: In the event of a failure the customer will be notified of the failure to determine the best course of action. The study will not be altered or stopped based on any results unless explicitly communicated to [redacted] Retesting may result in a different interval being reported than originally requested.

9.3. Experimental Design

9.3.1. The testing dates may be reasonably adjusted based on laboratory needs to improve efficiency and to preserve quality or to ensure testing is scheduled during operating hours.

9.3.2. USP <71> Sterility amounts are based on a batch size of 50, which is the batch size relayed to [redacted] by the customer to calculate the number of containers required for Sterility Method Suitability.

9.3.3. Initial timepoint for Elevated Temperature Study will be shared with Room Temperature study.

ICH Elevated Temperature	Initial*	Day 45	Day 90	Day 180	Day 365	Retain	Total
Potency/Assay		1	Open	1	Open	1	3
USP <788> Particulate Matter for Injections					1	0	1
USP <85> Bacterial Endotoxin Test					1	0	1
USP <71> Sterility Test						0	0
Standard Sterility Test					1	0	1
						Total Samples Required:	**6**

ICH Room Temperature	Initial	Day 45	Day 90	Day 180	Day 270	Day 365	Retain	Total
Potency/Assay	1	Open	Open	1	Open	Open	1	3
USP <788> Particulate Matter for Injections	1					1	0	2
USP <85> Bacterial Endotoxin Test	1					1	0	2
USP <71> Sterility Test	5						0	5
Standard Sterility Test						1	0	1
							Total Samples Required:	**13**

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019-[redacted]

Potency Testing

9.4. Standard Preparation and System Suitability

9.4.1. Standard preparation and system suitability will be completed per [redacted] SOPs, Policies, and Procedures and will meet all criteria described therein.

9.5. Sample Preparation and Runs

9.5.1. This compound contains 1 active that requires potency testing.

9.5.2. Using the sample portions designated for potency testing, dispense sample into a test tube and dilute, if required, an aliquot of the samples to the working concentration as described in current [redacted] SOPs, Policies, and Procedures utilizing a validated proprietary method.

9.6. Sample Calculations

9.6.1. Calculations are described in current [redacted] SOPs, Policies, and Procedures and will meet all criteria described therein.

9.6.2. Report the potency for the sample on [redacted] website.

9.7. Specifications

9.7.1. System suitability must meet specifications outlined in current [redacted] SOPs, Policies, and Procedures and will meet all criteria described therein.

9.7.2. Results for percent recovery for the active Pentobarbital Sodium must meet specifications of 92.0 – 108.0% as listed within the USP monograph for Pentobarbital Sodium Injection.

9.8. Experimental Design

9.8.1. The designated number of containers is recorded in the table in Sample Compounding and Experimental Design section.

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019-[redacted]

11. USP <788> Particulate Matter in Injections

11.1. Sample Preparation and Runs

11.1.1. The appropriate number of samples and method, *Method 1 Light Obscuration Particle Count Test* or *Method 2 Microscopic Particle Count Test*, will be used to analyze per [redacted] SOPs, Policies, and Procedures, based on USP <788>. If applicable USP <789> will supersede this section.

11.2. Specifications for *Method 1 Light Obscuration Particle Count Test*

11.2.1. For containers considered small volume, 100mL or less, limits below will be applied.

11.2.1.1. Particles ≥ 10 µm or larger cannot exceed 6,000 parts/container

11.2.1.2. Particles ≥ 25 µm or larger cannot exceed 600 parts/container

11.2.2. For containers considered large volume, greater than 100mL, limits below will be applied.

11.2.2.1. For particles ≥ 10 µm max allowable is ≤25 parts/mL

11.2.2.2. For particles ≥ 25 µm max allowable is ≤3 parts/mL

11.3. Specifications for *Method 2 Microscopic Particle Count Test*

11.3.1. For containers considered small volume, 100mL or less, limits below will be applied.

11.3.1.1. Particles ≥ 10 µm or larger cannot exceed 3,000 parts/container

11.3.1.2. Particles ≥ 25 µm or larger cannot exceed 300 parts/container

11.3.2. For containers considered large volume, greater than 100mL, limits below will be applied.

11.3.2.1. For particles ≥ 10 µm max allowable is ≤12 parts/mL

11.3.2.2. For particles ≥ 25 µm max allowable is ≤2 parts/mL

11.4. Experimental Design

11.4.1. The designated number of containers is recorded in the table in Sample Compounding and Experimental Design section.

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019-[redacted]

12. USP <71> Sterility Testing

12.1. Sample Management receives sample and bins out the sample according to test type.

12.2. The sterility scheduler reviews the sample and schedules the sample.

12.3. The samples are prepared and sent into the cleanroom per [redacted] SOPs, Policies, and Procedures, based on USP <71>, and will meet all criteria described therein.

12.3.1. The samples are tested per [redacted] SOPs, Policies, and Procedures and will meet all criteria described therein.

12.3.2. Testing that is not validated at the time of the testing is not compliant with USP <71>.

12.3.3. The specification is Negative at 14 days

12.4. Experimental Design

12.4.1. The designated number of containers is recorded in the table in Sample Compounding and Experimental Design section.

12.4.2. Based on the batch size of 50.

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019-[redacted]

13. USP <85> Bacterial Endotoxin Testing

13.1. Sample Management receives sample and bins out the sample according to test type.

13.2. The endotoxin technician schedules and prepares the sample per [redacted] SOPs, Policies, and Procedures, based on USP <85>, and will meet all criteria described therein.

13.2.1. The result must be ≤ assigned endotoxin release limit per USP based on maximum dose given in an hour and an average adult human weight.

13.2.2. The result must have a CV <20%

13.2.3. The result must have a PPC between 50% - 200%

13.2.4. Information listed within the USP Monograph for Pentobarbital Sodium Injection to help establish the endotoxin limit, is "It contains not more than 0.8 USP Endotoxin Unit per mg of pentobarbital sodium."

13.2.5. [redacted] will use an endotoxin limit of ≤ 40.0 EU/mL as the established endotoxin limit.

13.3. Experimental Design

13.3.1. The designated number of containers is recorded in the table in Sample Compounding and Experimental Design section.

[redacted]

[redacted]

Pentobarbital Sodium 50mg/mL Injectable 50 mL fill in 50 mL Amber Vial; Pentobarbital Sodium; Store 1 lot at ICH Room Temperature and 1 lot at ICH elevated Conditions; Time Study/Protocol 2019 [redacted]

14. Post Production Tasks

14.1. Final Report

[redacted]

[redacted]

CERTIFICATE OF ANALYSIS

[redacted]

Customer:	[redacted]	Storage:	Room Temperature
Received:	04/09/2019	Device/Amount:	vial(s) 1 x 50 ml
Compound:	Pentobarbital Sodium 50mg/mL Injectable	Sample Number:	[redacted]
Lot Code:	[redacted]	DEA:	Yes

RESULTS

Test	Active	Test Spec	Test Result	Test Date	Tech Review Date	Comment
Potency Method Development		Meets Requirements	Meets Requirements	05/14/2019	05/14/2019	

Date Compounded: 4/4/2019

Limited Warranty

[redacted] guarantees the testing services provided are performed satisfactorily for the use for which they are intended. It is the practitioner's responsibility to exhibit professional judgment regarding the release of any product for dispensing purposes. The liability of [redacted] under this warranty is limited to service credit or replacement at the discretion of [redacted] shall not be responsible for incidental or consequential damages of any kind. This warranty is exclusive and in lieu of all other warranties expressed or implied. [redacted] does not make any warranty of merchantability with respect to the products tested, and there are no other warranties extending beyond the description on the face hereof.

Final QA By: [redacted] Date: 05/14/2019

[redacted]

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted] **Product ID:** [redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV

Test / Specification	Results	Test Method	Date Tested
Sterility Sterile / Not Sterile	Sterile	USP <71>	05/16/2019
Particulate Matter ≥ 10 µm: ≤ 6000/container ≥ 25 µm: ≤ 600/container	≥ 10 µm: 343.3/container ≥ 25 µm: 6.7/container	USP <788>	05/17/2019
Potency/Purity 92 – 108%	93.1%	HPLC	05/21/2019
Bacterial Endotoxin NMT 40 EU/mL	< 0.10 EU/mL	USP <85>	06/03/2019

Respectfully,

[redacted]

[redacted]

CERTIFICATE OF ANALYSIS

[redacted]

Customer: [redacted]
Received: 05/15/2019
Compound: Pentobarbital Sodium 50mg/mL Injectable
Lot Code: [redacted]

Storage: Room Temperature
Device/Amount: vial(s) 1 x 50 ml
Sample Number: [redacted]
DEA: Yes

[redacted]

RESULTS

Test	Active	Test Spec	Test Result	Test Date	Tech Review Date	Comment
Validation Extension : HPLC[1]	Pentobarbital Sodium	Meets Requirements	Meets Requirements	06/27/2019	07/03/2019	Sample Precision=1.2%, Recovery=96.3%, Room and Heated Temperature Placebo Height=0.0%

Date Compounded: 5/14/2019

1. This test only applies to the specific container closure and formulation.

Limited Warranty

[redacted] guarantees the testing services provided are performed satisfactorily for the use for which they are intended. It is the practitioner's responsibility to exhibit professional judgment regarding the release of any product for dispensing purposes. The liability of [redacted] under this warranty is limited to service credit or replacement at the discretion of [redacted] shall not be responsible for incidental or consequential damages of any kind. This warranty is exclusive and in lieu of all other warranties expressed or implied. [redacted] does not make any warranty of merchantability with respect to the products tested, and there are no other warranties extending beyond the description on the face hereof.

Final QA By: [redacted]

Date: 07/03/2019

[redacted]

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV – Room Temp

Test / Specification	Results	Test Method	Date Tested
Potency/Purity 92 – 108%	95.5%	HPLC	07/01/2019
pH Trend	10.00	USP <791>	07/08/2019

Respectfully,

[redacted]

[redacted]

Certified Reference Material CRM

[redacted]

