IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION AT COLUMBUS

In re: OHIO EXECUTION PROTOCOL LITIGATION,

: Case No. 2:11-cv-1016

Chief Judge Edmund A. Sargus, Jr.
Magistrate Judge Michael R. Merz

This Order relates to Plaintiffs Phillips, Tibbetts, and Otte.

DECISION AND ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION

This consolidated case under 42 U.S.C. § 1983 is brought by Ohio inmates under a sentence of death and seeks relief from a number of asserted constitutional deficiencies in Ohio's new lethal injection protocol adopted October 7, 2016.

The above-named inmates and the State of Ohio unanimously consented to plenary magistrate judge jurisdiction over their cases (ECF No. 732) and Chief Judge Sargus referred these three cases on that basis (ECF No. 734). Hence the Magistrate Judge is authorized to decide the pending motions for temporary injunctive relief even though they are classified as "dispositive" motions under 28 U.S.C. § 636(b)(1)(A).

This Decision and Order embodies the findings of fact and conclusions of law required for a preliminary injunction decision under Fed. R. Civ. P. 52. They are not binding at trial on

the merits. *United States v. Edward Rose & Sons*, 384 F.3d 258, 261 (6th Cir. 2014), citing *Univ. of Texas v. Camenisch*, 451 U.S.390, 395 (1981).

In the most recent preliminary injunction decision in this case, Judge Frost wrote:

> The recent history of this litigation and its often frustrating factual developments can be found in the following Opinion and Orders, which this Court expressly incorporates herein by reference: *In re Ohio Execution Protocol Litigation (Phillips)*, No. 2:11-cv-1016, 2013 U.S. Dist. LEXIS 159680, 2013 WL 5963150 (S.D. Ohio Nov. 7, 2013); *In re Ohio Execution Protocol Litigation (Hartman)*, 906 F. Supp. 2d 759 (S.D. Ohio 2012), *In re Ohio Execution Protocol Litigation (Wiles)*, 868 F. Supp. 2d 625 (S.D. Ohio 2012), *In re Ohio Execution Protocol Litigation (Lorraine)*, 840 F. Supp. 2d 1044 (S.D. Ohio 2012), *Cooey (Brooks) v. Kasich*, Nos. 2:04-cv-1156, 2:09-cv-242, 2:09-cv-823, 2:10-cv-27, 2011 U.S. Dist. LEXIS 128192, 2011 WL 5326141 (S.D. Ohio Nov. 4, 2011), and *Cooey (Smith) v. Kasich*, 801 F. Supp. 2d 623 (S.D. Ohio 2011).

In re Ohio Execution Protocol Litigation, 994 F .Supp. 2d 906, 908, n.2 (S.D. Ohio 2014).

Rather than incorporate by reference another judge's writing, this Court states it considers itself bound by the law of the case stated in these decisions and by decisions of the Sixth Circuit in prior appeals in this case and 2:04-cv-1156.

Current Litigation Context

Most Ohio death row inmates are Plaintiffs in this case which has been pending under the above case number since 2011 and under the prior caption *Cooey v. Strickland*, 2:04-cv-1156, since shortly after the Supreme Court authorized use of § 1983 to attack methods of execution in *Nelson v. Campbell*, 541 U.S. 637 (2004).

Each of the above-named three Plaintiffs has an execution date set between February 15 and April 12, 2017. Although execution dates for these three Plaintiffs were first set some time ago, they have been extended by action of Governor John Kasich several times, most recently by Warrants of Reprieve as to Plaintiffs Phillips and Tibbetts (ECF No. 848).

The intention of the State of Ohio to proceed with three executions in the first quarter of 2017 was announced to Plaintiffs' counsel in open court on October 3, 2016. At that time the State also announced its intention to promulgate, on October 7, 2016, the protocol by which the executions would be carried out (see Minute Entry, ECF No. 655; Transcript, ECF No. 672).

Based on this announcement, the Court vacated the stay of these proceedings as to the three named Plaintiffs and set a schedule for the filing of a Fourth Amended Complaint to reflect the new protocol and the briefing of motions for preliminary injunctive relief (Order Partially Vacating Stay and Setting Schedule, ECF No. 658). In compliance with that schedule, each of these Plaintiffs filed a motion for preliminary injunctive relief, including a stay of execution (ECF Nos. 714, 715, 718). As required by the same scheduling order, Defendants filed their consolidated memorandum in opposition a week later (ECF No. 730).

To protect the decisional process of the Sixth Circuit on the then-pending interlocutory appeal in this case, the Court entered a preliminary injunction *pendente lite* (ECF No. 834) which was appealed by the State (ECF No. 841). The Sixth Circuit then decided the interlocutory appeal on Judge Frost's protective order. *Fears v. Kasich*, ___ F.3d ___, 2016 U.S. App. LEXIS 23424 (6th Cir. Dec. 30, 2016). This obviated the reason for the *pendente lite* stay and it was dissolved (ECF No. 910). The Court commenced a five-day evidentiary hearing on the preliminary injunction motions January 3, 2017.

The Pending Motions for Injunctive Relief

As provided in the Court's scheduling order, each of the above-named Plaintiffs filed a Fourth Amended Complaint on October 26, 2016, to address Ohio's newly revised execution protocol (ECF Nos. 691, 692, 695).[1] Complying with the same Order, they each filed Motions for Preliminary Injunction and concomitant stays of execution in November (ECF Nos. 714, 715, 718).[2]

Plaintiffs claim that their executions under the new Ohio protocol would violate their constitutional rights as follows:

1. Under the Cruel and Unusual Punishment Clause of the Eighth Amendment because the new protocol embodies a reversion to a "more primitive, less humane execution method" than Ohio has heretofore used. (E.g., Plaintiff Raymond Tibbetts' First Claim for Relief, denominated *Wilkerson-Kemmler* Claim and relying on *Wilkerson v. Utah*, 99 U.S. 130 (1879); *In re Kemmler*, 136 U.S. 436 (1890); and *Trop v. Dulles*, 356 U.S. 86 (1958). Plaintiffs argue separate Eighth Amendment claims in their Proposed Findings as an "evolving standards of decency"/"devolution" claim under *Trop* and an Eighth Amendment claim under *Wilkerson-Kemmler* in which they are not required to prove an available alternative method of execution.

2. Under the Cruel and Unusual Punishment Clause of the Eighth Amendment because a three-drug execution method which includes midazolam, a paralytic, and potassium

[1] The Sixth Circuit has previously held that the statute of limitations for a § 1983 action challenging a method of execution begins to run anew any time the execution protocol is amended. *Cooey (Beuke) v. Strickland*, 604 F.3d 939, 942 (6th Cir. 2010).

[2] Plaintiffs Tibbetts and Otte make claims that do not overlap with those of Plaintiff Phillips. These non-overlapping claims are not ripe and were not heard on the evidence in the early January hearing. All three Plaintiffs included requests for temporary restraining orders which are mooted by the preliminary injunction hearing.

chloride creates a substantial risk of serious harms (E.g., Plaintiff Raymond Tibbetts' Third and Fourth Claims for Relief, denominated *Baze-Glossip* Claims and relying on *Baze v. Rees*, 553 U.S. 35 (2008), and *Glossip v. Gross*, 576 U.S. ___, 135 S. Ct. 2726, 192 L. Ed. 2d 761 (2015).)

3. Under the Equal Protection Clause on a class-of-one theory and relying on the State of Ohio's alleged violations of prior execution protocols (E.g., Plaintiff Raymond Tibbetts' Eighth Claim for Relief).

4. On claims under the doctrines of judicial admissions, judicial estoppel, and promissory estoppel (E.g., Plaintiff Raymond Tibbetts' Sixth Claim for Relief).

Standard for Preliminary Injunctive Relief

In determining whether preliminary injunctive relief is merited in a capital § 1983 case, a trial or appellate court applies the following established standards:

> (1) whether [petitioner] has demonstrated a strong likelihood of success on the merits; (2) whether he will suffer irreparable injury in the absence of equitable relief; (3) whether the stay will cause substantial harm to others; and (4) whether the public interest is best served by granting the stay. *Workman v. Bredesen*, 486 F.3d 896, 905 (6th Cir. 2007); *[N.E.]. Ohio Coal. for Homeless & Serv. Employees Int'l Union, Local 1199 v. Blackwell*, 467 F.3d 999, 1009 (6th Cir. 2006). "These factors are not prerequisites that must be met, but are interrelated considerations that must be balanced together." *Mich. Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 153 (6th Cir. 1991).

Cooey (Biros) v. Strickland, 589 F.3d 210, 218 (6th Cir. 2009). Judge Frost applied these same criteria in a prior preliminary injunction decision in this case. *In re: Ohio Execution Protocol Litig.(Lorraine)*, 840 F. Supp. 2d 1044, 1048 (S.D. Ohio 2012). They are consistently applied by

the Sixth Circuit to preliminary injunctive relief requests across subject matter areas, *Overstreet v. Lexington-Fayette Urban Co. Gov't*, 305 F.3d 566, 573 (6th Cir. 2002); *Nightclubs, Inc. v. City of Paducah*, 202 F.3d 884, 888 (6th Cir. 2000); *Washington v. Reno*, 35 F.3d 1093, 1099 (6th Cir. 1994); *NAACP v. City of Mansfield*, 866 F.2d 162, 166 (6th Cir. 1989); *Frisch's Restaurant, Inc. v. Shoney's, Inc.*, 759 F.2d 1261, 1263 (6th Cir. 1985); *In re DeLorean Motor Co.*, 755 F.2d 1223, 1228 (6th Cir. 1985).

Supreme Court case law is consistent.

> 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 the equities tips in his favor, and that an injunction is in the public interest.

Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008), *citing Munaf v. Geren*, 553 U.S. 674, 689-90 (2008); *Amoco Prod. Co. v. Gambell*, 480 U.S. 531, 542 (1987); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311–12 (1982). The Court notes the Supreme Court statement of the standard does not attempt to quantify the degree of likelihood of success.

The purpose of a preliminary injunction is to preserve a court's power to render a meaningful decision after a trial on the merits. *Alabama v. U.S. Army Corps of Engineers*, 424 F. 3d 1117, 1128 (11th Cir. 2005), quoting Wright, Miller & Kane, Federal Practice and Procedure: Civil, § 2946.

> Although the fundamental fairness of preventing irremediable harm to a party is an important factor on a preliminary-injunction application, the most compelling reason in favor of entering a Rule 65(a) order is the need to prevent the judicial process from being rendered futile by defendant's action or refusal to act. . . . [T]he preliminary injunction is appropriate whenever the policy of preserving the court's power to decide the case effectively

> outweighs the risk of imposing an interim restraint before it has done so.

Id. at § 2947.

In a case such as this, a § 1983 challenge to the constitutionality of an imminently pending execution, failure to enjoin the execution will obviously render the case moot long before trial. Nevertheless, stays of execution are not to be granted routinely. A court must weigh the interest of a State in carrying out a lawful death sentence and its parallel interest in finality of criminal judgments. *Workman, supra.*

This Decision is divided into four sections paralleling the four factors required to be found:

I. Likelihood of success on the merits with each of Plaintiffs' claims discussed separately;

II. Irreparable harm;

III. The balance of equities; and

IV. The public interest.

I. The Likelihood of Success on the Merits

Plaintiffs' Eighth Amendment Claims

Although much prior litigation in this case has focused on Equal Protection claims, here, as in the *McGuire* preliminary injunction proceeding, the focus is on the Eighth Amendment. Plaintiffs assert they can prevail under any one of three purportedly distinct Eighth Amendment theories. They make what they describe as *Baze/Glossip* Claims, *Wilkerson/Kemmler* Claims,

and Evolving Standards of Decency/Devolution Claims (Plaintiffs' Amended Proposed Findings of Fact and Proposed Conclusions of Law (ECF No. 895-1, PageID 30028).)

The *Wilkerson/Kemmler* Claim

As the Court understands the *Wilkerson/Kemmler* Claim, it is based on Justices Thomas and Scalia's concurrence in *Baze*. As the Supreme Court in *Glossip* read that concurrence, it would have upheld any method of execution against an Eighth Amendment challenge "unless it is deliberately designed to inflict pain." *Glossip*, 135 S.Ct. at 2738, n. 2, *citing Baze*, 553 U.S. at 94. Plaintiffs here assert the Ohio three-drug protocol is so likely to inflict severe pain that its use should be read as a deliberate infliction of pain or at least as recklessly indifferent to that possibility. Success on such a claim, they assert, does not depend on their proof of a readily available alternative method of execution, an element of an Eighth Amendment claim under *Baze/Glossip*.

This Court is not persuaded that Supreme Court Eighth Amendment jurisprudence recognizes these three disparate theories. The *Wilkerson/Kemmler* theory is based on a concurrence which did not command a majority of the Court. If that theory were the law, moreover, it would not be successful here. Based particularly on the testimony of Ohio Department of Rehabilitation and Corrections ("ODRC") Director Gary Mohr,[3] the Court concludes that the State's efforts have been directed toward making executions more humane and less painful, and not just minimally constitutional. Plaintiffs did not prove at the preliminary

[3] Testimony confirmed that it is the ODRC Director who adopts the Ohio execution protocol. (ECF No. 925, PageID 31261.)

injunction hearing that an execution under the current protocol would be so likely to inflict serious pain that anyone using it would have to know that fact and intend the result.

Evolving Standards of Decency Claim

The Evolving Standards of Decency/Devolution Claim is also made under the Eighth Amendment. Plaintiffs outline that claim in their Proposed Conclusions of Law as follows:

> 1. A state's punishment is assessed under the Eighth Amendment against the evolving standards of decency that mark the progress of a maturing society. *Trop v. Dulles*, 356 U.S. 86, 100–101 (1958) (plurality opinion).
>
> 2. An execution method can be unconstitutional if the method represents "devolution to a more primitive" method that is a "step in the opposite direction" under society's evolving standards of decency and humanity, *Glossip*, 135 S. Ct. at 2795–97 (Sotomayor, J., principal dissent), such as if an execution method is less humane than the method used before.
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> * * *
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> 5. If a method of execution is categorically barred, then it can *never* be imposed regardless of whether another form of execution is available. *See Graham v. Florida*, 560 U.S. 48, 59 (2010) (the Eighth Amendment prohibits "inherently barbaric punishments under all circumstances."); *Penry v. Lynaugh*, 492 U.S. 302, 330 (1989) (the "Eighth Amendment categorically prohibits the infliction of cruel and unusual punishments.").
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> 6. Because the State may not impose a death sentence upon any inmate using an unconstitutional method of execution, there is no requirement to plead an alternative method of execution when claiming the method is categorially unconstitutional. "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." *Glossip v. Gross*, ___U.S.___, 135 S. Ct. 2726, 2793 (2015) (Sotomayor, J., dissenting, joined by Ginsburg, J., Breyer, J., and Kagan, J.) (quoting *Helling v. McKinney*, 509 U. S. 25, 36 (1993) (emphasis in original)).
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> * * *

8. When Defendants changed their protocol to abandon the three-drug method and to abandon the paralytic drug and potassium chloride, they expressly did so to be more humane, and the courts gave them credit for that. By reintroducing a three-drug execution method, reintroducing a paralytic drug, reintroducing potassium chloride, and using a first drug that is demonstrably incapable of protecting the inmate against the torturous pain and suffering associated with the second and third drugs and the process of dying from injection of those drugs, Defendants have now gone backwards, contrary to their expressed purpose of the previous evolution and their promises to this Court and the Sixth Circuit.

9. The key is not the devolution going backwards itself, but that Defendants evolved for the purpose of making execution procedures more humane, and were blessed by the courts for that evolution, and are now devolving to a markedly less safe and humane execution method. In such circumstances, devolution is not permissible.

10. By intentionally reintroducing the second and third drugs back into DRC Defendants' execution protocol, and by reintroducing the three-drug execution method, DRC Defendants have intentionally, knowingly or recklessly moved backward to an execution method that is a devolution from the previous protocol.

(ECF No. 895-1, PageID 30095-96.)

The evolving standards of decency language, though its lineage is fifty years older than *Baze*, is no firmer a foundation for Plaintiffs' claims. It finds its source in *Trop v. Dulles*, *supra*. In *Trop*, the Supreme Court held that use of denaturalization as a punishment for wartime desertion from military duty was barred by the Eighth Amendment. Chief Justice Warren wrote:

> The [Eighth] Amendment must draw its meaning from the evolving standards of decency that mark the progress of a maturing society. . . . [U]se of denaturalization as a punishment is barred by the Eighth Amendment. There may be involved no physical mistreatment, no primitive torture. There is instead the total destruction of the individual's status in organized society. It is a form of punishment more primitive than torture, for it destroys for the individual the political existence that was centuries in the development.

356 U.S. at 101.[4]

Just prior to this passage, however, he wrote:

> At the outset, let us put to one side the death penalty as an index of the constitutional limits on punishment. Whatever the arguments may be against capital punishment, both on moral grounds and in terms of accomplishing the purposes of punishment – and they are forceful – the death penalty has been employed throughout our history, and, in a day when it is still widely accepted, it cannot be said to violate the constitutional concept of cruelty.

Id. at 99. Thus the *Trop* plurality expressly excluded the death penalty from its consideration.

Trop makes its appearance in *Furman v. Georgia*, 408 U.S. 238 (1972), in the concurrence of Justice Douglas and very extensively in the concurrence of Justice Brennan, who noted that *Trop* left open the future constitutionality of capital punishment. *Id.* at 285, n. 33. He concluded

> It is a denial of human dignity for the State arbitrarily to subject a person to an unusually severe punishment that society has indicated it does not regard as acceptable, and that cannot be shown to serve any penal purpose more effectively than a

[4] For the evolving meaning of the Eighth Amendment, the Chief Justice relied on *Weems v. United States*, 217 U.S. 349 (1910), where the Court held "[t]he [Cruel and Unusual Punishment] clause of the Constitution in the opinion of the learned commentators may be therefore progressive, and is not fastened to the obsolete but may acquire meaning as public opinion becomes enlightened by a humane justice. See *Ex parte Wilson*, 114 U.S. 417, 427; *Mackin v. United States*, 117 U.S. 348, 350. . ." *Id.* at 378. The commentator referred to is Thomas M. Cooley whose Treatise on Constitutional Limitations was probably the most influential legal text published in 19th century America.

> significantly less drastic punishment. Under these principles and this test, death is today a "cruel and unusual" punishment.

Id. at 286. Justice Brennan never deviated from this absolute position, one to which he eventually persuaded Justices Marshall and Souter. But that position never became the law of the land and in *Glossip* the Court again affirmed the constitutionality of the death penalty against an Eighth Amendment claim.

While the "evolving standards of decency" language from *Trop* has never been repudiated by the Court, and was relied on by the Court in *Atkins v. Virginia*, 536 U.S. 304, 311-12 (2002), and *Roper v. Simmons*, 543 U.S. 551, 561 (2005),[5] neither has it become the basis for declaring the death penalty per se unconstitutional. In interpreting *Trop,* this Court is aware of Justice Frankfurter's dissent where he wrote:

> All power is, in Madison's phrase, "of an encroaching nature." Federalist, No. 48 (Earle ed. 1937), at 321. Judicial power is not immune against this human weakness. It also must be on guard against encroaching beyond its proper bounds, and not the less so since the only restraint upon it is self-restraint.

Trop, 396 U.S. at 119. What is true for Supreme Court Justices is truer still for trial courts, whose business lies in obeying. "Unless we wish anarchy to prevail within the federal judicial system, a precedent of this Court must be followed by the lower federal courts no matter how misguided the judges of those courts may think it to be." *Hutto v. Davis*, 454 U.S. 370, 375 (1982). Following precedent is, of course, an art form, not a matter of blind obedience. Sometimes a district court can accurately anticipate where the Supreme Court is ready to go. See *Obergefell v. Kasich*, 2013 U.S. Dist. LEXIS 102077 (S.D. Ohio 2013)(Black, J.), affirmed *sub nom Obergefell v. Hodges*, 135 S.Ct. 2584 (2015). But because this Court believes neither the

[5] In these two cases, the Supreme Court held that the execution of the intellectually challenged and juveniles, respectively, violated the Eighth Amendment to the Constitution.

Sixth Circuit nor the Supreme Court is prepared to recognize an "evolving standards of decency" claim, it concludes Plaintiffs are unlikely to prevail on this claim.

The *Baze/Glossip* Claim

In *Baze v. Rees,* 553 U.S. 35 (2008), the Supreme Court upheld Kentucky's lethal injection protocol which called for an initial injection of sodium thiopental, a second such injection if the first did not render the inmate unconscious, then the paralytic drug pancuronium bromide and finally potassium chloride to cause cardiac arrest. Petitioners conceded that the protocol itself was humane and constitutional if performed properly, but asserted there was a significant risk the thiopental sodium would not be administered properly and the inmate would suffer severe pain when the other two drugs were administered. Plaintiffs proposed alternatives which they claimed would eliminate an "unnecessary risk" of serious harm. The plurality opinion rejected that standard in favor of the "substantial risk of serious harm" or "objectively intolerable risk of harm" standards adopted in *Farmer v. Brennan*, 511 U.S. 825 (1994). As noted above, Justices Scalia and Thomas concurred in the judgment, but believed the Court's standard departed inappropriately from the original meaning of the Cruel and Unusual Punishments Clause.

In *Glossip v. Gross*, 576 U.S. ___, 135 S.Ct. 2726 (2015), the Supreme Court considered Oklahoma's lethal injection protocol which required administration of a 500 milligram dose of midazolam, followed by a paralytic agent and potassium chloride. Justice Alito wrote for a majority and reaffirmed *Baze*'s requirement that, to prevail, inmates challenging a method of execution must 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." *Id.* at 2731 citing *Baze*. He wrote that

> 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] means of carrying it out." *Id.*, at 47, 128 S. Ct. 1520, 170 L. Ed. 2d 420. 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.

Id. at 2732-33. *Glossip* was before the Court on appeal from denial of a preliminary injunction. In that context, "[t]he 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." *Id.* at 2737. Noting the preliminary injunction standard from *Winter, supra,* the Court observed that the determining question was likelihood of success on the merits.[6]

To prevail on their *Baze/Glossip* claim, Plaintiffs must show that use of midazolam as the first of three drugs prescribed in Ohio's lethal injection protocol (1) "creates a demonstrated risk of severe pain" and (2) "that the risk is substantial when compared to known and available alternatives." To prevail at the preliminary injunction stage, they must show it is likely they can prove these two elements at a trial on the merits.

[6] The Court at least three times states the standard as "likelihood" without quantifying the probability. This Court reads that standard as more probable than not, rather than requiring a "strong" probability. Compare *Workman v. Bredesen, supra.; Cooey (Biros) v. Strickland, supra.*

Midazolam as an Execution Drug

Ohio's new lethal injection protocol calls for the initial intravenous administration of 500 milligrams midazolam,[7] followed by a second dose of the same size if the inmate appears to be still conscious when a consciousness check is performed. If the consciousness check is negative, the execution will proceed by IV injection of a paralytic drug, followed by potassium chloride, which is intended to precipitate cardiac arrest. The chief focus of the evidentiary hearing was on the first drug, midazolam.

The Dennis McGuire Case

Midazolam made its debut as an American execution drug with Ohio's execution of Dennis McGuire on January 16, 2014. McGuire was a Plaintiff in this case and Judge Gregory Frost, to whom this case was previously assigned, held an evidentiary hearing on McGuire's constitutional objections to the then-extent Ohio execution protocol which required a single injection of a combination of 10 mg of midazolam and 40 mg of hydromorphone (DX 2: ODRC 01-COM-11, eff. 10/10/2013).

Although prior litigation in this case had focused on Equal Protection claims,

> Today's challenge returns the focus to the Eighth Amendment so that the question is not whether Ohio can be trusted to do what it says it will do, but whether following the protocol will subject McGuire to an unconstitutional substantial risk of severe pain that constitutes cruel and unusual punishment.

[7] The protocol (often referred to in the testimony as 01 COM 11) provides that the 500 milligrams of midazolam is to be prepared in two syringes, each containing 250 milligrams of the drug, and that they be administered sequentially. (Defendant's Exhibit (hereafter "DX") 1, also found at ECF No. 667-1, PageID 19828).

In re: Ohio Execution Protocol Litig.(McGuire), 994 F. Supp. 2d 906, 908 (S.D. Ohio 2014)(Frost, D.J.).[8]

Judge Frost understood the standard for judging McGuire's Eighth Amendment claims to have been set by the Sixth Circuit:

> The Sixth Circuit has explained that "[t]o demonstrate that Ohio seeks to impose 'cruel and unusual' punishment, [a plaintiff] must show that its protocol ignores a '*sure or very likely*' risk of serious pain 'and needless suffering,' . . . which 'creates a demonstrated risk of severe pain' that is 'substantial when compared to the known and available alternatives.' "

McGuire, 994 F. Supp. 2d at 911, quoting *Cooey (Biros)*, 589 F.3d at 220 (quoting *Baze v. Rees*, 553 U.S. 35 (2008) (plurality opinion)).

The State objected that McGuire had not presented an alternative means of execution. Judge Frost concluded that, whether formally "presented" by McGuire or not, "[t]o this Court and no doubt to everyone present in the courtroom during the evidentiary hearing, however, the message was clear. A far greater dose of midazolam would be an alternative." *Id.* at 911. Judge Frost declined to find that the suggested alternative would be preferable, noting

> "[T]he Constitution does not allow the federal courts to act as a best-practices board empowered to demand that the states adopt the least risky execution protocol possible." *Cooey (Biros)*, 589 F.3d at 220-21. Instead, this Court's "rightful function [is] as a constitutional check on the 'wanton infliction of pain' by the state." Id. at 233 (quoting *Louisiana ex rel Francis v. Resweber*, 329 U.S. 459, 463, 67 S. Ct. 374, 91 L. Ed. 422 (1947) (plurality opinion)).

Id. at 912.