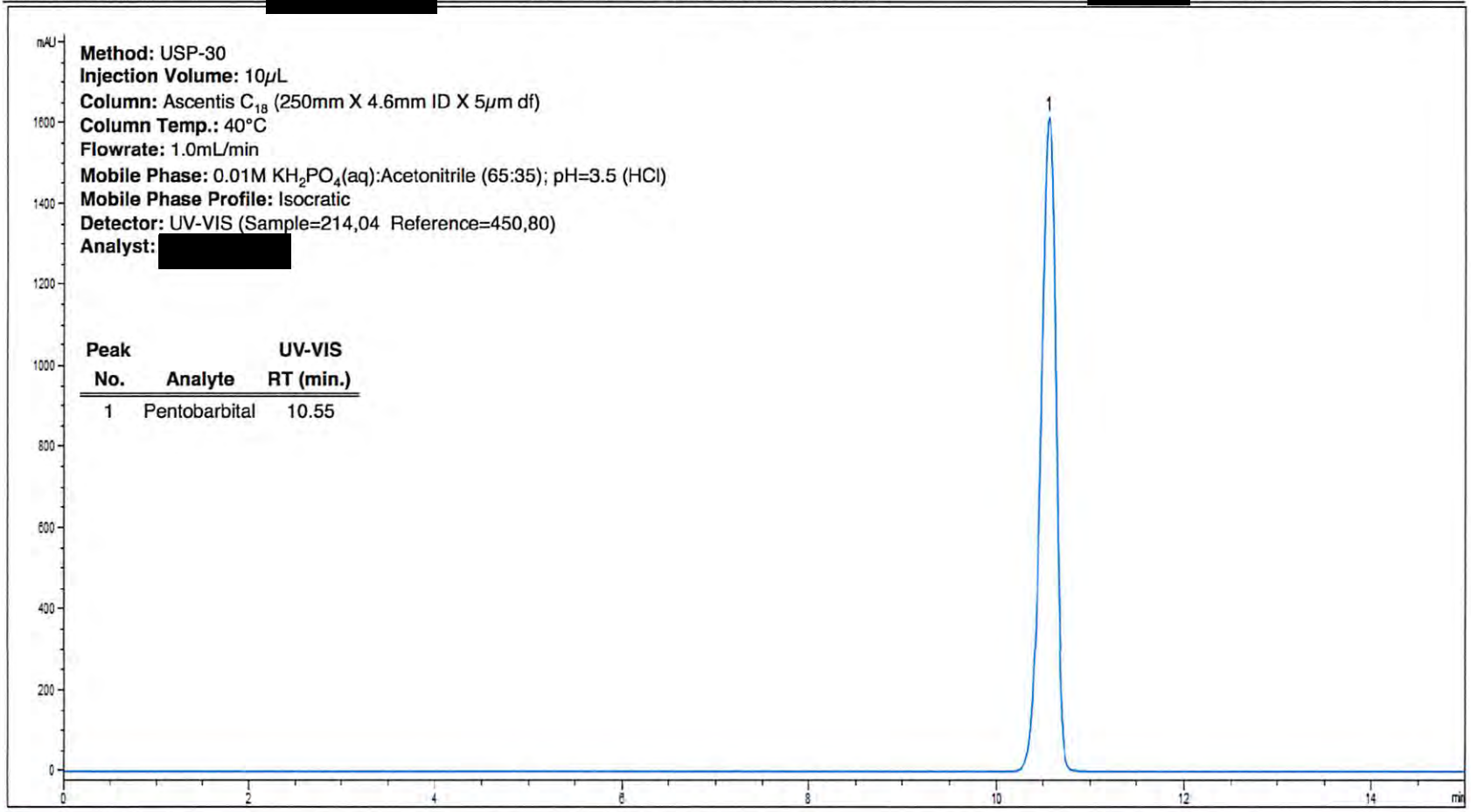
CERTIFIED WEIGHT REPORT

Part Number: [redacted]
Lot Number:
Description: Pentobarbital sodium salt

Expiration Date: 070324
Recommended Storage: Refrigerate (4 °C)
Mass(g): 150.0
NIST Test ID#: [redacted] [redacted] Balance Uncertainty

[redacted]
Formulated By: [redacted] DATE
[redacted]
Reviewed By: [redacted] DATE

Compound	RM#	Lot Number	Purity (%)	Uncertainty Purity (%)	Assay (%)	Target Weight (g)	Actual Weight (g)	SDS Information (Solvent Safety Info. On Attached pg.) CAS#	OSHA PEL (TWA)	LD50
1. Pentobarbital sodium salt	[redacted]		100	0.5	90.7	150.0000	150.0000	[redacted]	N/A	N/A



Peak No.	Analyte	UV-VIS RT (min.)
1	Pentobarbital	10.55

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV – Elevated Temp

Test / Specification	Results	Test Method	Date Tested
Potency/Purity 92 – 108%	90.8%	HPLC	07/10/2019
pH Trend	9.91	USP <791>	07/03/2019

Respectfully,

[redacted]

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV - Room Temp

Test / Specification	Results	Test Method	Date Tested
Potency/Purity 92 – 108%	94.6%	HPLC	08/21/2019
pH Trend	10.03	USP <791>	08/13/2019

Respectfully,

[redacted]

[redacted]

Certificate of Analysis

Client: [redacted]

[redacted]

Lot Number: [redacted]

Description: Pentobarbital Sodium 50 mg/mL Injection Solution SDV – Elevated Temp

Test / Specification	Results	Test Method	Date Tested
Potency/Purity 92 – 108%	92.2%	HPLC	08/21/2019
pH Trend	10.12	USP <791>	08/14/2019

Respectfully,

[redacted]

BOP EXECUTION PROTOCOL

 2019

Federal Bureau of Prisons
Execution Protocol Manual

INTRODUCTION: GENERAL PROVISONS

I. Purpose of Manual

The purpose of this manual is to outline Federal Bureau of Prisons (BOP) policy and procedures for planning and carrying out the execution of a person convicted of a capital offense. These procedures should be observed and followed as written unless deviation or adjustment is required, as determined by the Director of the BOP or the Warden. This manual explains internal government procedures and does not create any legally enforceable rights or obligations.

II. Organization

This manual provides specific time related checklists for pre-execution, execution and post execution procedures as well as detailed procedures related to the execution process, command center operations, contingency planning, news media procedures, and handling stays, commutations and other delays.

III. Cross References

A. Title 28, Code of Federal Regulations, Chapter 1, Part 26

B. Title 28, Code of Federal Regulations, Chapter 1, Part 1

C. Correctional Systems Manual – Program Statement 5800.15, Paragraph 803

D. Searching, Detaining, or Arresting Visitors to Bureau Grounds and Facilities – Program Statement 5510.09

E. News Media Contacts – Program Statement 1480.05

F. Accounting Management Manual – Program Statement 2000.02, Chapter 10950

G. Receiving and Discharge Manual – Program Statement 5800.18

IV. Procedure

A. The BOP will ensure the execution of a person sentenced to death under federal law by a court of competent authority and jurisdiction be carried out in an efficient and humane manner.

B. The BOP will make every effort in the planning and preparation of an execution to ensure the execution process:

1. Faithfully adheres to the letter and intent of the law;

2. Is handled in a manner that minimizes the negative impact on the safety, security, and operational integrity of the correctional institution in which it occurs and the BOP in general;

3. Accommodates the public's right to obtain information concerning the event;

4. Reasonably addresses the privacy interests of those persons for whom the law and BOP policy require such privacy;

5. Provides sufficient contingency planning to ensure that unforeseen problems can be addressed and overcome;

6. Allows for stays of execution, commutations and other delays in the execution countdown;

7. Provides an opportunity for interested person to exercise their First Amendment rights to demonstrate for or against capital punishment in a lawful manner; and

8. Ensures a firm and adequate response to unlawful civil disobedience, trespass, or other violations of the law by persons attempting to disrupt or prevent the execution.

C. The BOP will seek the arrest and encourage the prosecution of persons, including but not limited to those, who:

1. Violate prohibitions against filming, taping, broadcasting, or otherwise electronically documenting the death of the inmate;

2. Trespass or otherwise enter upon BOP property without proper permission and clearance from the Warden;

3. Participate in unlawful demonstrations;

4. Unlawfully attempt to disrupt, prevent, or otherwise interfere with the execution;

5. Are inmates involved in disruptive, assaultive, or other unlawfully proscribed behavior related to an execution; or

6. Unlawfully threaten, intimidate, or terrorize persons involved in the execution process.

D. BOP staff involved in the execution will make every effort, within the limits of these procedures and the laws of the United States, to:

1. Display appropriate levels of professionalism, restraint, and courtesy, in interaction with witnesses, demonstrators, news media, and other persons during the execution process;

2. Prevent emotion or intimidation from hindering efforts to carry out assigned duties; and

3. Conduct themselves at all times in a manner reflecting the solemnity and sensitivity of the occasion.

E. BOP staff trained in crisis support will be available for counseling sessions with all personnel participating directly in an execution process, before and after an execution.

CHAPTER 1: PRE-EXECUTION CHECKLIST

I. General Provisions

A. Purpose of Chapter

1. The purpose of this chapter is to provide a checklist of procedures and events that should occur between the period of time prior to the establishment of an execution date and 24 hours prior to the execution.

2. Full detail will not be provided for each procedure or event in this chapter. For detail, refer to specific chapters which follow.

3. This chapter covers the following time periods:

   a. Prior to the execution date being established;

   b. Establishment of the execution date to thirty days prior to the execution;

   c. Twenty-nine to fourteen days prior to the execution;

   d. Thirteen to seven days prior to the execution;

   e. Six to three days prior to the execution; and

   f. Forty-eight to twenty-four hours prior to the execution.

B. Procedure

1. A systematic countdown to an execution must be completed to ensure that all procedures and events necessary to adequately prepare for the execution are completed in a timely manner.

2. Absent intervention by the court system or the President as noted in Chapter 7, delays in the countdown process will only occur in extraordinary situations relating to the security and good order of the institution as approved by the Director of the BOP.

II. Establishing of an Execution Date

After a sentencing hearing is conducted in a United States District Court resulting in a determination that a criminal defendant be sentenced to death for commission of an offense described in a federal statute, and the sentencing judge signs the appropriate Judgment and Order:

A. Except to the extent a court orders otherwise, the Director of the BOP will designate a date and time for the execution of the sentence. The following individuals/offices will be advised in writing of the execution date: the sentencing judge, Attorney General, Office of the Deputy Attorney General, Office of the Pardon Attorney, the Assistant Attorney General for the Criminal Division, the Chief of the Capital Case Unit, Director for the United States Marshals Service (USMS), the Office for Victims of Crime, Assistant Director for Correctional Programs Division, Assistant Director for General Counsel and Review Division, appropriate Regional Director, United Sates Attorney's Office for the district of conviction, United Sates Attorney's Office for the Southern District of Indiana and Warden of USP Terre Haute.

B. Under current federal regulations, the date established will be no sooner than 60 days from the entry of the judgment of death (28 C.F.R.§ 26.3 (a) (1)) and notice of it must be given to the defendant no later than 20 days before the execution (28 C.F.R.§ 26.4 (a)). If the date designated passes by reason of a stay of execution, then a new date will be promptly designated by the Director of the BOP when the stay is lifted.

C. The Warden of USP Terre Haute will notify, in writing, the inmate under sentence of death, of the date designated by the Director for execution at least 90 days in advance. If the designated execution date is stayed, notice of the new execution date must be given no later than 20 days before the execution, if time permits and if not, as soon as possible. If the execution date is set by a judge, the Warden will notify the inmate, in writing, as soon as possible. The Warden will include information concerning the clemency application process in the written notice. Under 28 C.F.R. §1.10(b), a petition for commutation of sentence should be filed no later than 30 days after the inmate has received notification from the Warden of the execution date.

D. Unless the President interposes, the execution of the sentence will not be stayed on the basis of the inmate filing a petition for executive clemency.

III. Period of Time Between Establishment of an Execution Date to Thirty Days Prior to the Execution

The following procedures should be completed between the time an execution date is set and 30 days prior to the execution.

A. Briefing the Inmate

As soon as practical after establishment of the execution date, the Warden at USP Terre Haute or designee, will personally brief the inmate regarding relevant aspects of the execution process including information contained in items C through F of this section. A briefing sheet outlining these aspects of the execution will be given to the inmate. If requested, a copy of the briefing sheet will be given to a representative identified by the inmate. In addition, the Warden will ascertain the inmate's religious preference.

B. Inmate's Choice of Witnesses

When the inmate is informed by the Warden of the execution date, he/she will be advised that he/she may designate not more than one spiritual adviser, two defense attorneys, and three adult friends or relatives (at least 18 years old) to be present at the execution. The inmate will be asked to submit the list of his/her witnesses to the Warden no later than 30 days after notification of the date of the scheduled execution.