[8] In *McGuire*, the State asserted an equitable bar to relief because McGuire had waited until ten days prior to his scheduled execution to seek a stay, citing the "strong equitable presumption" against a stay in like circumstances recognized in *Workman v. Bredesen*, 486 F.3d 896, 911 (6th Cir. 2007). The State does not raise such a bar here, nor could it successfully do so, because the named Plaintiffs moved as promptly as possible and on a court-ordered schedule to present their claims.

McGuire's claim was based directly on the expert testimony of Dr. David Waisel who opined:

> [McGuire] possesses physical and medical characteristics that increase his risk of obstructive sleep apnea. This proclivity toward obstruction means that following the administration of midazolam and hydromorphone, his breathing will be suppressed, he will experience a consequent rise in the amount of carbon dioxide in his system, he will experience a need or sensation to breathe, and he will suffer an obstruction that he will be unable to mitigate through physical manipulation or otherwise. This in turn will lead him to experience "air hunger," which Waisel characterized as a terrifying inability to obtain a breath to satisfy the ventilatory drive. Waisel testified that this will result because the ventilatory depressant effects of the protocol will occur prior to the pain relief or sedative effects. Stated most simply: McGuire asserts that there will be up to a 5-minute window before the drugs alleviate his awareness of air hunger and that he will suffer air hunger during this time period.

Id. at 912. The State's expert, Dr. Mark Dershwitz, contradicted Dr. Waisel's prediction, opining instead that

> [T]he timing of the effects of the protocol drugs and the effect of the hydromorphone dose involved [are such that] the analgesic effect occurs earlier so that it will precede ventilatory depression. Moreover, because the amount of hydromorphone administered under the protocol is so massive, its effect must be regarded on a sliding scale that does not track traditional therapeutic dosing. In other words, McGuire will not be experiencing terror but rather possible euphoria, and even in the event of a possible obstruction, he will likely be unconscious by the time that happens. Again attempting to summarize most simply: Defendants assert that the window for experiencing air hunger is so much less than McGuire argues that it is likely non-existent or at worst far less than 5 minutes.

Id. at 912. Judge Frost found Dr. Dershwitz more persuasive and concluded McGuire was unlikely to experience "air hunger," even assuming *arguendo* that "the sensation of air hunger sufficiently constitutes severe pain within the Eighth Amendment prohibition." *Id.* Nonetheless, Judge Frost had doubts which he expressed as follows:

> There is absolutely no question that Ohio's current protocol presents an experiment in lethal injection processes. The science involved, the new mix of drugs employed at doses based on theory but understandably lacking actual application in studies, and the unpredictable nature of human response make today's inquiry at best a contest of probabilities. To pretend otherwise, or that either of the experts or this Court truly knows what the outcome of that experiment will be, would be disingenuous. But as odd as it sounds, this is not a problem until it is actually a problem. The law teaches that Ohio is free to innovate and to evolve its procedures for administering capital punishment until such experimentation sufficiently risks running afoul of the constitutional protections afforded every citizen, regardless of his or her status, crime, or punishment. *See Cooey (Biros)*, 589 F.3d at 229-30.
>
> The evidence before this Court fails to present a substantial risk that McGuire will experience severe pain. This is not to say that the Court is convinced that the execution will be pain free or even complication free. There is always a possibility of human error or unfortunate misadventure. There is also the possibility that in the earliest moments of his execution, McGuire could experience an obstruction. This Court credits the evidence that he has characteristics suggesting, if not establishing, a propensity for possible obstruction. The simple possibility of obstruction leading to air hunger of which McGuire would be cognizant does not amount to a sufficient probability, however, and the weight of the evidence leads to the conclusion that the hydromorphone overdose employed in Ohio's protocol will most likely offset the risk factors and preclude the experience of air hunger. Thus, although the Court is not without concern over what could transpire during McGuire's execution, the applicable law looks at the degree of risk and the amount of pain involved. The only fair evaluation of the evidence here leads to the conclusion that the degree of risk that

> Ohio's protocol presents is acceptable within the contours of the Constitution.

Id. at 913.

Midazolam's Career as an Execution Drug After Judge Frost's *McGuire* Decision

The Actual Dennis McGuire Execution

Judge Frost's decision was not appealed and McGuire was executed on January 16, 2014, using a single injection which combined 10 mg of midazolam and 40 mg of hydromorphone. During the January evidentiary hearing in this case, the Court heard from three eyewitnesses to Dennis McGuire's execution: ODRC Director Gary Mohr, Execution Team Member No. 10, and Columbus Dispatch reporter Alan Johnson.

Director Mohr described what he saw

> As the drugs were going in, Mr. McGuire looked over, said -- what I think he said was " I love you." It was not -- that was not audible to me, but the mouth was pretty clear that he was. And leaned back down, and his head was kind of straight.
>
> And what I saw for the first five to six minutes was no movement. I saw, you know, after the first minute or so, no movement.

(Evid. Hrg. Tr., ECF No. 925, PageID 31357.)

Director Mohr's perception was that McGuire became unconscious faster than had happened with the pentobarbital executions he had witnessed. *Id.*. After McGuire was "at peace and motionless," "I saw the stomach first. I saw what looked like a knot in his stomach . . . and his stomach was moving. I had not seen that before. And then I saw his mouth open, and I heard

audible sounds. I don't know whether it was like a snore or a snort. . . ." *Id.* at PageID 31358-59. Director Mohr observed McGuire's stomach continue to knot up and relax and snort multiple times. *Id.* at PageID 31360. Because he had not seen these phenomena before and was concerned, he convened a meeting of the medical team and was assured that McGuire was not aware and "we've seen this in our experience." *Id.* After a five minute wait recommended by the medical team, the drug administrator told Director Mohr he could detect no heart sounds or breathing sounds. *Id.* at PageID 31362. Director Mohr has overseen eleven executions. *Id.* at PageID 313784.

Execution Team Member 10[9] testified he was in the death chamber with McGuire during the execution. When the syringe was empty and the execution drugs were in the process of entering McGuire's body,[10] McGuire had a "dry mouth swallow, which is normal in that case. (Evid. Hrg. Tr., ECF No. 922, PageID 30672.) He lifted his head and whispered "I love you" to his family and "immediately laid back down." *Id.* Team Member 10 was standing at the head of the execution gurney and McGuire tilted his head back toward No. 10. *Id.* at PageID 30673. His jaw relaxed and he snored three or four times – "pretty common at that time in the process." *Id.* He appeared to Number 10 to be unconscious at 10:31 a.m. One-and-a-half to two minutes later, Team Member 10 noticed a swelling in the belly area, but the IV site appeared normal. *Id.* at PageID 306749. There was a wave in the belly followed by a snort which happened eight to ten times. *Id.* There was no movement after that. *Id.* at PageID 30675. Team Member 10 has witnessed approximately forty-nine executions. *Id.* at PageID 30694.

[9] Throughout this litigation, the Court has preserved the anonymity of execution team members by referring to them by number and permitting them to testify from behind a screen.

[10] The execution drugs are administered through a long IV line from an equipment room separate from the death chamber.

Reporter Alan Johnson covers Ohio state government for the Columbus Dispatch and has done so since 1990. *Id.* at PageID 30702. He has witnessed twenty Ohio executions, including McGuire's. *Id.* at PageID 30703. He testified:

> [T]ypically after five minutes [from the time the drugs begin to flow], things calm down in an execution in my experience. But after the end of five minutes, roughly, inmate McGuire began coughing, gasping, choking in a way that I had not seen before at any execution. And I remember it because I relived it several times. Frankly that went on for 12 to 13 minutes.

Id. PageID 30706. McGuire gasped fifteen to sixteen times "in a way that would almost seem to be choking. And he attempted to kind of lift up off the table. His hands were clenching and unclenching." *Id.* In the other nineteen executions Johnson had witnessed, he had seen "very minor reactions" – sometimes clenching of the hands, sometimes a chest compression or an eyelid flutter, "but nothing of that intensity or that duration in any of the 19 previous executions." *Id.* at PageID 30708.

Other Midazolam-Involved Executions

Ohio has executed no one since Dennis McGuire. But Plaintiffs presented testimony from eyewitnesses to other executions in which midazolam was the first part of the protocol.

The State objected to the relevance of this testimony and testimony regarding McGuire's execution in that (1) the present protocol calls for a different usage and fifty times larger dose of midazolam than that used with McGuire, (2) executions in other States using midazolam involved different protocols, and (3) problems with other executions may have resulted from maladministration of the drugs, e.g., from infiltration into muscle tissue instead of proper

intravenous infusion. This concern is well taken as a reservation on how directly probative other executions may be, but does not lead the Court to conclude the evidence has no probative value, particularly in a matter in equity tried to the bench alone.

Ronald Smith was executed by Alabama on December 8, 2016 (Evid. Hrg. Tr. ECF No. 922, PageID 30609). Spencer Hahn, an Assistant Federal Defender for the Middle District of Alabama Capital Habeas Unit, was assigned to witness Smith's execution. *Id.* at 85. Alabama's protocol called for a 500 mg dose of midazolam, followed by 600 mg of a paralytic drug and 240 milliequivalents of potassium chloride. *Id.* at PageID 30611.

At some point after administration of the midazolam, Smith was coughing, clenching and unclenching his fists, "and trying to mouth words that I could not make out." *Id.* at PageID 30609-10. The attending corrections officer performed several "consciousness checks" on Smith including calling his name, brushing his eyelid, and pinching his arm. *Id.*.at PageID 30616-18. After a second consciousness check, Smith appeared to Hahn to still be conscious and he assumed the execution would be stopped. *Id.* at PageID 30618. At about seventeen minutes from the start of drug flow, it appeared to Hahn that the paralytic was administered. Summarizing, Hahn said:

> [T]here were two periods in which he appeared to rest somewhat briefly, as if in reaction to something. Followed by coughing, heaving, flailing, or attempting to flail arms, clenching and unclenching of fists, movement of lips, trouble, almost as if he were hyperventilated, and then doing this asthmatic cough, barking-type cough.

Id. at PageID 30619.

Sonya Rudenstine, a lawyer in a solo practice in Florida who specializes in capital post-conviction work, witnessed the execution of Paul Howell in Florida (Evid. Hrg. Tr. ECF No.

924, PageID 31199). She identified the Florida execution protocol in place for the Howell execution as that adopted September 9, 2013. *Id.* at PageID 31202, identifying Plaintiff's Exhibit (hereafter "PX") 71. That Florida protocol called for injection of 500 milligrams of midazolam in two separate injections of 250 milligrams each, followed by 200 milligrams of vecuronium bromide in two 100 milligram injections, followed by 240 milliequivalents of potassium chloride. *Id.* She observed Mr. Howell open his eyes after the consciousness check. *Id.* at PageID 31230. From logs produced by the Florida Department of Law Enforcement official witnesses, Ms. Rudenstine understood the midazolam began to be administered at 6:18 p.m. and was complete by 6:22. *Id.* at PageID 31216.

During the very course of the preliminary injunction hearing, to wit, on January 4, 2017, Florida changed its lethal injection protocol to replace midazolam as the first drug with etomidate. (PX 81, page 6).[11]

Dale Baich is supervisor of the Federal Defender Capital Habeas Unit in Arizona. He witnessed the July 2014 execution of Joseph Wood in that State. The protocol called for injection of a mixture of 50 mg of midazolam and 50 mg of hydromorphone. (ECF No. 940, PageID 31673-74.) In Mr. Wood's case, this mixture was injected fifteen separate times. *Id*. at PageID 31682. Wood continued to gasp and try to breathe until his death at 3:49 p.m., almost two hours after the process began. *Id*. at PageID 31683.

Mr. Baich also identified the settlement agreement and consequent dismissal order he negotiated on behalf of Arizona death row inmates (PX 69 and 70). In the Settlement Agreement, Arizona permanently foreswears the use of "midazolam, or any other benzodiazepine, as part of a drug protocol in a lethal injection execution" (PX 69, page 2).

[11] Florida also replaced potassium chloride with potassium acetate as the third drug. Dr. Stevens' rebuttal report, mentions that Dr. Antognini studied the effects of etomidate as an IV general anesthetic (Pl. Expert Ex. 8, p. 1035).

Terry Alang, who is an attorney employed as an investigator for the Capital Habeas Unit in the Middle District of Alabama, testified she witnessed the execution of Christopher Brooks in Alabama on January 20, 2016. (ECF No. 940, PageID 31721.) Midazolam was the first drug administered and Mr. Brooks' chest began heaving a few minutes after it was given. *Id*. at PageID 31723.

Dean Sanderford is an attorney with the Federal Public Defender in Denver, Colorado. His office was appointed by the Tenth Circuit Court of Appeals to witness the Oklahoma execution of Clayton Lockett. (ECF No. 940, PageID 13738.) Oklahoma's protocol calls for the administration of 100 mg of midazolam, followed by a paralytic agent and potassium chloride. *Id*. at PageID 31739. Three to four minutes after administration of the paralytic to Mr. Lockett, Sanderford observed Lockett attempt to speak and his body began writhing. *Id*. at PageID 31742. On cross-examination, Mr. Sanderford admitted this was the first execution he had witnessed and it was determined the drugs went into muscle tissue by process of infiltration. *Id*. at PageID 31754-55.

After the hearing in this case was completed, Virginia executed Rick Gray using a three-drug protocol with midazolam as the first drug. According to press accounts from his attorneys, he experienced many of the same phenomena testified to in the hearing, to wit, "labored breathing, gasping, snoring, and other audible and visible activity."[12] While this account is obviously hearsay and not in evidence, the account corroborates admissible testimony the Court did hear.

Witnesses to non-Ohio executions were from legal practices devoted to representing capital clients. Although such witnesses might be expected to be biased in favor of death row inmates, their testimony was carefully confined to observations rather than opinions on what they

[12] National Catholic Reporter, www.ncronline.org, visited January 24, 2017.

were seeing. This contrasts 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.

On the short notice involved with a preliminary injunction hearing, other evidence would have been difficult to obtain. Indeed, the State of Alabama moved in the Middle District of Alabama to quash Plaintiffs' subpoenas for records of the Smith execution and those documents were not produced.

Glossip v. Gross

In addition to its actual use in other executions, midazolam has received Supreme Court attention since the McGuire execution. In *Glossip v. Gross*, 135 S.Ct. 2726 (2015), the Court reviewed Oklahoma's three-drug lethal injection protocol which featured a 500 mg dose of midazolam as the first drug.[13] The district court had denied preliminary injunctive relief and the Tenth Circuit affirmed. The Supreme Court held:

> 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.

Id. at 2731.

[13] Oklahoma, like Ohio, had previously used the barbiturate sodium thiopental as the first drug in its three-drug protocol, but had switched to midazolam because, Justice Alito wrote, "anti-death-penalty advocates pressured pharmaceutical companies to refuse to supply the drugs used to carry out death sentences." *Glossip*, 135 S. Ct. at 2733.

As noted above, after reciting a brief history of execution methods in the United States, the Court reaffirmed its holding in *Baze v. Rees*, 553 U.S. 35 (2008), that

> [B]ecause it is settled that capital punishment is constitutional, "[i]t necessarily follows that there must be a [constitutional] means of carrying it out." *Id.*, at 47, 128 S. Ct. 1520, 170 L. Ed. 2d 420. 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.

Glossip, 135 S. Ct. at 2732-33. It noted the protocol found constitutional in *Baze* consisted of

> (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.

Glossip, 135 S.Ct. at 2732. This protocol was used in 2008 by at least thirty of the thirty-six States executing by lethal injection. *Id.*

Relying largely on press accounts, the Court majority found that thiopental sodium and pentobarbital had become unavailable, at least to Oklahoma. *Id.* at 2734. Florida became the first State to substitute midazolam for a barbiturate in October 2013. Oklahoma followed suit in 2014 and had already used its new protocol in the executions of Clayton Lockett (April 2014) and Charles Warner (January 2015).[14] The *Glossip* plaintiffs filed suit in June 2014. After a three-day evidentiary hearing, the District Court denied relief on the two independent bases eventually adopted by the Supreme Court:

[14] Although the McGuire execution and the amendment to Ohio's protocol that added midazolam both happened before *Glossip* was decided, the *Glossip* decision does not mention the McGuire case.

> [First, the petitioners] fail[ed] 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, 170 L. Ed. 2d 420). 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.

Glossip, supra, at 2736.

As to the second branch of the decision, the Court emphasized it was doing what is appropriate for an appellate court reviewing a district court finding of fact: it found that conclusion was not clearly erroneous. "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.'" *Glossip* at 2739, quoting *Anderson v. Bessemer City*, 470 U.S. 564, 573 (1985). As this Court has noted earlier, the affirmance in *Glossip* does not logically imply that it can never be proven that midazolam presents an objectively intolerable risk of harm. Instead, this Court must evaluate the evidence presented here, rather than the evidence the Oklahoma District Court heard in *Glossip*, which is not before this Court.

This distinction is necessary because some have read *Glossip* as holding the three-drug protocol at issue in that case is *per se* constitutional. ODRC Director Mohr testified he adopted Ohio's current protocol because he believed that is what *Glossip* held. (Evid. Hrg. Tr., ECF No. 925, PageID 31319.) The Sixth Circuit also opined that "The new [Ohio] protocol mirrors the Oklahoma protocol approbated by the Supreme Court in June 2015." *Fears v. Kasich*, ___ F.3d

___, 2016 U.S. App. LEXIS 23424 *5 (6th Cir. Dec. 30, 2016), citing *Glossip v. Gross*, 135 S. Ct. at 2734-35. What the Supreme Court held in *Glossip* was that the District Court was not clearly erroneous, not that it was clearly correct. This Court must therefore evaluate the evidence before it *de novo*.

Expert Testimony at the Preliminary Injunction Hearing

Given the experience with use of midazolam as an execution drug since the McGuire execution, the parties understandably focused their presentations on expert testimony about how that experience should be understood. That testimony is summarized here at length.

Craig Stevens, PhD

Plaintiffs called Dr. Craig Stevens, PhD., a Professor of Pharmacology at the Oklahoma State University. He was asked "to provide expert opinions regarding the use of midazolam, in itself and in comparison to pentobarbital, in the lethal injection procedures employed by the State of Ohio Department of Rehabilitation and Corrections ("DRC"). (ECF No. 836-1, PageID 24802). Dr. Stevens testified as to his education, employment, and experience in the field of pharmacology (Evid. Hrg. Tr., ECF No. 923, PageID 30735-44); his Curriculum Vitae is attached to his Expert Declaration (ECF No. 836-1, PageID 24834-47). Without objection by Defendants, the Court accepted Dr. Stevens as an expert witness in the field of pharmacology. (ECF No. 923, PageID 30744). On cross-examination, Dr. Stevens agreed that he is not an anesthesiologist and has no clinical experience. *Id*. at PageID 30917.

Dr. Stevens' expert opinion is four-fold:

> 1. Ohio's decision to use midazolam instead of an anesthetic (such as a barbiturate like pentobarbital) as the first drug in its three-drug lethal injection protocol is contrary to sound medical or scientific reasoning, and expert pharmacological advice.
>
> 2. Midazolam is a benzodiazepine drug while pentobarbital and thiopental are barbiturate drugs. For reasons of pharmacological classification, mechanism of action, therapeutic uses, and FDA scheduling, midazolam is NOT equivalent to pentobarbital or thiopental.
>
> 3. Midazolam in any amount cannot render and maintain the condemned inmate unaware and insensate to pain. That is the functional state of "General Anesthesia" as used in the medical context. The key consideration in the lethal injection execution context is not whether there is a formal medical assessment that the inmate is under General Anesthesia, but whether the drug is capable of rendering an inmate unaware and insensate. Midazolam cannot achieve that. Pentobarbital and thiopental can more reliably render the condemned inmate unconscious/unaware and insensate to pain.
>
> 4. Use of midazolam as the first drug in the State's three-drug lethal injection protocol (01-COM-11, eff. Date Oct 7, 2016) is highly likely to cause intolerable and severe pain and suffering in the condemned inmate.

(Declaration, ECF No. 836-1, PageID 24802-03.)

Dr. Stevens testified that he reviewed not only Ohio's October 2016 Execution Protocol, but also numerous other research sources, listed in section 5 of his Expert Declaration *Id*. at PageID 24830-33, and in his Rebuttal Report (ECF No. 900-1, PageID 30156-57). (ECF No. 923, PageID 30745). Dr. Stevens explained that midazolam is a benzodiazepine, a major class of drugs most commonly used as antianxiety drugs. *Id*. at PageID 30745-46. He further explained

that midazolam is "kind of a special" benzodiazepine because it comes in an intravenous ("IV") formulation. *Id*. at PageID 30746. Dr. Stevens testified that midazolam, along with an opioid, is commonly administered during such procedures as a colonoscopy. *Id*. He explained that midazolam has a sedative and amnesic effect, while whatever opioid is included would have an analgesic, or pain-blocking, effect. *Id*. at PageID 30746-47.

Referencing a table of four diagrams in his Expert Declaration (ECF No. 836-1, PageID 24805), Dr. Stevens laid out the differences between the chemical structures of benzodiazepines, such as midazolam and diazepam, and the chemical structures of barbiturates, such as pentobarbital and thiopental. (ECF No. 923, PageID 30748-50.) Dr. Stevens noted that pentobarbital used to be commonly used for everything from sleep, anxiety, and a number of disorders, for which benzodiazepines are now used because they are safer. *Id*. at PageID 30749. The importance of the difference in chemical structures between these two drug types, Dr. Stevens continued, is that they act on totally different targets on the brain or body, which determines where they act and how they act—or their "mechanisms of action." *Id*. at PageID 30751.

Dr. Stevens next testified about "GABA," an acronym for gamma-aminobutyric acid. According to Dr. Stevens, "[t]hat's a[n] amino-acid-derived neurotransmitter that is the most common *inhibitory* neurotransmitter in the brain." *Id*. at PageID 30752 (emphasis added). A substance called glutamate, by contrast, is the major *excitatory* neurotransmitter. Dr. Stevens explained that neurons connect with other neurons through a synapse--a small gap between one neuron and the next neuron—such that neurotransmitters from one neuron cross the synapse to another neuron and interact with receptors on that second neuron to either inhibit that second

neuron or excite it. *Id*. at PageID 30752-53. Dr. Stevens used an easel to demonstrate this process. *Id*. at PageID 30754-56.

GABA, Dr. Stevens explained, acts on a receptor called $GABA_A$, by opening it (as a door) and allowing in chloride ions that bring a negative charge to that neuron, or inhibit it. When midazolam is introduced, it binds to a separate place on the $GABA_A$ receptor and increases the flow of chloride ions into the receptor, which increases depression of neural activity. *Id*. at PageID 30756-57. To that point, Dr. Stevens emphasized that if there is no $GABA_A$ on the receptor, midazolam does not open up the channel to inhibit the neurons. In other words, "midazolam can only work when $GABA_A$ is present on the receptor." "Without $GABA_A$ present," Dr. Stevens expounded, "midazolam cannot open those doors or cause any inhibition of the neuron." I*d*. at PageID 30759. Dr. Stevens analogized this concept to "Boy Scouts helping a little old lady crossing the street." *Id*.

> The little old lady is GABA, and the Boy Scouts were midazolam trying to help her across the street. So that if there is only one little old lady, no matter how many Boy Scouts you have, you are still going to just get one activity there.

Id. at PageID 30759. During cross-examination, Dr. Stevens did not appear to agree with, or find any significance to, studies indicating midazolam interferes with the "reuptake" of GABA, thereby causing an accumulation of GABA. *Id*. at PageID 30930-33.

Dr. Stevens next turned to what happens when a barbiturate such as pentobarbital is introduced. He testified that even without GABA present, pentobarbital can open up the channel and decrease neuronal activity. *Id*. at PageID 30760. That, Dr. Stevens explained, is the key difference between a benzodiazepine such as midazolam and a barbiturate such as pentobarbital: barbiturates can work without GABA present, while midazolam is limited by the need for GABA

and therefore has a ceiling effect. *Id*.. Dr. Stevens further explained that while midazolam has the effect of opening the channel to allow in inhibiting ions more frequently, pentobarbital has the effect of increasing the duration of the channel staying open. *Id*.

Dr. Stevens proceeded to testify about a section of his Expert Declaration entitled "Midazolam is a partial agonist, and pentobarbital is a full agonist." (ECF No. 836-1, PageID 24807-208.) "An agonist," Dr. Stevens explained, "is a drug that does something that activates the receptor and turns it on." By contrast, an "antagonist" hits a receptor and does not do anything. *Id*. at PageID 30762. Dr. Stevens noted that although midazolam and pentobarbital are agonists insofar as they turn on receptors, the effect of turning on the receptors is opening channels (or doors) to allow in ions that inhibit neural activity. *Id*. Dr. Stevens proceeded to explain:

> So if you have an assay where you are measuring the effect of midazolam and pentobarbital, what you will see in that assay is that pentobarbital can produce a very potent effect. So let's just say we are measuring inhibition of a neuron. We have a neuron in a cell dish or something we are dropping the drugs on. So pentobarbital, we will see the full effect, full inhibition of those neurons, whereas midazolam we wouldn't. It would be limited by the amount of GABA present, for example. And so because we don't see the full effect, it's called a partial agonist. It's just a pharmacological term.

Id. at PageID 30763.

As a partial agonist, Dr. Stevens continued, midazolam will have a ceiling effect. Referring to a figure in his Expert Declaration (ECF No. 836-1, PageID 24808), Dr. Stevens explained that the X-axis depicts increasing doses of benzodiazepines and barbiturates, while the Y-axis depicts the increasingly different effects of those drugs—sedation, then hypnosis (sleep), then anesthesia, then coma, and finally death. (ECF No. 923, PageID 30764; ECF No. 836-1,

PageID 24808.) Dr. Stevens testified that with barbiturates, as you increase the dose, you increase the potency of inhibiting neurons to the point where the person is sedated, then asleep, then anesthetized, then comatose, and then dead. That line on the graph goes diagonally up from the lower left corner to the upper right corner. *Id*. at PageID 30765. Dr. Stevens testified that "the greater the dose, the greater the effects along that vertical or Y-axis." *Id*.

With respect to benzodiazepines, according to Dr. Stevens:

> [A]t some dose this effect does not keep going up along the Y axis. You get a plateau. And in this case, it's drawn just below anesthesia. So just below anesthesia you start to see it level off. It's either called a plateau effect or a ceiling effect.