C. Disposition of Person Property and Accounts

The Warden will review the options available to the inmate for property/account distribution and will ask the inmate to provide instructions, no later than 14 days prior to the execution, concerning the disposition of the personal property and funds in any accounts controlled or administered by the BOP. If the inmate fails to provide instructions for such disposition, the property/accounts will be disposed on in accordance the Accounting Management Manual and the Receiving and Discharge Manual.

D. Organ Donation

The inmate's body will not be used for organ donation.

E. Disposition of Body

The Warden will review options available to the inmate following the release of the body to the Vigo County Coroner. The Warden will ask the inmate to provide instructions concerning disposition of his/her body no later 14 days prior to the execution. If the inmate fails to provide instructions, the body will be handled in accordance with the Accounting Management Manual.

F. Designation of Persons Required to Assist with the Execution

1. Those persons necessary to carry out the execution will be identified.

   a. The Warden, with the assistance of the Director, USMS, and the Director, BOP, will be responsible for identifying, selecting and obtaining the services of the individuals administering the lethal injection.

   b. The Warden, in conjunction with the Regional Director, is responsible for selection of the local staff involved in perimeter security, transportation, and command post operations, as well as crowd control, support functions and access screening.

2. All individuals identified for placement in vital or important positions and identified alternates, will be attired in a uniform as determined by the presiding Regional Director.

3. No officer or employee of the Department of Justice will be required to be in attendance at or participate in any execution if such attendance or participation is contrary to the moral or religious convictions of the officer or employee. Staff participation in the execution process must be on a voluntary basis.

G. Other Approved Witnesses

1. In addition to the United States Marshal designated by the Director of the USMS (hereafter called the "Designated United Sates Marshal") and the Warden, the following persons will be present at the execution.

   a. Necessary personnel selected by the Designated United States Marshal and the Warden.

   b. Those attorneys of the Department of Justice whom the Deputy Attorney General determines are necessary.

   c. Not more than the following members of persons selected by the Warden:

      (1) Up to eight citizens (in identifying these individuals, the Warden, no later than 30 days after the setting of an execution date, will ask the United States Attorney for the jurisdiction in which the inmate was prosecuted to recommend up to eight individuals who are victims

or victim family members to be witnesses of the execution); and

(2) Ten representatives of the press.

2. No other person will be present at the execution unless such person's presence is granted by the Director of the BOP. No person younger than 18 years of age will witness the execution.

3. The Warden will notify all witnesses of the date, time and place of the execution as soon as practicable before the designated time of execution.

H. Contact with the Vigo County Coroner

1. The Warden will contact the Vigo County Coroner to coordinate the Coroner's role.

2. The Vigo County Coroner will be requested to provide direction concerning:

a. Transfer of custody of the body of the executed individual from the Warden to the Vigo County Coroner;

b. Transportation of the body from the Execution Room to the Vigo County Coroner's facility; and

I. Briefing of Institution Staff

1. It is necessary to modify prison operations and communicate with local staff throughout the execution process.

2. Local prison administrators should be briefed by the Warden, as appropriate, on plans for the execution, restrictions on access, crowd control, additional security procedures, etc., on an on-going basis.

3. As soon as plans begin to evolve which will affect general prison operations, briefings should begin and continue until operations return to normal.

IV. Period of Time Between Twenty-Nine to Fourteen Days Prior to the Execution

A. Witnesses

1. To the extent possible, the Warden will develop a final list of citizen and inmate's witnesses.

2. All witnesses/participants will be required to sign an agreement prior to being cleared and added to the witness list. Included in the document will be an agreement to be searched before entering the Execution Facility and not to photograph or make any other visual or audio recording of the execution (see Appendix A.).

B. Qualified Person

The Warden will finalize arrangements for a qualified person to be present at the execution and to declare the executed individual deceased.

C. Inmate's Property and Account

The Warden will finalize arrangements for disposition of the inmate's property and accounts no later than 14 days prior to the scheduled execution date.

D. Disposition of Body

The Warden will finalize arrangements with the Vigo County Coroner for disposition of the body, security for the Vigo County Coroner's vehicle, and transfer of custody of the body in accordance with appropriate state and local laws.

E. Selection of Executioner (s)

The Warden, with the assistance of the Regional Director, Director and USMS will finalize the selection of executioner(s) and their alternates.

F. Training

The Regional Director will ensure that appropriate training Sessions are held for persons involved in the various aspects of the execution event.

V. Period of Time Between Thirteen to Seven Days Prior to the Execution

A. Inmate's Property and Accounts

All paperwork regarding disposition of property and accounts should be completed.

B. Food Services

At least seven days prior to execution, the Warden or designee will contact the inmate to arrange for his/her last meal.

C. Purchase of Substances to be Used in Lethal Injection

The Bureau of Prisons will ensure the purchase of lethal substances to be used in the execution. Once purchased, the lethal substance or substances will be secured in the institution until called for by the Regional Director.

D. Law Enforcement Coordination

1. The Warden will meet with federal, state, and local law enforcement personnel to coordinate support related to the execution.

2. Joint practices should be conducted between law enforcement staff involved to ensure coordination and interaction is well defined and understood.

E. Restrictions on Inmate's Visitors

Beginning seven days prior to the designated date of execution, the inmate will have access only to his/her spiritual advisers (not to exceed two), his/her defense attorneys, members of his/her family, and designated officers and employees of the BOP. Upon approval of the Director of the BOP, the Warden may grant access to such other proper persons as the inmate may request.

VI. Period of Time Between Six to Three Days Prior to the Execution

A. Witnesses

Non-media witness agreements should be signed by the witnesses and reviewed by the Regional Director.

1. The Warden will provide a final list of witnesses to the:

a. Director, Bureau of Prisons

b. Assistant Director, Correctional Programs Division;

c. Assistant Director, Information, Policy, and Public Affairs Division;

d. Assistant Director, Office of General Counsel

e. Director, USMS; and

f. Designated United States Marshal

g. United States Attorney's Office – district of conviction

h. United States Attorney's Office- Southern District of Indiana

2. Persons who refuse to sign agreements will not be allowed to attend the execution.

B. Brief Affected Law Enforcement Agencies

The Warden will ensure that staff from other law enforcement agencies who have not participated in practice session or have not otherwise been briefed previously will be briefed and their responsibilities explained.

C. Inmate's Property and Accounts

Verify arrangements are complete.

D. Executioner(s)

An individual designated by the Warden will:

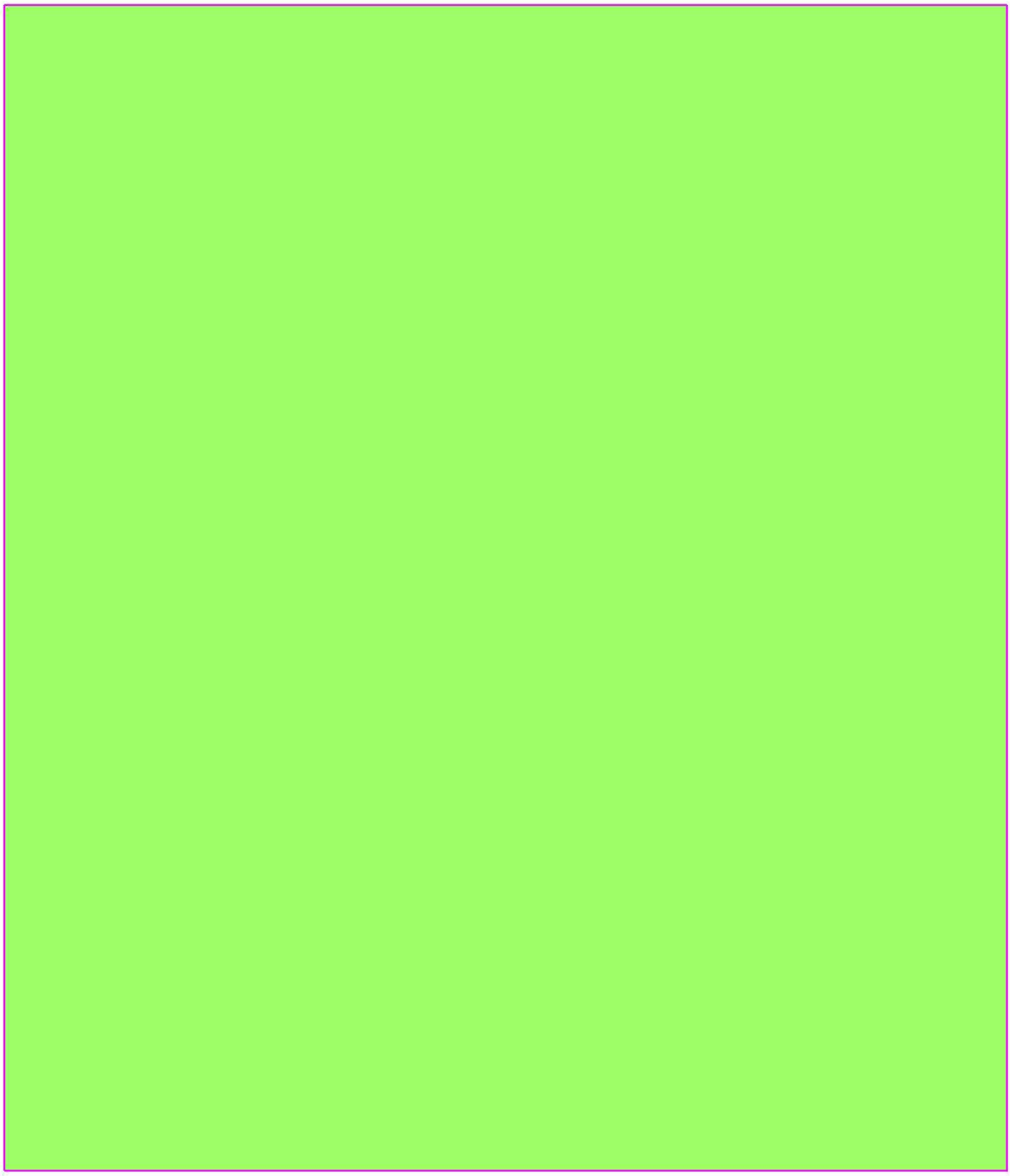
1. Review with executioner(s) and alternates arrangements for their transportation and escort to the Execution Facility; and

2. Review with participants' arrangements for security of executioner(s) and protection of their identities.

E. Equipment Check/Inventory

All equipment necessary to conduct the execution will be inventoried and checked at least 72 hours prior to the execution by individuals designated by the Regional Director.

VII. Period of Time Between Two Days to One Day Prior to the Execution



B. Practices

Final practices will be conducted as directed by the Regional Director.

C. Equipment Checks

Maintenance staff should verify necessary installation of and test electrical, heating/air conditioning, backup generator and communications equipment in:

1. BOP Execution Facility;

2. Command Center.

D. Regional Director and/or Warden Contacts

1. To ensure that coordination efforts are in place, the following entities and specifically identified individuals will be contacted by the Regional Director and/or the Warden:

   a. Department of Justice Command Center (to ensure communications, if required, by the Attorney General, the Supreme Court, the President of the United States and the affected United States Attorneys Offices);

   b. BOP Director's Office;

   c. USMS Director's Office; and

   d. Affected law enforcement agencies.

E. Equipment Check Verification by the Regional Director

1. The Regional Director will ensure completion of pre-execution inventory and equipment check in the BOP Execution Facility.