Id. at PageID 30765-66.

Dr. Stevens agreed during cross-examination that while pentobarbital has a lethal dose range, midazolam does not. *Id*. at PageID 30926. When pressed to explain fatalities that had been reported from doses of midazolam ranging from as little as .04 to .07 mg per kilogram, Dr. Stevens expressed his belief that such fatalities are more likely "when there is another drug on board," and further testified that fatalities from midazolam alone are "very, very rare." *Id*. at PageID 30936. Dr. Stevens also agreed on cross-examination that midazolam package inserts include a "black box warning" about the drug's potential dangers, but noted that "[i]t is not rare to have a black box warning." *Id*. at PageID 30937-38.

Dr. Stevens several times cautioned that his diagram was theoretical, in the sense that he did not assign values or doses, but that "you could take experiments where they have looked at actual assays and cell cultures, for example, and you could come up with values along [the X-axis or dose line]." Id. at PageID 30766. Dr. Stevens thus clarified that although his diagram was illustrative in nature, what that diagram represents has been confirmed through experiments. *Id.* at PageID 30766-67.

Dr. Stevens next testified about precise (and imprecise) uses of the terms "anesthesia" and/or "general anesthesia." Relying on the approach taken by the American Society of Anesthesiology ("ASA"), Dr. Stevens explained that "we have to be very careful to only use general anesthesia when we're talking about the stage of anesthesia that is deep enough to do surgery, for example, where you have loss of awareness, you have loss of consciousness, and no response to noxious stimulus." *Id*. at PageID 30767-68; ECF No. 836-1, PageID 24809-10. Dr. Stevens further explained that although there are different levels of sedation—minimal, moderate, and deep—there is only one level of general anesthesia, which is beyond the deepest level of sedation. (ECF No. 923, PageID 30768-69; ECF No. 836-1, PageID 24810.) Dr. Stevens then opined that because the "responsiveness" associated with general anesthesia is "unarousable even with painful stimulus," that is the state in which you would want a condemned inmate to be. (ECF No. 923, PageID 30768.)

With respect to the different levels of sedation, Dr. Stevens testified that minimal sedation would be associated with premedication before a root canal; that moderate sedation would be greater premedication; and that deep sedation would be that achieved by IV midazolam. *Id*. at PageID 30769. On cross-examination, Dr. Stevens agreed that the ASA chart in his report states that, under a level of deep sedation/analgesia, "reflex withdrawal from painful stimulus is NOT considered a purposeful response." *Id*. at PageID 30934 (citing ECF No. 836-1, PageID 24810.) Dr. Stevens continued that whereas different levels of sedation can involve drug-induced *depression* of consciousness, but the ability to respond purposefully, "only at general anesthesia do we have a drug-induced *loss* of consciousness." *Id*. at PageID 30770 (emphasis added). Stated another way, Dr. Stevens explained, if a person who is sedated is exposed to increasingly severe stimulation, that person will eventually respond, but a person

under general anesthesia would not respond to even the most painful stimulus. *Id*. at PageID 30770-71 (relying on ECF No. 836-1, PageID 24810 "Continuum of Depth of Sedation"). Benzodiazepines, Dr. Stevens testified, cannot bring someone to a level of general anesthesia. (ECF No. 923, PageID 30771.) Dr. Stevens confirmed on cross-examination that he was not aware of any state other than general anesthesia where a patient would lose consciousness. *Id*. at PageID 30920.

Returning to his Y-axis / X-axis illustrative diagram in his Expert Declaration (ECF No. 836-1, PageID 24808), Dr. Stevens explained that if one were to attempt to assign dose values along the X-axis, one would never plot a dose of 500 mg because "there is no data that exists." (ECF No. 923, PageID 30772.) "There is no data at the level of dosage," Dr. Stevens continued, "because it's way beyond any clinical usage of that drug." *Id*. at PageID 30773). Dr. Stevens also testified that there is no evidence to support the proposition that a plot point of 500 mg of midazolam would achieve general anesthesia. *Id*. Dr. Stevens explained that the highest dosage level of midazolam for which he had seen clinical data was 2 or 3 mg per kilogram. *Id*. at 30773-74.

Dr. Stevens next returned to the concept of "ceiling effect." After agreeing that the concept of a ceiling effect is not controversial, Dr. Stevens likened a ceiling effect to the amount of pain relief an over-the-counter analgesic, such as Advil or aspirin, would provide for a severe injury such as the loss of a limb or a gallbladder attack—that is, "[i]t could maybe cause 20 percent decrease in your pain, but it's going to level off and show a ceiling effect." *Id*. at PageID 30774-75. "[T]he main point," Dr. Stevens explained, "is that you can't just give more of a drug and expect the nature of the drug to change." *Id*. at PageID 30776.

Dr. Stevens stated his understanding of Ohio's current execution protocol:

> Yes. I believe the first drug is two syringes full of 250 milligrams each of midazolam. So those are infused IV. And then after a consciousness check, the second drug is a muscle paralytic; pancuronium, vecuronium, one of paralytic drugs, which, if course, paralyzes muscles so there is no movement, including breathing. And then the third drug is potassium chloride, which basically is an electrolyte that stops the heart. So that's my understanding.

Id. at PageID 30777. Dr. Stevens was next asked what is known about how the second and third drugs would feel to someone who is *not* unaware and *not* insensate to pain. On the basis of a few papers he had researched concerning cases where patients were administered a paralytic while conscious and without having been sedated (ECF No. 836-1, PageID 24811), Dr. Stevens testified that those patients reported feeling terrible and in severe pain, like being buried alive or already dead, panicked, and as if they were suffocating. (ECF No. 923, PageID 30777-78.) Dr. Stevens agreed on cross-examination that with respect to the complaint of feeling panic or terror, that part of the pharmacological effect of midazolam is, in fact, relief of anxiety. I*d*. at PageID 30951. To that point, Dr. Stevens also agreed that midazolam has an anterograde amnesic effect that can suppress a patient's ability to form memories while under the effect of the midazolam. *Id*. at PageID 30951-52. Dr. Stevens agreed with earlier testimony in this litigation to the effect that the level of fear, pain, and panic associated with the feeling of being buried alive would almost surely break through and overcome the anti-anxiety effect of midazolam. *Id*.at PageID 30959.

With respect to the third drug, potassium chloride, Dr. Stevens testified about a patient who had reported a severe pain that spread up his arm after the potassium chloride was injected IV and a ringing in his ears, before losing consciousness. *Id*. at PageID 30779. He cited another study where potassium chloride produced severe pain at the injection site, and four cases where

the patients screamed out in pain. *Id*. Dr. Stevens testified, "it's obvious, I think, and accepted that potassium chloride without being in a state of general anesthesia would always cause severe and intolerable pain and suffering." *Id*. To that point, Dr. Stevens agreed it would not be acceptable medical practice to administer the second or third drug to someone not in a state of general anesthesia, though he qualified that opinion by noting that he is not a medical doctor. *Id*. at PageID 30780.

Dr. Stevens proceeded to testify about a table in his Expert Declaration labeled "Comparison of therapeutic uses for five benzodiazepines and five barbiturates." (ECF No. 836-1, PageID 24812.) He testified that what the table ends up demonstrating is that there is not much overlap. "In other words," he explained, "the FDA has clearly shown that these are separate entities, separate classes of drugs with separate therapeutic uses." (ECF No. 923, PageI# 30781.) He continued, "benzodiazepines are not a good pharmacological substitute for barbiturates." *Id*. He testified as to his understanding that midazolam is approved for inducing anesthesia, but not for maintaining general anesthesia. *Id*. at PageID 30781-83; ECF No. 836-1, PageID 24812. When questioned on cross-examination whether the Seventh Edition of *Miller's Anesthesia* states that midazolam is the benzodiazepine of choice to induce anesthesia and is safe in doses of as little as .2 mg for that purpose, Dr. Stevens answered that he believed a later edition of *Miller*'s may have been updated on that point. (ECF No. 923, PageID 30948-49.)

Dr. Stevens was asked about a section of his Expert Declaration discussing the Drug Enforcement Agency's ("DEA") scheduling of midazolam and pentobarbital. He explained that under the Controlled Substances Act of 1970, drugs are assigned to schedules ranging from I to V, with Schedule I listing drugs with no medical use and are illicit. *Id*. at PageID 30783; ECF No. 836-1, PageID 24814. Schedule II drugs are medically used but highly addictive—such as

morphine, methamphetamine, and cocaine. *Id*. Dr. Stevens then explained that another reflection of the differences between barbiturates and benzodiazepines is the fact that they are scheduled differently: barbiturates are more susceptible to being abused and are accordingly scheduled higher than are midazolam and other benzodiazepines: midazolam is on Schedule IV, whereas most barbiturates are on Schedule II. (ECF No. 923, PageID 30785; ECF No. 836-1, PageID 24814.)

Dr. Stevens testified generally about various calculations he conducted and/or data he relied on in estimating what level of midazolam in the brain would produce a ceiling effect. (ECF No. 923, PageID 30788 (discussing ECF No. 836-1, PageID 24815-28)).[15] He explained the need to examine in-vitro studies—or "cells in petri dishes" in a laboratory setting—because that is the best data available. (ECF No. 923, PageID 30788.) Using that data, Dr. Stevens testified that when those cells reached approximately 100 nanomoles of GABA (a measure of concentration), they leveled off, such that even if GABA were increased, that fact would not show a greater effect in the cell models. *Id*. at PageID 30788-89. On cross-examination, Dr. Stevens could not confirm at what temperature the various specimens were tested. *Id*. at PageID 30940. He also attempted to explain variations, means, and true values inherent in these in-vitro studies. *Id*. at PageID 30940-43. On redirect examination, Dr. Stevens confirmed that no matter what level of drug concentration the ceiling effect of midazolam is calculated to be, it would not change Dr. Stevens' conclusion as to the substantial likelihood of harm from using any amount of the drug as the first in Ohio's three-drug protocol. *Id*. at PageID 30959-60.

[15] Later in his testimony, Dr. Stevens explained a calculation error he had made that was identified by one of the Defendants' experts, Dr. Joseph Antognini. (ECF No. 923, PageID 30803-30805.) The error was corrected in Dr. Stevens' rebuttal declaration, and Dr. Stevens also testified that that error did not change his opinions. (See also ECF No. 923, PageID 30959-30960.)

In addition to considering in-vitro data, Dt. Stevens also looked at some clinical studies that showed a ceiling effect. *Id*. at PageID 30793. Specifically, Dr. Stevens referenced a section in his Expert Declaration titled "Clinical studies of midazolam and BIS." (ECF No. 836-1, PageID 24826.) Dr. Stevens explained that "BIS" is an acronym for bispectral index—a proprietary algorithm that takes raw EEG brain waves, filters them through some transformations, and comes up with a single number on a scale from 100 to zero. A reading of 100 means the individual is completely awake and aware, while zero means there is no brain wave activity. (ECF No. 923, PageID 30793-30794.) Dr. Stevens explained that BIS value is a good proxy for determining how much the brain activity is depressed and can be used during surgical procedures for measuring depths of sedation and determining when general anesthesia has been reached. *Id*.at PageID 30794.

Ultimately, Dr. Stevens concluded that midazolam reaches a ceiling effect at about 228 mg *id*. at PageID 30800, and that Ohio's dosage of 500 mg is 2.192 times higher than the concentration at which midazolam produces a ceiling effect. *Id*. at PageID 30799. The relevance of that conclusion to a lethal injection protocol, Dr. Stevens explained, is that because 500 mg is beyond the ceiling effect, greater doses will not produce a greater effect. *Id*.at PageID 30799. Dr. Stevens clarified that if a dose of 500 mg were administered, a second dose of 500 mg would have "[n]o effect." *Id*. at PageID 30800. Referring to midazolam's "mechanism of action," Dr. Stevens further explained:

> I mean, all the clinical studies support that there is a ceiling effect of midazolam. Midazolam cannot get past a deep sedative level, deep sedation, according to ASA, and it hasn't been ever shown to product general anesthesia. I have found no clinical studies to do that.
>
> ***

> [I] think that's the key point. As much as you might want it to, one cannot change the nature of a drug by giving more and more and more of it.

Id. at PageID 30801. Dr. Stevens agreed on cross-examination, however, that "it's not possible to experiment on humans administered doses greater than those used clinically." *Id*. at PageID 30935. He further offered that, despite his view that midazolam is not dangerous, he did not belief that any institutional review board would approve a study in which humans were given 500 mg of the drug. *Id.* PageID 30935.

Dr. Stevens concluded with his opinion that, to a reasonable degree of scientific certainty, "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 PageID 30802-03.

Dr. Stevens agreed on cross-examination that fast-acting barbiturates such as thiopental and pentobarbital are pharmacologically more suitable for lethal injection protocols, insofar as they would produce the state of general anesthesia that the first drug is intended to produce. *Id*. at PageID 30921-22, 30927. 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. *Id*.at PageID 30924-325. Dr. Stevens also agreed on cross-examination that in an earlier report he had prepared and submitted in a 2015 lethal injection case in Arkansas, he opined that a massive dose of an opioid would be an alternative method of execution. *Id*. at PageID 30952-53. Dr. Stevens was unable to recall whether he was aware that Ohio had conducted an execution in 2014 using a mixture of midazolam and the opioid hydromorphone

when he wrote his 2015 Arkansas report, but he did state that combining those drugs would render a synergistic effect, which is to say that in combination, each drug would amplify the strength or effect of the other.*Id*. at PageID 30954-55.