2. The Regional Director will verify that the Execution Facility's equipment checks have been completed.

CHAPTER 2: EXECUTION CHECKLIST

I. General Provisions

A. Purpose of Chapter

1. This chapter provides a checklist of procedures and events that should occur during the final 24 hours prior to the execution.

B. Procedure

The execution will be carried out in a manner consistent with Title 28, Code of Federal Regulations, Part 26.

II. Period of Time Within Twenty-Four Hours Prior to the Execution

B. Inmate Communication

1. Excluding calls to the inmate's attorney(s) of record and calls specifically approved by the Warden, the inmate's telephone privileges will be terminated 24 hours prior to the execution.

2. The inmate's attorney(s) of record, spiritual adviser(s), or other persons approved by the Director of the BOP, will be given visiting privileges during the final 24 hours as determined by the Warden. Visiting privileges will be suspended when preparations for the execution require suspension.

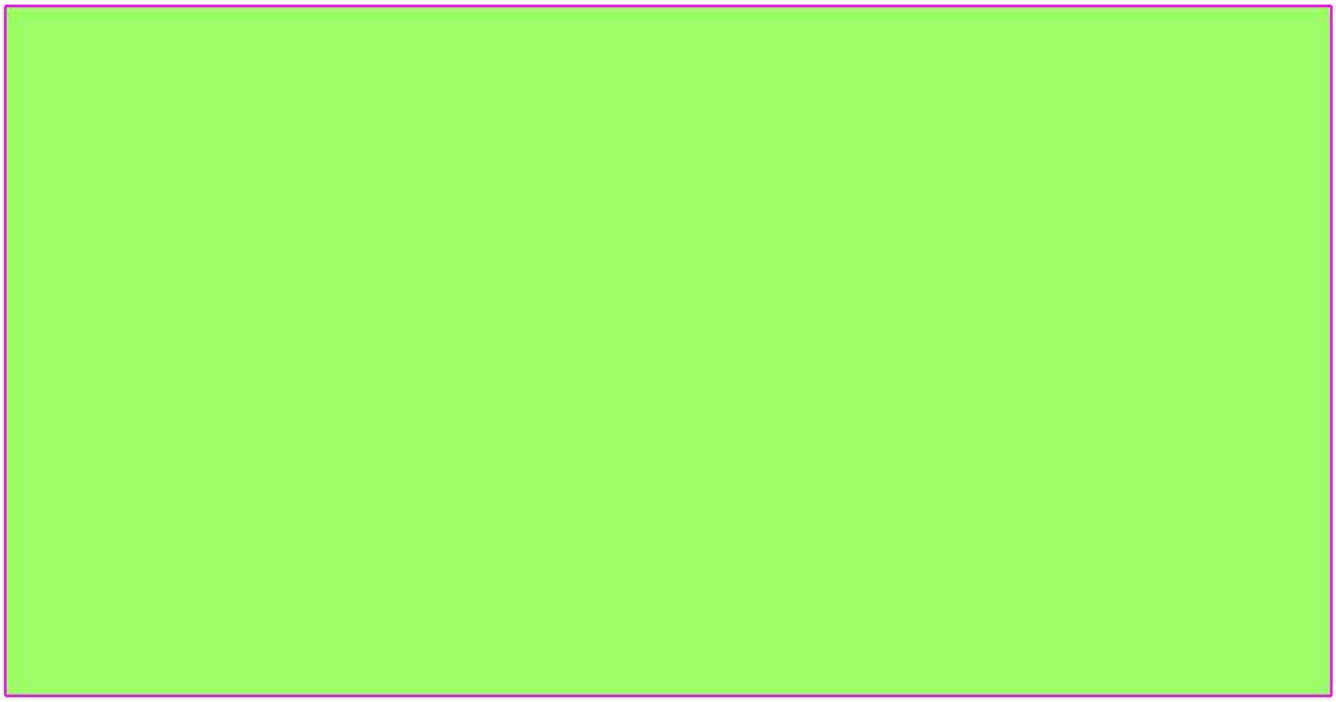
C. Food Service

The Warden will contact the inmate to finalize arrangements for his/her final meal and ensure that it is properly prepared and served by staff.

D. Maintenance Response Team

Beginning eight hours prior to an execution, the Facility Manager or other appropriate individual will ensure that a Maintenance Response Team is available to provide necessary maintenance and repair of systems at the Execution Facility or in other areas of the institution.

E. Access to the Execution Facility



III. Period of Time Between Twelve to Three Hours Prior to the Execution

A. Final Briefing

2. A final briefing will be held, attended by senior BOP and Marshals Service staff, the Regional Director, and representatives deemed appropriate by the Regional Director. The Regional Director will conduct the meeting, with the senior staff providing guidance and policy decisions, as needed.

3. During the briefing, participants will:

   a. Identify problems, develop solutions, and specific time lines;

   b. Provide status reports;

   c. Coordinate support services involvement; and

   d. Conduct a final review of procedures.

B. Food Service

The inmate will be served a final meal at a time determined by the Warden.

C. Visits

Visits by attorneys, religious representatives, and other persons approved by the Director of the BOP, will be at the discretion of the Warden.

D. Restricting Access to Prison Property

1. At the discretion of the Warden, during the final 12 hours prior to the execution, access to prison property will be limited to:

   a. On-duty staff;

   b. On-duty contract workers;

   c. Volunteers deemed necessary by the Warden;

   d. Approved delivery vehicles;

   e. Law enforcement personnel on business-related matters;

   f. Routine inmate visitors; and

   g. Other persons approved by the Warden.

2. During the final eight hours:

   a. All off-duty Department of Justice personnel will be required to leave institution property;

E. Establishment of Command Center

IV. Period of Time Between Three Hours to Thirty Minutes Prior to the Execution

A. Pre-Execution Procedures

1. The Regional Director will ensure that all countdown procedures for required activities and actions are progressing.

2. Immediate action to complete any unfinished required procedures will be initiated.

3. The Warden will designate a recorder who will begin logging execution activities in the official execution log commencing three hours prior to the scheduled execution. The log will reflect, at a minimum, the time each of the following events occurs:

a. Inmate removed from Inmate Holding Cell;

b. Inmate strapped to gurney;

c. Arrival of government/community witnesses;

d. Arrival of inmate's authorized witnesses;

e. Arrival of media witnesses;

f. Opening of drapes;

g. Last statement by inmate;

h. Reading of statement conveying inmate's sentence of death;

i. Upon Designated United States Marshal's approval, the execution process begins;

j. Signal by Executioner(s) that lethal substances have been administered;

k. Determination of inmate's death by designated qualified person;

l. Announcement of death of inmate;

m. Closing of drapes;

n. Notification of outside media and demonstrators of inmate's death;

o. Removal and transportation of media witnesses to media center;

p. Removal of inmate's authorized witnesses;

q. Removal of government/community witnesses;

r. Restraint Team/Vigo County Coroner enter Execution Room to remove body;

s. Removal of body to Vigo County Coroner's vehicle;

t. Performance of any necessary cleaning chores;

u. Directive by Warden to secure Execution Facility.

B. Execution Room Staff Assemble

1. The Executioner(s) will be escorted into the Execution Facility and will inventory supplies and ensure that everything is ready.

3. All other Execution Room staff will be assembled on-site for final instructions at least forty five minutes prior to the scheduled execution.

C. Contact with the Department of Justice Command Center

[redacted]

V. The Final Thirty Minutes Prior to the Execution

A. Final Sequence of Events: Preparation

1. Bringing the Inmate to the Execution Room

At the appropriate time, the inmate will be:

a. Removed from the Inmate Holding Cell by the Restraint Team;

b. Strip-searched by the Restraint Team and then dressed appropriately;

c. Secured with restraints;

d. Escorted to the Execution Room by the Restraint Team.

2. Restraint Team Procedures And Preparation

   a. In the Execution Room the ambulatory restraints will be removed and the inmate will be restrained to the Execution Table.

   b. The inmate will then be assessed and prepared for execution by qualified medical personnel.

3. Admit Witnesses

   a. Subsequent to appropriate search procedures, witnesses will be admitted to the witness rooms.

   b. The government/community witnesses will then enter and will be escorted to their assigned area. The escorts will remain with the witnesses.

   c. The authorized witnesses invited by the inmate individual will be admitted and escorted to their assigned area.

      1. If any of the inmate's invited witnesses wish to be on-site, but not actually witness the execution, accommodations will be made for them by the Warden.

      2. Escorts will remain with the inmate's witnesses. There will be a minimum of two escorts for each witness group.

   d. The last witnesses to be admitted will be the news media representatives. The members of the news media selected to witness the execution will be escorted to their assigned area. Escorts will remain with the news media witnesses and ensure their separation from the other witnesses while at the Execution Facility. Media witnesses will not be permitted to interview or question staff or other witnesses while at the Execution Facility.

VI. Final Sequence of Events: Execution

A. Staff Witnesses

1. Staff participating in the preparation for the execution will exit the Execution Room but stand by in an adjacent area.

2. Staff members participating in and/or observing the execution will include the:

a. Designated United States Marshal;

b. Senior BOP Official;

c. Executioner(s);

d. Other staff authorized by the Director of the BOP.

B. Countdown

1. Upon the direction of the Senior BOP Official, staff inside the Execution Room will open the drapes covering the windows of the witness rooms.

2. The inmate will be asked if he/she has any last words or wishes to make a statement. The inmate will have been advised in advance that this statement should be reasonably brief.

3. At the conclusion of the remarks, or when a determination is made to proceed, the documentation deemed necessary to the execution process will be read. Once the Designated United States Marshal makes a final determination that the execution is to proceed, the executioner(s) will be directed to administer the lethal injection.

4. If the execution is ordered delayed [redacted] the Designated United State Marshal will notify the Senior BOP Official who will in turn instruct the Executioner(s) to step away from the execution equipment and will notify the inmate and all present that the execution has been stayed or delayed.

C. Determination of Death

1. After the lethal injection has been administered:

a. The inmate will be monitored until apparent signs of life have ceased;

b. The time of death will be announced prior to the drapes being closed.

2. The Designated United States Marshal will complete and sign the Return described in 28 C.F.R. § 26.2(b) and will file such document with the sentencing court.

CHAPTER 3: POST-EXECUTION CHECKLIST

I. General Provisions

A. Purposes of Chapter

The purpose of this chapter is to:

1. Provide the procedures to be followed after the execution of the inmate;

2. Identify the responsibilities for tasks to be completed; and

3. Provide for the transfer of the body of the inmate from the custody of the BOP.

B. Procedure

It is the procedure of the BOP that:

1. The inmate will be examined by a specified qualified person following the administration of the lethal substances to ensure that death has occurred;

2. When the qualified individual is satisfied that death has occurred, the time of death will be announced to the witnesses;

3. The witnesses to the execution will then be removed from the Execution Facility and returned to their individual staging areas so that they may leave the institution. News media witnesses will be removed to a secondary press location where they will participate in a press briefing;

4. The body of the inmate will be surrendered to the Vigo County Coroner;

5. After removal of the body, the site will be cleaned and restored to its previous condition.

II. Removing Witnesses from the Execution Facility

A. After the pronouncement of death, the witnesses will be escorted from the facility in the following order:

1. News media witnesses;

2. Inmate's authorized witnesses; and

3. Government/community witnesses.

B. Each group of witnesses will be kept separate from the others and escorted to waiting vehicles to be driven to separate designated sites.

III. Removal of the Body of the Inmate

A. After the witnesses have departed, the restraints will be removed from the inmate's body.

B. The Vigo County Coroner or designee will be escorted into the Execution Facility. The body will be removed by the Vigo County Coroner, who will place it in a coroner's vehicle for transportation.

IV. Site Clean-Up

A. Under the supervision of an individual designated by the Warden, staff will clean and secure the Execution Facility.

B. The Execution Facility will be locked and secured when the Warden is satisfied that clean-up has been completed.

V. Returning to Routine Operations

A. Following the execution, Department of Justice and BOP staff involved in the execution will be deactivated, as appropriate, under direction of the DOJ, BOP and USMS staff on-site.

B. The designated public affairs representative will determine when to secure the media assembly site after the news conference is complete.

C. The Warden will bring the institution security back to routine operations as he/she sees fit.

CHAPTER 4: Command Center

I. General Provisions

A. Purpose of Chapter

The purpose of this chapter is to:

1. Identify the role and function of the Command Center;

2. Specify the individuals authorized to staff the Command Center; and

3. Provide an inventory of the minimum resources required in the Command Center.

B. Procedure

It is the procedure of the BOP that:

1. The Bureau operate a local, emergency Command Center during the execution operation to:

   a. Coordinate security, transportation, crowd control, access and other processes;

   b. Provide policy and procedural advice, as needed, or upon request;

   c. Coordinate inter-agency functions; and

   d. Serve as an information processing and operations information center for the execution.

II. Location, Role and Function

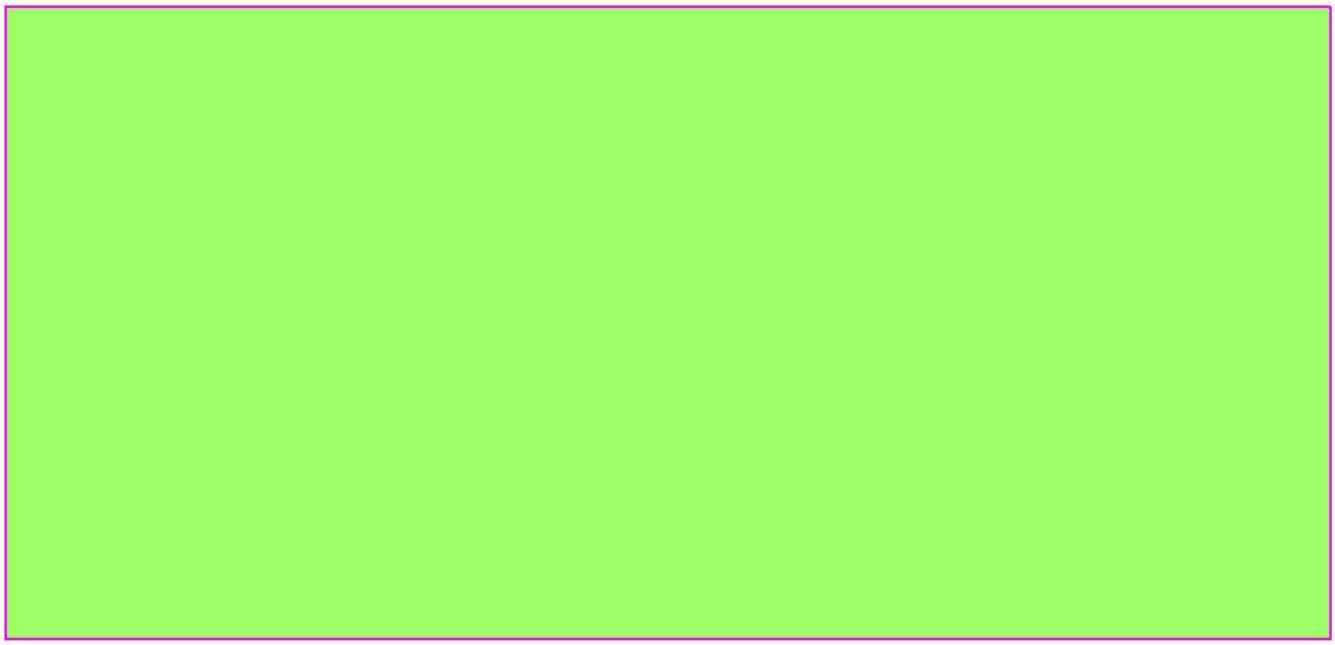
A. The Command Center will be operational prior to the scheduled execution and maintained for the duration of the execution operation.

B. The roles and functions of the Command Center include:

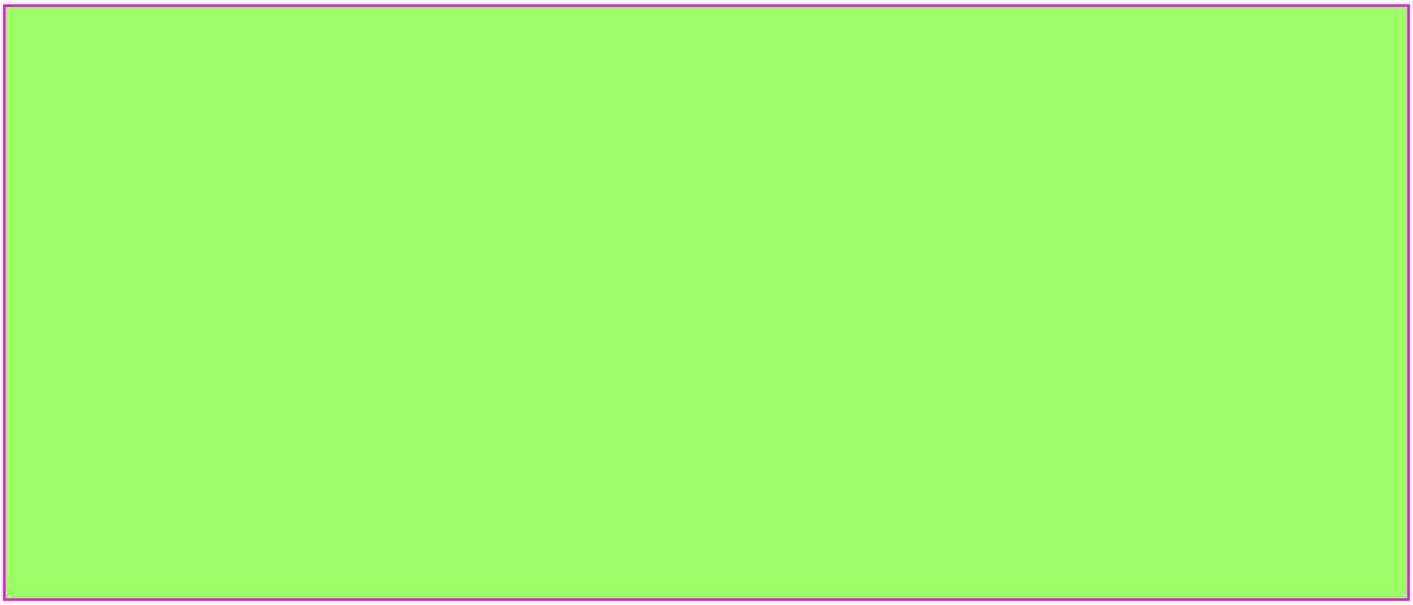
1. Coordinating the various personnel, components and elements of the execution operation;

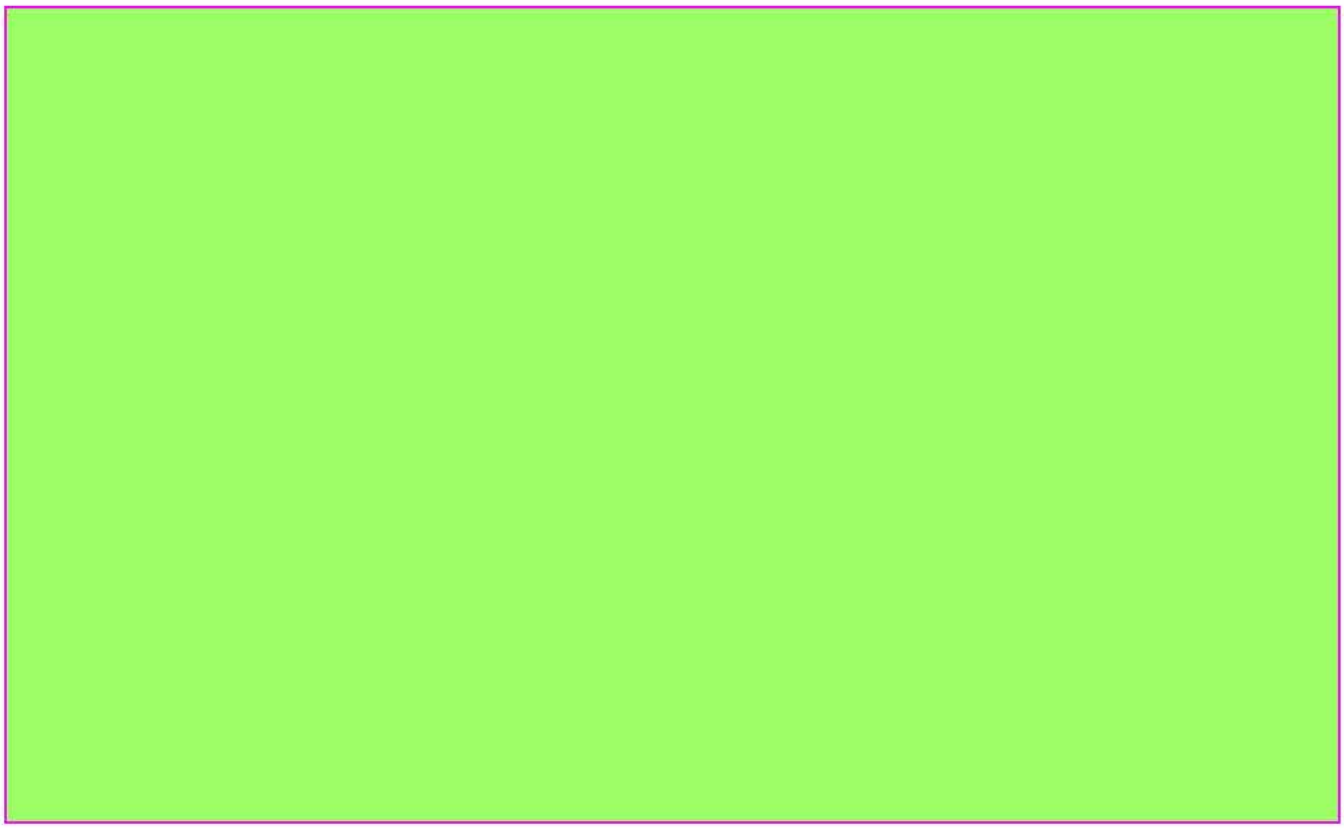
III. Command Center Staffing

A. Command Center staff should include the following positions:



B. Access to the Command Center will be limited to persons specifically authorized by the Command Center Director or Warden.





CHAPTER 5: CONTINGENCY PLANNING

I. General Provisions

A. Purpose of Chapter

The purpose of this chapter is to:

1. Aid in the development of a predetermined contingency plan to assist staff in the management of the execution event and in responding to related emergency situations;

2. Identify the role and function of staff needed to formulate and activate the plan, if needed; and

3. Identify specific areas to stage staff and equipment. The location of witness processing will be pre-determined by the Warden on a case-by-case basis.