Sergio Bergese, M.D.

Plaintiffs' next expert witness was Dr. Sergio Bergese, M.D, a Professor of Anesthesiology and Neurological Surgery, as well as a practicing anesthesiologist, at the Ohio State University Wexner Medical Center. Dr. Bergese testified as to his education, employment, and experience in the field of anesthesiology (Evid. Hrg. Tr., ECF No. 923, PageID 30812-18); his Curriculum Vitae is attached to his Expert Declaration (ECF No. 844-1, PageID 24992-61.) Without objection by Defendants, the Court ruled that Dr. Bergese was qualified to testify as an expert. (ECF No. 923, PageID 30819.)

Dr. Bergese's expert opinions, as set forth in his Expert Declaration, are as follows:

> 4. There are no clinical data establishing what will happen to an individual upon injection of 500 mg of midazolam, nor are there any clinical data establishing what will happen upon injection of 1000 mg of midazolam or any higher doses.
>
> 5. There now exists, however, sufficient real-world data taken from lethal injection executions using midazolam to be able to conclude that using midazolam in a lethal injection protocol will not cause immediate death and will cause the inmate to suffer an excruciating and torturous execution while the inmate experiences and feels that pain and suffering.
>
> 6. When there is not an effective chemical mask in place to hide what the inmate is experiencing, the inmate in every

execution using midazolam has exhibited bodily movements that demonstrated he was sensate following injection of midazolam. The inmate was aware and therefore experiencing the pain and suffering of noxious stimuli.

7. The painful stimulus in a lethal injection execution using Ohio's protocol can be in the form of air hunger, which is the sensation of being unable to catch one's breath, like a fish out of water. Descriptions of movements by Dennis McGuire in Ohio, Joseph Wood in Arizona, and Ronald Smith in Alabama all strongly suggest those individuals experienced air hunger during their executions.

8. While McGuire was injected with 10 mg of midazolam, Mr. Wood was injected with 750 mg of midazolam, and reports suggest Mr. Smith was injected with at least 500 mg and possibly 1000 mg of midazolam.

9. The painful stimulus using Ohio's execution protocol can be in the form of feelings of suffocation like being buried alive, which will occur when the respiratory system's muscles are paralyzed by the paralytic agent. The person will be unable to perform the muscle movements necessary to breathe while aware.

10. The painful stimulus using Ohio's execution protocol can be in the form of feeling like being burned alive from the inside, as if fire is being poured into the veins, when potassium chloride is injected into the blood vessels causing irritation.

11. The painful stimulus using Ohio's execution protocol can be in the form of a searing pain of a massive heart attack as potassium chloride disrupts the electrical activity of the heart and cause cardiac arrest.

12. Reports of executions in which a condemned inmate was first injected with midazolam and then bodily movement such as moving the extremities or opening of one or both

eyes was observed following injection of the paralytic drug and/or potassium chloride suggest those individuals were aware or at least able to feel and experience the stimuli associated with the second and third drugs, and were responding to one or more of these stimuli. Further responsive movements were subsequently hidden behind the chemical veil of the paralytic drug taking full effect.

13. Because the inmate will not be rendered and kept unaware and insensate quickly following the initial injection of midazolam in a three-drug protocol using a paralytic agent and potassium chloride, and will not be rendered and kept unaware and insensate throughout the entire process until death occurs, the inmate will experience any or all of those stimuli during his execution.

14. The use of midazolam in Ohio's three-drug lethal injection protocol creates a substantial and unnecessary risk of a severely painful, torturous death process. There is more than a substantial and unnecessary risk; it is a virtual certainty, based on the only data from real-world applications of midazolam of the amounts used in lethal injection executions.

15. The pain associated with the second and third lethal injection drugs would be excruciating, equivalent or worse than the pain associated with a major surgical intervention with no anesthesia. Similarly, the air hunger caused by respiratory suppression from midazolam would be terrifying and painful. Unless the IV-administered midazolam would induce and maintain a state of being unaware and insensate deep enough to withstand at least the pain of a major surgical intervention, or to not be overcome by the painful stimulus of air hunger, it is ineffective in its intended role in Ohio's execution protocol No amount of midazolam can do that, however.

16. It is my expert opinion, based in substantial part on reviewing the reports from lethal injection executions, that an IV injection of 500 mg of midazolam, or a 1000 mg IV

injection of midazolam, or a greater dose, is incapable of rendering and holding an inmate in an unaware and insensate state through the experience of air hunger and the sensations associated with the second and third lethal injection drugs in Ohio's protocol.

17. Midazolam's inability to render and hold an inmate unaware and insensate in the presence of painful stimuli from the second and third drugs makes midazolam unsuitable from use as contemplated by Ohio's execution protocol.

18. Midazolam's inability to render and hold an inmate sufficiently unaware and insensate in the presence of painful stimuli from suffering air hunger makes midazolam wholly unsuited for use as contemplated by Ohio's execution protocol.

19. My opinion is not just based on having administered midazolam (and many other true general anesthetic drugs) many thousands of times over the course of my medical career. Leading medical texts, pharmacological references, and research papers confirm midazolam cannot induce and maintain a sufficiently deep state of unawareness and being insensate in the presence of painful stimuli. An established body of information, therefore, confirms the real-world data we have from lethal injection executions using midazolam.

20. The reason midazolam cannot sufficiently depress electrical activity in the brain to hold an inmate unconscious in the presence of pain stimuli is directly tied to the biochemical mechanism by which midazolam exerts action in the brain. This specific biochemical mechanism places a firm limit on the maximum pharmacological effect that midazolam can have. This specific biochemical mechanism means that midazolam is chemically incapable of depressing neuronal activity to the same extent as general anesthetics such as propofol.

21. Midazolam does not render and maintain a person unaware and insensate through the application of a painful stimulus. For midazolam to keep a person unaware it would have to work also on the implicit memory, otherwise it only would cause memory dissociation. It does not depress electrical activity to a deeper level than would be provided by, for example, pentobarbital. Midazolam does not produce any analgesic ("pain blocking") effect.

22. Even the memory dissociation and limited depression in neuronal activity midazolam induces will have a ceiling effect and it will wear off rapidly. It is highly likely the maximum effect of midazolam will begin to wear off, manifested by a measurable increase in neuronal activity, within approximately fifteen minutes following administration.

23. The properties of midazolam limit its ability to fully depress electrical activity in the brain. The lack of any analgesic (pain blocking) properties renders midazolam incapable of maintaining even that limited level of depressed electrical activity under the undiminished pain and suffering associated with the drugs in Ohio's execution protocol.

24. The "consciousness assessment" called for in Ohio's protocol is undefined. But if it does not involve the use of reliable instrumentation-based assessments of awareness and the ability to feel and experience pain, it is not an adequate means of assessing whether an inmate is unaware and insensate before administration of the second and third lethal injection drugs. Furthermore, the execution rehearsal documentation I have seen demonstrates that Ohio execution personnel will conduct an extremely short consciousness check, mostly based on the lack of reflex, much too soon after they conclude injecting the first 500 mg of midazolam, and that they will proceed to inject the second and third drugs far too soon after injection of that midazolam. A lack of reflex does not constitute a lack of awareness or a lack of pain.

(ECF No. 844-1, PageID 24942-47.)

Dr. Bergese testified that the field in which he primarily practices, anesthesia during surgical procedures on the brain, puts more emphasis on managing a patient's brain before, during, and after surgery. When asked whether consciousness is the same thing as awareness, Dr. Bergese answered, "No, they are concepts that clearly cross paths, but you can be unconscious and be aware."[16] (ECF No. 923, PageID 30819.) Dr. Bergese further testified that "we can make the same assumption from pain. So you can be unconscious and you can have pain." *Id*. at PageID 30820. He explained that a patient who is unconscious but experiencing pain might exhibit such signs as hypertension, tachycardia, high blood pressure, increased heart rate, sweating, or movement. *Id*. at PageID 30821.

Dr. Bergese defined general anesthesia as the state at which a patient can undergo surgery, and is defined by achieving (1) immobility, (2) lack of consciousness, and (3) lack of pain. *Id*. at PageID 30821. Dr. Bergese testified that as a general rule, anesthesiologists use multiple drugs for a surgical procedure, using one drug to induce anesthesia and another drug or drugs to maintain anesthesia. *Id.* at PageID 30821-22. Dr. Bergese proceeded to explain the nature and use of Bispectral Index ("BIS") as a proprietary algorithm that measures EEG and other data to produce an index that provides an understanding of the depth of anesthesia of a patient. He continued that on a scale from zero to 100, the range of forty to sixty would reflect a state of general anesthesia. *Id*. at PageID 30823.

When asked whether midazolam has analgesic properties, Dr. Bergese answered, "[c]linically I will say no." Dr. Bergese then clarified that BIS monitors have nothing to do with

[16] The Court notes, so the record is clear, that while the Court found Dr. Bergese's command of the English language to be fluent, Dr. Bergese did speak with a pronounced-accent.

treating or gauging pain. *Id*. at PageID 30824. Dr. Bergese denied that he would ever use midazolam by itself as the sole anesthetic for a procedure.[17] *Id*. at PageID 30825. When asked during cross-examination whether midazolam is ever used alone to sedate a patient before intubation, Dr. Bergese stated that midazolam is not "commonly used alone, but you can use it alone, true." *Id*. at PageID 30901. He also allowed that in certain circumstances such as a patient in distress during an emergency, midazolam might be used alone. *Id*. at PageID 30900. Dr. Bergese explained that although midazolam is "very commonly" used for colonoscopies, midazolam is never used alone,and is instead used with an opioid which treats the pain. *Id*. at PageID 30825-26. Dr. Bergese testified that one would typically give the opioid followed by midazolam because due to pharmacokinetics, if the patient's pain is treated first, he or she can then be given a lower dose of a sedative to achieve the degree of sedation desired.[18] Dr. Bergese also testified that a person undergoing a colonoscopy "absolutely" actually experiences the pain as the procedure is happening. *Id*. at PageID 30826-27. He explained that midazolam also has an amnesic effect, such that a patient could feel a painful experience as it is happening but not remember that later. (*Id*. at PageID 30828-29.

Dr. Bergese testified that the amnesic quality of injected midazolam would not have the ability to stop an inmate from actually experiencing any pain associated with his execution by lethal injection. *Id*. at PageID 30829-30. He clarified that the pain experienced would depend on how much the inmate's consciousness is depressed, noting that consciousness is not an all-or-

[17] Dr. Bergese later testified on cross-examination that he disagreed with an opinion rendered by expert Dr. David Waisel, who testified in these proceedings some three years ago, that there is a level of IV-administered midazolam that could result achieve a state of general anesthesia. (ECF No. 923, PageID 30890.) When asked during cross-examination whether he was aware that another expert who had testified in this litigation, Dr. Mark Dershwitz, stated that he had used midazolam as the primary drug to induce anesthesia for neurosurgeries, Dr. Bergese answered that he did not recall reading that but agreed that it was "possible" to use midazolam under those circumstances. *Id*. at PageID 30902. Finally, Dr. Bergese admitted during cross-examination that he was not aware of testimony by yet another expert who had testified in this litigation, Dr. Mark Heath, that very high doses of midazolam would completely ablate consciousness. *Id*. at PageID 30902-30903.

[18] This is apparently consistent with Dr. Dershwitz's testimony about the likely effect of the drugs used on McGuire.

nothing proposition, but rather, is a spectrum of different grades. *Id*. at PageID 30830. Dr. Bergese then testified that if an inmate's consciousness were not depressed enough, that inmate would not only feel, but would react to, pain,which could not be relieved by midazolam's amnesic effect. (*Id*.at PageID 30830. Explaining this concept in the context of a routine colonoscopy, during which a combination of an anesthetic and an opioid would be used, Dr. Bergese testified that a patient's inability to remember the procedure or any attendant pain does not mean that the patient did not actually experience the pain. *Id*. at PageID 30831-32.

Dr. Bergese next testified that movement(s) sometimes occur after a patient has been sedated. As a preliminary matter, Dr. Bergese testified that movements while under sedation mean that the anesthesiologist is "not doing a very good job," in view of the fact that one of the three goals of anesthesia is immobility. *Id*. at PageID 30834. While acknowledging a theoretical difference between movements that are reflexive and movements that might indicate some level of consciousness or awareness, Dr. Bergese testified that if a patient exhibited movement during surgery, he as the anesthesiologist would immediately give more anesthetic because as soon as the patient moves, consciousness is going to follow. *Id*. at PageID 30835. Dr. Bergese noted that this is an example of where a BIS monitor can be valuable because it would show whether a patient's EEG is becoming more active, indicating a return to consciousness. *Id*. at PageID 30836. Dr. Bergese appeared to agree on cross-examination that even if it would be difficult to draw any conclusions from reports of movements such as eye movements alone, when such movements happen frequently, "it makes me believe that that involuntary movement may have a lot to do with consciousness." *Id*. at PageID 30892.