B. Procedure

It is the procedure of the BOP to:

1. Prepare and test contingency plans;

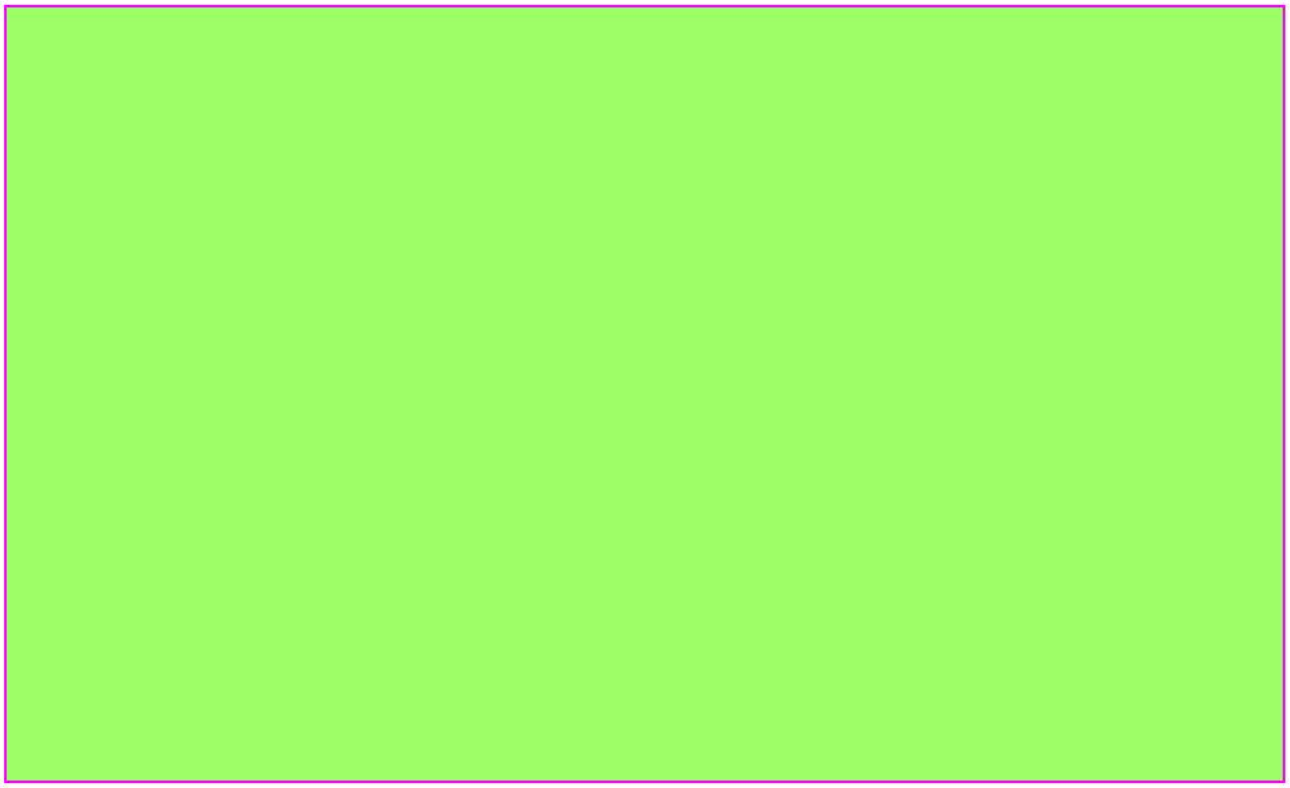
2. Identify all security measures needed to protect staff and inmates of an institution as well as BOP property; and

3. Coordinate all resources to ensure the safety of the public, staff, and inmates.

II. Specific Procedures

A. An individual identified by the Warden will prepare contingency plans related to an emergency occasioned by the execution, such as an institution disturbance, hostage taking, outside demonstration, outside assault on the facility, etc. All plans will be reviewed and approved by the Warden and the Regional Director.

B. Plans will include provisions for:



C. Intelligence Operations

[redacted]

D. Staging Areas

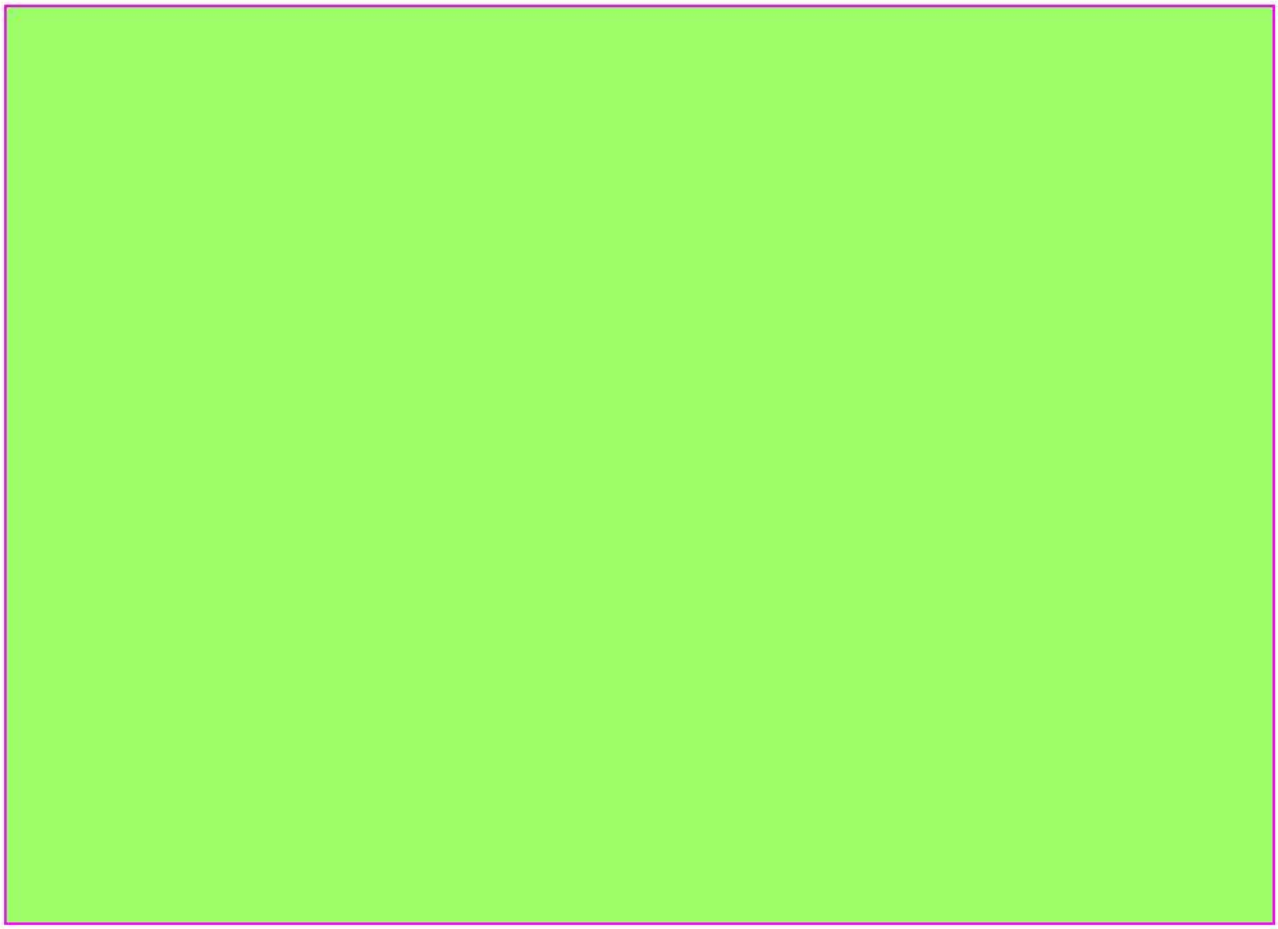
[redacted]

E. Tactical Deployment

[redacted]

III. Execution Witness Management

[redacted]



4. While all witnesses to the execution are subject to search, no pat or visual search of any witness will be conducted unless the Warden has reasonable suspicion to believe the witness is concealing weapons, drugs, audio or visual recording devices, or any other item not expressly authorized and the witness agrees to be searched. If the witness refuses to be searched, he/she will not be permitted to serve as a witness.

5. Staff at each staging area will notify the Command Center when all execution witnesses are accounted for and processed.

6. Escorts will remain at their assigned staging areas until the Command Center directs them to transport the witnesses to the Execution Facility.

B. Transportation to the Execution Facility

3. Escorts will ensure that witness groups do not come into contact with each other.

4. Escorts will transport witnesses to the Execution Facility and notify the Command Center when each group of witnesses is secured in the assigned observation area.

5. Once each group is secured, the next group will be moved as directed by the Command Center.

6. The Command Center will be notified by the appropriate staff member when all groups are in place.

7. The Command Center, in turn, will notify the Warden or designee.

C. Transportation from the Facility

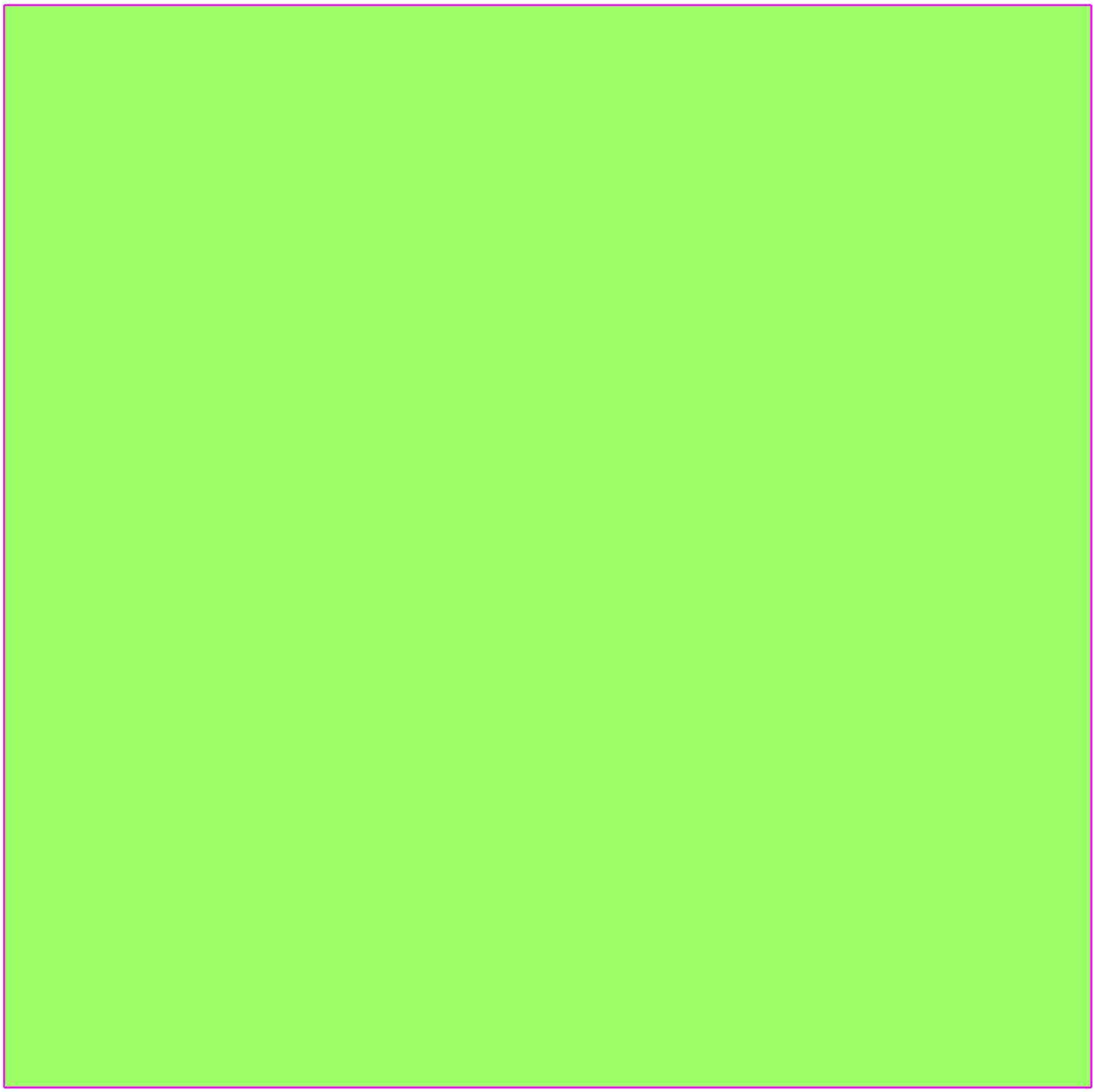
2. The groups will be returned to the staging areas by the escorts, who will ensure that no group comes in contact with another group.