Applying these principles to an execution context, Dr. Bergese agreed that it is very important with a three-drug protocol that the first drug works to render the inmate fully unaware,

fully insensate, and unconscious. *Id*. at PageID 30837. When asked why that is so important, Dr. Bergese answered, "[w]e know, for instance, rocuronium, [the] second drug[] that you are going to use, is painful on injection." *Id*. at PageID 30837-38. Dr. Bergese further testified that the pH of potassium chloride, the third drug in Ohio's three-drug execution protocol, is caustic and would cause pain. *Id*. at PageID 30838. He added "there are things that we don't know," such as whether the process of dying is something that might cause an inmate being executed react differently than a patient undergoing surgery. *Id*. at PageID 30838. He also explained that it would never be medically acceptable to paralyze a fully conscious patient because it is absolutely terrifying not being able to move and being aware of not being able to move. *Id*. at PageID 30840-41.

When asked whether, hypothetically, he could have offered any opinion three years ago about an execution protocol involving a mixture of 50 mg of hydromorphone and 50 mg of midazolam, Dr. Bergese answered that he would not have offered an opinion because there was no scientific or real-world data upon which to rely. *Id*. at PageID 30842-44. By contrast, he testified that he was now in a position to offer opinions about Ohio's three-drug execution protocol because "[n]ow we have real data that we cannot ignore," referring to eyewitness accounts of midazolam-involved executions. *Id*. at PageID 30844-45. He continued:

> We just cannot ignore the people are gasping, the people are going 20 minutes, that people are going 40 minutes. It's your responsibility as a citizen to act on this.
>
> I was in Europe last time that I hear this. People talk to you like we are inhumane, that we are just having people 20 minutes, 30 minutes, 40 minutes. So clearly we are here today because we have a problem, and clearly we have to address this problem. So that's why I accepted this time and say yes, I will do a report.

Id. at PageID 30845. Dr. Bergese explained that for science to reach valid conclusions, it must consider "every single piece of data." *Id*. at PageID 30845. In this context, Dr. Bergese continued, while it is important to consider pharmacology, pharmacodynamics, and clinical data, "I think that the strongest data that you have is what happened in those executions." *Id*. at PageID 30846. Dr. Bergese explained during cross-examination that although it is important to consider every piece of available data, he respectfully did not place much stock in what findings any court might have made about something as complex as "consciousness." *Id*.at PageID 30894-95.

Dr. Bergese was asked about the recent executions to which he was referring, beginning with Alabama's execution of Ron Smith. Testimony and evidence demonstrated that Smith was executed with a three-drug protocol that began with an IV administration of 500 mg of midazolam, followed by a paralytic and then potassium chloride. Dr. Bergese testified that he had reviewed news stories of eyewitness accounts, as well as a sworn declaration by Spencer Hahn. *Id*. at PageID 30849. Dr. Bergese found significance in accounts that Smith appeared be speaking for several minutes after the injection of midazolam. *Id*. at PageID 30850. Dr. Bergese explained:

> I think it's telling us that here we have something that is different, that we haven't seen [with] other type of hypnotics. I do anesthesia every day, and when you put somebody else asleep – and I'm talking about smaller doses, people just don't talk. People just don't do those kind of things. So here to me what it's signaling, what it's telling me is that it's a higher recruiting on the brain of consciousness for this person to be able to do this kind of thing, to be able to speak, to be able to think.
>
> So it's very difficult. Like I said before, we work in a black box. We don't know what happened in the middle. It's no different than when we do general anesthesia. So sometimes it's very difficult to get conclusions when you see a little movement in here,

> a little movement in there. You can argue either way. But, here, clearly, the state of consciousness of this patient is much, much higher than you will expect for somebody else to just move a muscle, who has a twitch.

Id. at PageID 30849-50. Dr. Bergese continued that talking requires a significant amount of brain activity. *Id*. at PageID 30850. Later, during cross-examination, Dr. Bergese agreed that although he was aware of one or two executions during which the inmate(s) purportedly spoke, he was aware that there have been quite a few more executions during which the inmates did not speak. *Id*. at PageID 30896. Dr. Bergese explained that the fact that midazolam has appeared to "work" for some people does not invalidate his opinion as to the inmates on whom it did not appear to work as expected with respect to depressing those inmates' level of awareness. *Id*. at PageID 30896-97. When asked about the validity of an opinion based on one or two isolated incidents, Dr. Bergese explained that the unusual occurrences of people exhibiting any kind of movement or speaking validated his reaching an opinion based on the few cases in which inmates moved or spoke during their executions: "When [I] put a patient asleep, people don't do those kinds of things . . . and since we are not measuring electrical function of the brain [during executions], we just don't know the answer. That's my concern." *Id*. at PageID 30898.

Later during cross-examination, Dr. Bergese agreed that it would be very difficult to conduct research on the effects of the dosage level of midazolam prescribed by Ohio's current execution protocol because that dosage level far exceeds a clinical level. *Id*. at PageID 30908-09. He also agreed that although data extrapolations about high dosages could "[g]o either way," he maintained that "there is data, sufficient data [that] led me to believe that some of those inmates were conscious beyond what I expected with the dose." *Id*. at PageID 30909.

Continuing with the Smith execution, Dr. Bergese also found significance in accounts that five minutes after being injected with midazolam, Smith was pinched on the back of the arm and yanked away from that pinch. *Id*. at PageID 30851. Dr. Bergese explained that withdrawing from pain is a complex thing and that a person who is unconscious will not withdraw from pain. *Id*. at PageID 30851. Dr. Bergese explained that there is a difference between involuntary movement and voluntary movement, and that voluntary movement requires a much higher state of consciousness. *Id*. at PageID 30851.

When asked about accounts that Smith lifted his head, looked around, and moved his arms, Dr. Bergese continued:

> That is not normal by any means. I was thinking about this this morning when I put two patients asleep. And I counted and I never do and I counted this morning and 18, 20 seconds later it tells patients, they were gone. They did not move. They did not do anything else. So clearly the quantity of midazolam that was used is not working as my propofol that I used this morning. So is something quite different here. Those drugs are affecting consciousness in a different way. So that's my conclusion.

Id. at PageID 30852. Such purposeful movements such as the clenching and unclenching of one's fists, as opposed to perhaps the opening and closing of the eyes requires a more active brain. *Id*. at PageID 30852. Dr. Bergese stated that, with a high degree of certainty, a person exhibiting such purposeful movements is not insensate. *Id*. at PageID 30852. And given that Smith was actually injected with a second dose of 500 mg of midazolam, Dr. Bergese stated again that "that's where science goes wrong. . . . So clearly, again, I['m] going to insist, my observation is that this drug is not working as we thought it would." *Id*. at PageID 30853.

Dr. Bergese was next asked about the January 16, 2014, execution of Dennis McGuire in Ohio. He testified that accounts that McGuire was opening and closing his fists after being

injected with a mixture of 10 mg of midazolam and 40 mg of hydromorphone indicated "that the brain is working to the point that the inmate can do purposeful movement[s]" and that the inmate "[i]s not fully unconscious for sure." *Id*. at PageID 30855. With respect to accounts that after administration of the two-drug mixture, McGuire said "I love you" toward his children, Dr. Bergese testified that "speaking is even a more elaborate function." *Id*. at PageID 30855. He also offered that "[s]omebody else who [is] speak[ing] will feel pain for sure." *Id*. at PageID 30855. That McGuire was injected with an opioid in addition to the midazolam did not change Dr. Bergese's assessment as to the use of midazolam as it relates to consciousness as the first drug in a three-drug protocol. *Id*. at PageID 30855-56. He reiterated that conclusion during cross-examination, testifying that although a lower dose of midazolam was used than that now prescribed by Ohio's execution protocol, Dr. Bergese would have expected the midazolam to have a "higher effect," given the fact that opioids and midazolam have a synergistic effect. *Id*. at PageID 30899. Dr. Bergese explained that what happened during the McGuire execution, followed by what happened during the Ronald Smith execution in Alabama, begins to establish a pattern showing that midazolam is not having the expected effect during executions. *Id*. at PageID 30857.

Dr. Bergese was asked about the execution of Clayton Lockett in Oklahoma. Referring first to the autopsy report, Dr. Bergese noted that there were 1400 nanograms of midazolam per gram of tissue, "which is above and beyond what you need for general anesthetic, for instance." *Id.* at PageID 30858. Asked to comment on evidence that following the injection of lethal injection drugs and originally appearing unconscious, Lockett proceeded to speak, writhe, clinch his fists, and try to lift himself off the table, Dr. Bergese responded, that if Lockett's brain was

still active enough to perform those actions after administration of the drugs, then the drugs were not having the intended effect. *Id*. at PageID 30858.

Turning to the execution of Joseph Wood in Arizona, Dr. Bergese was asked about accounts that Wood was injected with a total of 750 mg of midazolam and 750 mg of hydromorphone over the course of two hours, but attempted to breathe and gasped over 640 times. *Id*. at PageID 30859. Dr. Bergese stated:

> I think it's more or less what we were talking about. It's a long period of time. Two hours is a long time. You don't expect that hiatus. I mean, it is a long period. There [are] a lot of drugs that were given and still they are not doing what you think [they're] supposed to do.

Id. at PageID 30859. Dr. Bergese could not give a definitive answer as Wood's state of consciousness during his lengthy execution. *Id*. at PageID 30860. Similarly, he could not say whether the movements and breathing actions that Ohio inmate Dennis McGuire exhibited during his execution were incident to the act of dying or an indication that his brain still had some level of functioning. *Id*. at PageID 30861.

Dr. Bergese was next asked about evidence from Florida executions indicating that following an injection of 500 mg of midazolam followed within a minute or two by an injection of a paralytic agent, certain inmates exhibited minimal movements such as eye opening. *Id*. at PageID 30862. Dr. Bergese appeared to question the application of the paralytic so quickly, noting the importance of being very sure that the inmate was insensate and unconscious before receiving the paralytic. *Id*. at PageID 30862-63. During cross-examination, Dr. Bergese did not dispute that as of April 15, 2015, Florida had conducted a total of eleven lethal injection executions using 500 mg of midazolam as the first drug in a three-drug protocol. *Id*. at PageID 30886-87. Dr. Bergese acknowledged that he considered how quickly the paralytic agent

follows the administration of the midazolam in Florida, and the manner in which Florida immobilizes inmates' hands during executions in forming his opinion, to the extent that he did, about the Florida midazolam-involved executions. *Id*. at PageID 30887.

Dr. Bergese continued that an immediate injection of the paralytic would mask movements such as were witnessed in the McGuire (Ohio), Wood (Arizona), and Lockett (Oklahoma) executions, but would not guarantee that the inmate was unconsciousness and insensate. *Id*. at PageID 30863. A person fully paralyzed and fully conscious, would experience considerable terror. *Id*. at PageID 30863. Dr. Bergese continued that nothing about consciousness should be gleaned from the absence of movements during executions in which the paralytic drug was injected very quickly after the first drug. *Id*. at PageID 30863-64.

Dr. Bergese testified that what occurred during the four executions he was asked about indicate to him that for whatever reason, midazolam "is not doing what you thought it would."[19] *Id*. at PageID 30864. Dr. Bergese "absolutely" agreed, to a reasonable degree of medical certainty, that Plaintiffs Tibbetts, Phillips, and Otte would be subjected to a substantial risk of experiencing the pain and suffering of an execution is they were executed using Ohio's current protocol. *Id*. at PageID 30865.

Dr. Bergese agreed on cross-examination, however, that he was not testifying that there were no circumstances under which the dosage of midazolam set forth in Ohio's current execution protocol could render an inmate sufficiently sedated to not be aware of the noxious stimuli of the second and third drugs. *Id*. at PageID 30873. Dr. Bergese also agreed on cross-

[19] Dr. Bergese later testified, in response to questioning by the Court, that although he did consider the fact that many of the accounts of these executions were provided by highly biased witnesses, he ultimately regarded the data as reliable because "the majority of the data points to the same place." (ECF No. 923, at PageID # 30869-30870). To that point, Dr. Bergese testified on cross-examination that although he truly thought about the biases that might be underlying eyewitness accounts of these executions, "the reasons that I got to a different opinion is because two hours of breathing is two hours of breathing and you can't – anybody else who is breathing for two hours after the drugs were given, I don't know how you can slice it different." *Id.* at PageID # 30893.

examination that if midazolam administered during an execution does not appear to have the effect desired it could be because the midazolam was not properly administered. (*Id*. at PageID 30874. Dr. Bergese stated that he is 100 percent certain that the dosage level of midazolam called for in Ohio's execution protocol will not render the inmate insensate to the noxious stimuli of the second and third drugs in the protocol.[20] *Id*. at PageID 30875.