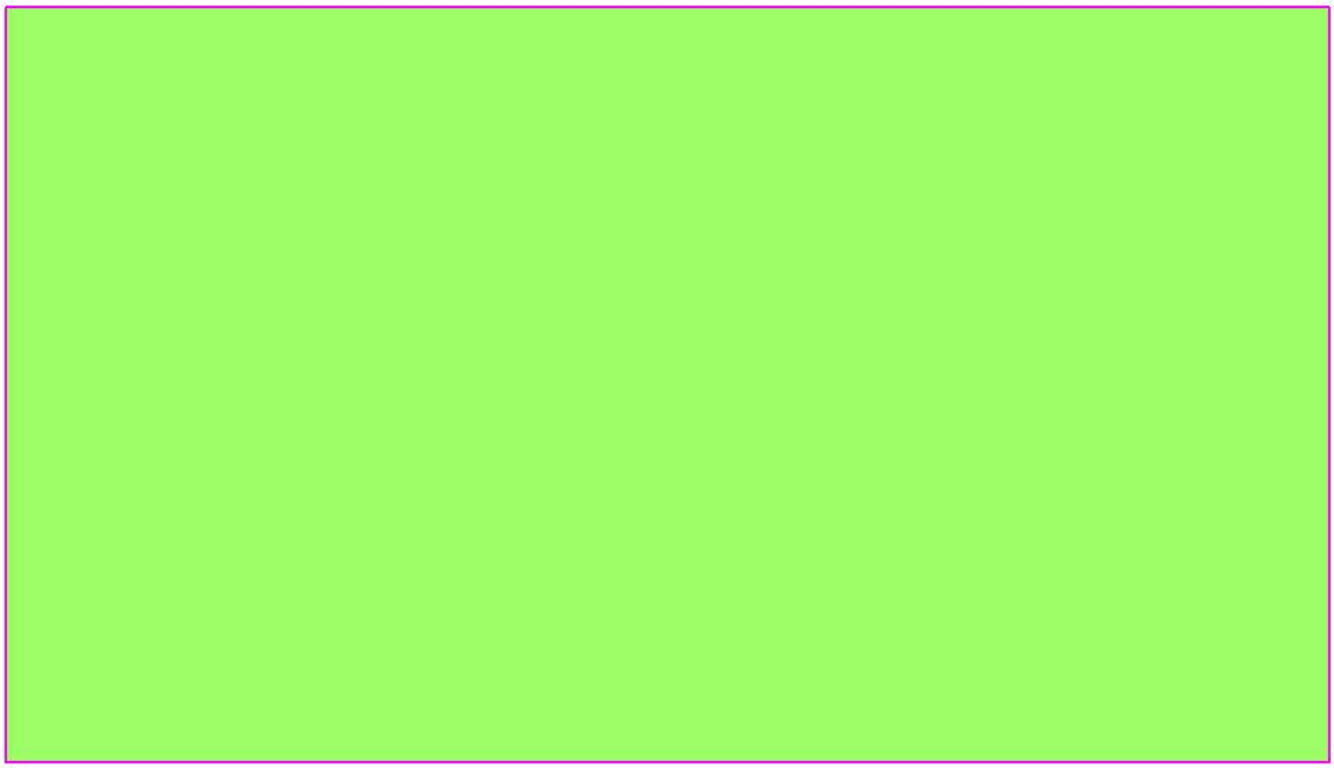
3. Escorts will notify the Command Center as each group returns to the staging area.

4. The Command Center will direct each move to expedite departures and also to prevent groups from encountering one another in the parking lot.

5. Media witnesses will be returned to the Media Center to have a press pool briefing as outlined in Chapter 6.

IV. Reservation Security Plan





3. BOP staff will be available and will accompany execution witnesses.

CHAPTER 6: NEWS MEDIA PROCEDURES

I. General Provisions

A. Purpose of Chapter

This chapter describes the procedures and requirement for allowing representatives of the news media access to an inmate sentenced to death, as well as procedures for news media access to the execution. This chapter also provides procedures for releasing information relating to the execution.

B. Procedure

The BOP recognizes the desirability of establishing procedures which afford the public information about its operations through the news media. In accordance with established policy, reasonable efforts will be made to accommodate representatives of the news media before, during, and after a scheduled execution. Media representatives will be treated in a fair and consistent manner in accordance with current policies and procedures of the BOP. The agency has the responsibility, however, to ensure the orderly and safe operation of its institutions, and therefore must regulate media access.

C. Roles

1. Representatives of the news media are those individuals described in Program Statement 1480.0*5*, News Media Contacts, whose principal employment is to gather and report news.

2. The Regional Director will designate a specific staff member as the official representative to the news media regarding death penalty issues and the scheduled execution.

3. The BOP Assistant Director, Information, Policy and Public Affairs Division, will coordinate the release of information to the news media and assist the Regional Director in the selection of individual news media witnesses. The Department of Justice Office of Public Affairs will be kept informed of these matters.

II. Inmate Interviews

A. Purpose

As stated in Program Statement 1480.05, News Media Contacts, it is not the BOP's intent to provide publicity for an inmate or special privileges for the news media, but rather to ensure a better informed public.

B. Limits

With this in mind, representatives of the news media may be permitted to conduct interviews with inmates. Guidelines regarding the frequency and length of interviews, as well as accompanying security, will reflect BOP/institution policy and will be established by the Warden, who will take into account the available resources.

C. Prohibition

Ordinarily, no media interviews will be permitted with the inmate once the execution date is within seven days.

III. Media Orientation

A. Definition

Ordinarily one day before a confirmed execution date, the institution will hold a Media Orientation to provide media representatives with information on the scheduled execution. No other press conference or Media Orientation regarding the execution will be scheduled or held until after the scheduled execution, except as provided below in subsection B. Every effort will be made by the Warden's representative to notify local, state and national media representatives of the scheduled Media Orientation. Central Office Public Affairs staff will provide assistance in this area.

1. All persons, including media representatives, must have appropriate identification to enter the institution on any occasion. Media representatives must have appropriate press credentials. This requirement includes camerapersons, sound technicians, and reporters.

2. All individuals will be advised that they are subject to search of their person and equipment prior to entering and prior to leaving a BOP facility.

B. Updates Prior to the Execution

Following activation of the Media Center, the Warden's representative will provide the news media with regular briefings or updates of the execution process.

1. No later than eight hours prior to the scheduled execution, a Media Center will be activated. Telephone lines, tables, risers for cameras and outlets for electrical equipment and cameras will be available. Restroom facilities will also be provided.

2. A BOP representative will be present in the Media Center to provide regular announcements.

C. Media Orientation Releases

During the Media Orientation, the following information will be made available to members of the media:

1. General information regarding the scheduled execution and about the individual scheduled for execution.

2. Specific information regarding procedures to be followed by the media on the date of the scheduled execution.

3. Media representatives will be reminded that there are obvious security concerns about aircraft flying over federal correctional facilities and therefore, their assistance and cooperation in this matter is expected.

4. Media representatives will be informed of how the press pool will be established (see paragraph IV D 2) and advised that if they are selected as press pool witnesses to the execution, they will agree prior to the execution to:

   a. Sign the document designated as the Media Witness Press Pool Agreement (see Media Witness Press Pool Agreement, Appendix B);

   b. Be subject to search which includes metal detection scanning;

   c. Not make any photographic, visual or audio recordings of the execution (each media witness will be provided only paper and a pencil or pen while in the execution witness area); and

   d. Return to the Media Center after the execution to answer questions of all other media represented concerning their observations during the execution.

5. After the BOP representative, media pool witnesses and appropriate Department of Justice staff, if available, have addressed the media in the Media Center, the press briefing will be terminated and all media personnel will leave the Media Center.

IV. Media Center Operations

A. Requesting Authorization

1. After an execution date is set by the Court/Director of the BOP, and no sooner than twenty days prior to the scheduled execution, news media representatives will be advised, in writing, by the BOP's representative that they may request, in writing, authorization to participate in the institution's Media Center activity in the hours preceding the scheduled execution (see Sample Letter to Media, Appendix C).

   The request, which must be in writing, should be received by the Warden no later than ten days prior to the execution. Requests must include names, social security numbers, and dates of birth for each representative of a media organization and his/her support staff. Only those media organizations submitting written requests, within the stated time frame, will be considered for participation in Media Center activities.

2. Requests for consideration may be granted by the Warden, provided they demonstrate that the requesting individual falls within the definition of "member of the press and broadcast media" set forth in BOP Program Statement 1480.05, News Media Contacts.

B. Possible Limitations

The number of media representatives may be limited by the Regional Director due to space and safety considerations, but care will be taken to include representatives from both the print and broadcast media.

C. Briefing Packets and Updates

1. Packets

   Following activation of the Media Center, the Warden's representative will provide press briefing packets for reporters in the Media Center. The contents of the press briefing packet will include, but not limited to, releasable information on the inmate, pool reporters (once selected), the sequence of events, and the history of federal executions.

2. Updates

   Written updates generally will be distributed to the press on a regular basis following activation of the Media Center. Updates will include:

a. A summary of activities related to the execution and sequence of events; and

b. A summary, cleared by the Warden, of the inmate's activities during his/her final twenty-four hours.

D. News Media Witness Selection

1. Number in Attendance
The Warden will permit no more than 10 members of the media to witness the execution. The number of additional media representatives authorized to remain in the Media Center of the day of the execution may be limited due to space and safety concerns.

2. Pool Selection Process

a. Press pool members will be selected by their peers at least three hours prior to the scheduled execution. Representatives from each of the following categories must be included:

(1) One local media source (located within the city or town of the institution);

(2) Three television news programs of a station or network holding an FCC license (at least two being national broadcast stations);

(3) Two media sources from the area where the crime was committed;

(4) One wire service;

(5) One radio station; and

(6) Two print media organizations.

b. Press pool witnesses will be selected from qualified media representatives who have been admitted into the institution's Media Center and who have provided staff with proper identification. A list of media representatives will be compiled by the BOP's representative and furnished to the media for their review in the selection process.

3. Signed Agreement

Media selected as press pool witnesses will then be required to agree to:

a. Act as a pool representative as described further in this chapter; and

b. Abide by all established conditions, rules, and regulations while in attendance at the execution; to include allowing a metal detector scan of their person.

4. Supplemental Representatives

In the event the media are unable to identify witnesses in each of the above described categories, the BOP's designated representative may name other qualifying media representatives to attend, with a maximum of 10 being named.

E. Media Witnesses to the Execution

1. Search Process

Each media pool witness attending the execution will be scanned by a metal detector prior to admittance to the Execution Facility.

a. While all witnesses to the execution may be subject to search, no pat or visual search of any media pool witness will be conducted unless the Warden has reasonable suspicion to believe the media representative is concealing weapons, drugs, audio or visual recording devices, or any other items not expressly authorized and the media representative agrees to be searched. If the representative refuses to be searched, he/she will not be permitted to serve as a media witness.

1. Electronic or mechanical recording devices include, but are not limited to, still, moving picture or video tape cameras, tape recorders or similar devices, and radio/television broadcasting devices.

2. The representative will only be permitted paper and a pencil or pen as provided by institution staff.

2. Witness Briefing

The 10 selected members of the news media will be required to sign both the witness agreement (Appendix A) and the Media Witness Press Pool Agreement (Appendix B). They must also attend the pre-execution briefing at the Media Center. This briefing, conducted by a representative of the Warden, will provide specific information on the event and expectations regarding their conduct. This will include:

a. Review of approved materials that can be taken to the

Execution Room;

b. Search procedures;

c. Escort procedures; and

d. The role of pool reporters.

3. Prohibition of Substitutes

No substitute media pool witness will be permitted after this briefing is conducted.

4. Segregation after the Search

After clearing the metal detector, all witnesses will be segregated and escorted to the Execution Facility. Media witnesses will not be permitted to have physical contact with any other persons during this time.

5. Excluding Witnesses

The Warden will not exclude any media witness duly selected in accordance with this chapter from attendance at the execution or cause a selected media witness to be removed from the media pool witness area unless the media witness:

a. Refuses to submit to a reasonable search as outlined in these regulations;

b. Faints, becomes ill, or requests to be allowed to leave during the execution;

c. Causes a disturbance within the media pool witness area that disrupts the orderly progress of the execution as determined by the Warden's representative on site; or

d. Fails to abide by the provisions of the Witness Agreement.

6. The Execution Process

The selected media pool witnesses will be escorted as a group to the execution location prior to the execution. A designated BOP Spokesperson will remain with the media pool witnesses throughout the process.

F. Death Announcement

Immediately following the execution and prior to the post-execution press pool briefing, a BOP representative will read the following prepared statement to the press and demonstrators:

SAMPLE STATEMENT

(To be read at post execution press briefing and to any assembled members of the public.)

_____, Warden of _____,

reports that pursuant to the sentence of the United States District Court in

_____, _____
(Inmate's Name)

has been executed by lethal injection.

_____ was pronounced dead at
(Inmate's Name)

_____ on _____.
(Time) (Date)

G. Press Pool Post-Execution Briefing

All news media press pool witnesses will, after being returned from the execution to the Media Center, immediately brief other media representatives covering the event. The pool witnesses will provide an account of the execution and will endeavor to answer all questions asked of them by other media representatives. They will not report their observations regarding the execution to their respective news organizations until after the non-witness media representatives have had the benefit of the pool representatives' accounts of the execution.

H. Post Execution Press Conference

If deemed necessary and appropriate, representatives of the Department of Justice, USMS, and BOP will answer questions from the assembled media for no more than 30 minutes after the press briefing.

V. The Execution Information Center

A. Responsibility

The BOP's representative will establish and operate an Execution Information Center.

B. Purpose

The Execution Information Center:

1. Is a central processing point for all incoming media and public interest telephone calls pertaining to the scheduled execution;

2. Allows the institution's staff to handle normal and routine business;

3. Handles "crank" calls and bomb threats in accordance with BOP policy; and

4. Establishes a log of calls for future reference, investigation and evaluation.

C. Location

1. The Execution Information Center will be located in an area identified by the Warden.

2. Only persons authorized by the Regional Director and/or Warden will be allowed in the Center's operational area. Center staff are responsible for keeping the area clear of unauthorized personnel.

D. Schedule

1. The Execution Information Center will commence operations approximately two working days prior to the scheduled execution. The Information Center will operate twelve hours a day on the days prior to the scheduled execution and for the eighteen hours immediately preceding the scheduled execution. The Center will remain in operation until approximately one hour after the execution.

2. The BOP's representative will arrange coverage of telephones, based on the volume of calls.

3. Staff for the Execution Information Center will be coordinated by the BOP's representative.

E. Screening Calls

1. Types of Calls

a. Business Calls

Calls from BOP staff or other Federal agencies relating to the execution; or from BOP staff relating to operational issues affected by the execution which may need to be forwarded to the Command Center.

b. Personal Calls

Calls intended for individuals (staff or witnesses) connected with the execution.

c. Inquiry Calls

Execution-related calls from the general public.

1. Staff will endeavor to answer every call in a professional, courteous and efficient manner.

2. If bomb threats are received, the staff member receiving the call will utilize established procedures. Bomb threats will be communicated to the Command Center immediately.

3. If possible, all "crank" calls and calls considered to be an emergency, should be recorded and traced.

CHAPTER 7: STAYS, COMMUTATIONS AND OTHER DELAYS

I. General Provisions

A. Purpose of Chapter

The purpose of this chapter is to:

1. Cite the entities capable of causing execution stays, commutations, and other delays;

2. Specify the manner of communicating such delays/commutations; and

3. Provide the procedures for implementing the delay/commutation.

B. Procedure

It is the procedure of the BOP that:

1. Processes must be in place to receive and ensure proper handling of legal interruptions of the execution countdown;

2. Staff understand their roles and the BOP's responsibilities in the event of such interruptions; and

3. Contingency plans provide methods for responding to:

   a. Temporary delays;

   b. Lengthy delays; and

   c. Commutations.

II. Presidential and Judicial Authority to Interrupt Execution

A. President

1. The United States Constitution confers upon the President the power to grant reprieves and pardons for offenses against the United States. This has been held to include the power to grant conditional pardons and commute sentences.

2. Neither Congress nor a State legislature can limit the President's power to pardon.

B. Courts

A federal court of competent jurisdiction may issue a stay of execution or invalidate a sentence of death as a result of appellate or collateral proceedings.

III. Communication of Pardons, Stays, Commutations or Delays

A. Prior to Final Execution Countdown

If the BOP receives an order from a federal court of competent jurisdiction or the President ordering a respite, reprieve, stay, commutation, pardon or other action which requires the suspension or termination of the execution:

1. The Attorney General's Office will be contacted for consultation; and

2. A decision will be made by the Director of the BOP concerning the status of planning and preparation for the execution.

B. During Final Execution Countdown

1. During the final twenty-four hours, the BOP and the USMS will maintain frequent contact with the Attorney General's Office

C. Final Clearance for Execution

At an appropriate time prior to the execution the Designated United States Marshal will verify clearance to continue with the execution

IV. Procedures to Implement Last-Minute Stays

A. Upon receiving a stay during the final countdown, the first effort will be to determine the probable length of the delay.

B. If the witnesses have not been moved from their staging areas, they will be held in those locations until further instructions are received from the Senior BOP staff to proceed with or terminate the execution.

C. If witnesses are already at the Execution Facility and the inmate is restrained:

1. If the delay appears to be relatively lengthy, the inmate will be returned to the Holding Cell by the Restraint Team. The witnesses will be returned to their staging areas in the order listed. There they will await further information.

2. If the delay is likely to be relatively short in duration, the witnesses will remain in place. The drapes will be closed and the inmate will remain restrained on the table.

3. If the execution is indefinitely stayed, set for re-sentencing, commuted, or halted by pardon, the execution will be halted, and the inmate and witnesses will be immediately advised. Witnesses will be returned to their staging areas and the inmate returned to appropriate quarters in the institution.

Appendix A

MEMORANDUM OF AGREEMENT
BETWEEN
FEDERAL BUREAU OF PRISONS
AND WITNESS

This agreement is made between the Federal Bureau of Prisons and the following witness:

_____

In accordance with Title 28, Code of Federal Regulations, Section 26.4, the Federal Bureau of Prisons may allow you, as a witness, to be present at the execution. However, your presence at the execution is not a right and, in order to be entitled to be present, you will be required to agree to the following conditions:

1. You will not bring onto institution grounds anything constituting legal or illegal contraband under applicable statute, regulation or policy, including, but not limited to, firearms, weapons, explosives, metal cutting tools, narcotic drugs, alcoholic beverages, or any item creating a threat to institution safety, security, or good order;

2. You agree to submit to a reasonable search for contraband and other searches as considered necessary by the Bureau of Prisons for entry into the institution;

3. You will conduct yourself in a lawful and orderly manner;

4. You will comply with all lawful directives of correctional personnel while on institution grounds;

5. You will not bring onto institution grounds any photographic or other visual or audio recording device, to include cellular devices; and

You have read, understand, and agree to the above. By signing this agreement, you agree to comply with its conditions and understand that failure to abide by them will result in your removal from institution grounds and could lead to prosecution for violation of Federal laws.

_____ _____
(Witness) (Date)

_____ _____
(Agency Representative) (Date)

Appendix B

MEDIA WITNESS PRESS POOL AGREEMENT

In consideration of having been selected as an official witness to the execution of _____ on _____,

I, _____,

hereby agree to act as a pool reporter and, not to interview non-media witnesses or Department of Justice staff at the Execution Facility. Following the execution, I agree to return immediately to the Media Center to brief my colleagues there regarding the execution and answer their questions. I also agree to file my story only after I have completed my responsibilities as a pool reporter.

NAME: _____
(Signature)

ORGANIZATION: _____

DATE: _____

_____
(BOP Staff Witness)

Appendix C

SAMPLE LETTER TO MEDIA
(Re: Media Center Operations)

In accordance with the provisions of 28 C.F.R., Part 26, Implementation of Death Sentences in Federal Cases,

_____ is scheduled to be executed
(Inmate's Name)

at _____ on _____.
(Institution) (Date)

No later than eight hours preceding the scheduled execution, a Media Center will be established at the _____ in Terre Haute, Indiana,
(Location)
and telephones will be available. Should you desire to cover the event from the Media Center, or if selected, be a media pool witness, please submit your written request to me, via fax or by mail, so that it is received in my office no later than
_____.
(Date 10 days prior to execution)

The request must include your name, the names of all support staff (sound technician, cameraperson, etc.) who may accompany you on this day. Social security numbers and date of birth for all participants, including yourself, must also be furnished in your letter so that appropriate security checks can be completed. You will be notified promptly if we have any concerns with your request. Space is limited and admittance to the Media Center will have to be on a first-come, first-accommodated basis.

Should you desire to be considered to be a media pool witness to the execution, you will also be required to sign agreements consenting to a search prior to entering the execution facility, and agreeing to abide by all relevant conditions, rules and regulations. Should you participate, your name is subject to being released to the media.

Please note that all media representatives will be required to sign a log and show proper press credentials in order to be admitted to the Media Center.

Sincerely,
Name
Title