Dr. Bergese next testified about conclusions he set forth in a Supplemental Expert Declaration—specifically with respect to the six different types of "consciousness checks" that could be used during executions under Ohio's current protocol. (ECF No. 897-1). Dr. Bergese explained:

> So the problem with this kind of quote-unquote consciousness check is that they are not truly consciousness check. All you doing is . . . checking a reflex or . . . checking pain. So if I touch your eye, all I am doing is . . . monitoring the trigeminal nerve and the facial manner and see[ing] their response.
>
> If I pinch you and you move your arm, all I know is you are withdrawing [from] pain but that doesn't talk about consciousness.
>
> So as general rule, if you do not have consciousness, you are not going to have reflex. But the opposite is not true. You can have no reflex and be fully conscious, as we talk[ed about] in the beginning of my declaration when I said, well, people who'[re] undergoing surgery sometimes do remember but don't have reflex.
>
> So, again, did we use that in anesthesia? Sure, we used that, but it is very rudimentary way to measure consciousness. That's why now we use EEG-based technology because you truly see what the

[20] Defendants attempted to ascertain during cross-examination whether Dr. Bergese was aware of the testimony in this litigation three years earlier during which Dr. David Waisel purportedly testified, or at least suggested, that Florida's prescription of 500 mg of midazolam at that time would have been sufficient to render an inmate insensate to pain. Several objections and responses leave open to interpretation whether that was actually Dr. Waissel's testimony. (ECF No. 923, PageID 30877-79). Dr. Waisel testified that he had been asked by a Florida inmate to review Florida's execution protocol, but that he ultimately did not testify on that inmate's behalf because "I did not feel I had anything credible to offer his case." Id. at PageID 30880. Neither party, in this Court's view, was able to establish through Dr. Bergese why Dr. Waisel felt he had nothing credible to offer the Florida inmate's case.

> brain is doing and that is not even 100 percent full [sic] proof. But, still, this is very rudimentary, number one.

Id. at PageID 30866-67. Dr. Bergese further testified that it matters who is performing a consciousness check, such that a neurologist or other similarly trained professional would be better capable of interpreting what any movements might mean. *Id*.at PageID 30867. Dr. Bergese agreed that although a response would indicate consciousness, a lack of response does *not* indicate a lack of consciousness. *Id*. at PageID 30868.

Dr. Bergese strenuously denied cross-examination suggestions that he considered only data that supported his opinions, and did not consider data inconsistent with his opinions. *Id*. at PageID 30888-89, 30907-08. Dr. Bergese denied that he is opposed to capital punishment as a matter of public policy. *Id*. at PageID 30904-05.

Joseph Antognini, M.D.

Defendants' first expert witness, Dr. Joseph Antognini, testified that he attended the University of Southern California, and performed his residency in anesthesiology at the University of California, Davis ("UCDavis"). (Evid. Hrg. Tr., ECF No. 924, PageID 31020.) After being in private practice for five years assisting in a variety of surgical procedures, Dr. Antognini joined the faculty at UCDavis where he performed clinical work, conducted research, and taught medical students and residents. *Id*. at PageID 31020-21. He has been retired from the active practice of anesthesiology for approximately one year and now volunteers as a clinical professor. *Id*. at PageID 31101.

In his clinical research, Dr. Antognini focused on the how anesthetics produced immobility, with a further concentration on the relationship between anesthesia and autonomic responses such as an increase in heart rate or blood pressure upon application of noxious stimulation. *Id*. at PageID 31022. He testified that in his work, he sought to determine where in the subject's body the anesthetics were producing their effects to result in immobility. *Id*. at PageID 31022-23. He acknowledged that most of his research in that area was performed using animal models. *Id*. at PageID 31023. His research did not include studying the consciousness of the animals, nor did he study the effects of midazolam or other benzodiazepines. *Id*. at PageID 31102-3, 31033.

In addition to his clinical work and teaching duties, Dr. Antognini's curriculum vitae lists over 160 articles in professional journals, 127 of which were peer reviewed; case reviews; and chapters in books he has authored. (Curriculum Vitae of Joseph F. Antognini, M.D.; DX 4, ECF No. 924, PageID 31020-33, 31102.) In addition, he has reviewed other authors' papers and served as an associate editor for the journal "Anesthesiology." *Id*. at PageID 31024. He has recently retired from teaching at UCDavis and from the active practice of anesthesiology. *Id*. at PageID 31026, 31150. He was permitted by the Court to testify as an expert witness without objection from Plaintiffs. *Id*. at PageID 31026.

Dr. Antognini identified three essential goals of anesthesia: amnesia, unconsciousness, and immobility. *Id*. at PageID 31026-27. To illustrate the order in which the three goals are reached when anesthesia is administered, Dr. Antognini drew a graph[21] showing that first the anesthetic affects memory, thus the amnesia goal is achieved; then consciousness, achieving the

[21] The graph Dr. Antonini drew for demonstrative purposes during the hearing is duplicated in his report. (Plaintiffs' Preliminary Injunction Hearing Exhibit 4, Declaration of Joseph F. Antognini, M.D., M.B.A., also filed at ECF No. 852-1, PageID 25790.)

second goal; and finally movement, completing the third goal of immobility. *Id*. at PageID 31029-30. He made it clear, however, that when referring to "movement," it was gross purposeful movement he was talking about, not a simple withdrawal reflex from noxious stimulus.[22] *Id*. at PageID 31031-32. He acknowledged that there is an element of arbitrariness in interpreting movements by a patient or subject of a study; where some practitioners or researchers will interpret reflexive movements as indicative of consciousness, others will not. *Id*. at PageID 31032. Although Dr. Antognini stated that he has not performed any studies of midazolam or on anesthesia as it relates to memory or consciousness, he acknowledged that memory and consciousness are more sensitive to anesthetics than mobility. *Id*. at PageID 31028, 31134.

Dr. Antognini testified that anesthesia acts on the spinal cord to achieve immobility. *Id*. at PageID 31133, 31138. It is not uncommon for patients to move during surgery, even though they are unconscious. *Id*. at PageID 31027-28. He noted that even brain-dead humans have demonstrated spontaneous movement or movement in response to noxious stimuli by sitting up in bed, crossing their arms over their chest, or turning their head, which is referred to as the Lazarus Phenomenon.[23] *Id*. at PageID 31035. He himself has witnessed some such movements in his work as an anesthesiologist assisting in harvesting organs from individuals declared brain dead. *Id*. at PageID 31036. In such circumstances, he observed the individual's blood pressure or heart rate increase, and such occurrences have been reported in the literature as well. *Id*.

Contrary to Dr. Bergese's testimony, Dr. Antognini denied that complex physical movements are always indicative of consciousness. *Id*. Referring to his graph, he explained that

[22] "Noxious stimulus" was defined as "a stimulus that causes or has a potential to cause tissue damage" by Dr. Antonini. (ECF No. 924, PageID 31034.) He provided examples of heat, chemical, mechanical, and electrical stimuli. *Id.*

[23] Referring to the story of Jesus raising his friend Lazarus from the dead, recounted at John 11:1-27.

consciousness is affected by anesthesia before gross purposeful movement is, and therefore an unconscious individual can exhibit complex movements while unconscious. *Id*. at PageID 31037. In fact, in the surgical context, patients can move their arms around, attempt to sit up, cough, and move quite violently when an incision is made even though they are unconscious. *Id*. Dr. Antognini appeared to qualify that statement somewhat, however, by immediately stating that it is difficult to achieve the correct level of anesthetization, and that sometimes misjudgment of the amount necessary for a particular patient does happen. *Id*. When asked how such complex movements are possible from an anesthetized patient, Dr. Antognini responded that

> 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 . . . 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.

Id. at PageID 31038. Dr. Antognini gave a further example of his point describing "the frog wiping reflex," in which a frog will use his back leg to wipe away a noxious stimulus applied to his front leg even after the connection between the brain and spinal cord has been surgically severed. *Id*. at PageID 31038-39.

In surgery Dr. Antognini would expect to see a variety of movements from the patients. *Id*. at PageID 31043. There could be violent thrashing about or "bucking," vigorous coughing, or movement of the arms and legs, and that is one of the reasons patients are strapped down during operations. *Id*. at PageID 31043-44. In addition, patients' eyes can remain open during surgery and dry out, which is why the eyes are almost always taped closed during surgery. *Id*. at PageID 31044. Movement during surgery can indicate the return of consciousness, the

emergence from the anesthesia. *Id*. at PageID 31160. Dr. Antognini's first response to such movement would be to administer additional anesthetic. *Id*.

Other responses would vary according to the circumstances of each case. *Id*. at PageID 31159. He might administer an opiate, an analgesic, or a muscle relaxant, depending upon whether the patient has suffered trauma, and if so the extent of the trauma, and the status of the patient's blood pressure. *Id*. at PageID 31159-60. The anesthesiologist must be cognizant of the risks presented by each of those options. Sometimes giving the patient a muscle relaxant is preferred because even though the patient may be moving, he or she may be sufficiently anesthetized to prevent the formation of memories and remain unconscious. *Id*. at PageID 31159.

Dr. Antognini was asked to explain the difference between a noxious stimulus and pain. In responding, he testified that a stimulus threatens to or causes damage to normal tissue whereas pain is "the conscious awareness or that unpleasant sensory and emotional experience associated with that noxious stimulation." *Id*. at PageID 31040. For instance, if one were struck in the knee with a hammer, he would experience pain, he would have a painful experience following the application of the noxious stimulus of the hammer. *Id*. But if one were anesthetized and a procedure equally as painful as a hammer strike to the knee were performed, upon awaking the patient would report having felt no pain. *Id*. at PageID 31041. In other words, Dr. Antognini believes any discussion of the experience of pain should be restricted to those individuals who are awake and conscious. *Id*. There is, however, no generally accepted objective measurement of pain. *Id*. at PageID 31098.

In determining the proper dosage of inhaled anesthetic for a particular patient, anesthesiologists are guided by the minimal alveolar concentration (MAC), which is the dose at

which fifty percent of the population would display gross purposeful movement and fifty percent would not. *Id*. at PageID 31041. Of course, that dose varies with the degree of pain the procedure would be expected to inflict on a conscious person. *Id*. at PageID 31042. Obviously, the greater the noxious stimulus, the greater the need for more of or a stronger anesthetic, and a patient in poorer condition may not be able to receive the dose that might be given to a healthier or younger individual. *Id*. at PageID 31043.

Dr. Antognini's attention was directed to a figure in *Miller's Anesthesia* that duplicates, for the most part, the information on the graph he drew in Court and which appears in his declaration, which attempts to explain in what order anesthesia affects amnesia, unconsciousness, and gross purposeful movement. (Plaintiffs' Expert Exhibit 9, Bates No. 1079; ECF 852-1, PageID 25790.) Dr. Antognini testified that although the graph relates to inhaled anesthetics, it is a conceptual drawing and therefore it has application to intravenous anesthetics as well. (ECF No. 924, PageID 31128.) He recognized that the three separate trajectories for amnesia, unconsciousness, and gross purposeful movement might very well appear different in relation to each other in a graph dedicated to intravenous anesthetics rather than the one for inhaled anesthetics. *Id*. at PageID 31128. The paucity of data on intravenous anesthetics' effect on memory, consciousness, and mobility is a result of the relative ease of conducting studies and measuring the results of inhaled anesthetics. *Id*. at PageID 31135. Rather than having to perform analyses on the concentration of the anesthetic in blood, the concentrations can be measured in exhalations from the lungs when inhaled anesthetics are studied. *Id*. Thus, there is no data from which to reliably conclude that the graph diagraming inhaled anesthetics' actions on memory, consciousness, and mobility is illustrative of the actions of injected anesthetics. *Id*. at PageID 31135-36.

Dr. Antognini testified that he is familiar with the benzodiazepine midazolam and described it as a short- and fast-acting drug used in his specialty for sedation in therapeutic doses. *Id*. at PageID 31045. As one might expect, dosage depends on the individual characteristics of the patient and the purpose for which the drug is being used. *Id*. The primary purpose of administering midazolam prior to surgery is to relieve anxiety and produce some level of sedation, but it is also used during procedures such as colonoscopies, and as a beginning of the process of putting a patient under anesthesia. *Id*. at PageID 31045-46. For a colonoscopy, for instance, Dr. Antognini might give one to five milligrams of midazolam to the patient with elderly patients generally receiving the lower dose and younger patients receiving a larger dose. *Id*. at PageID 31046. Beginning the process of anesthetization is called the "induction of anesthesia" and requires more of the drug than in the colonoscopy scenario. *Id*. at PageID 31047 Midazolam takes effect within one to two minutes in almost everyone. *Id*. at PageID 31048.

One of midazolam's most potent effects is to prevent the formation of memories, satisfying the first goal of anesthesia, amnesia. *Id*. While some drugs that cause amnesia can ablate memories formed prior to the administration of the drug, midazolam cannot. In that regard, midazolam causes anterograde amnesia rather than a retrograde amnesia. *Id*.

Midazolam can also cause unconsciousness and can, among other similar drugs, play a part in the induction of anesthesia, as noted above. *Id*. at PageID 31049. Midazolam may be used during the intubation procedure, which is a very "stimulating" procedure, meaning that it is extremely uncomfortable if performed without an anesthetic, but other drugs such as thiopental, propofol, etomidate, or ketamine, are preferred. *Id*. at PageID 31049-50. Other procedures in which midazolam may be used are endotracheal intubations, various endoscopies, cardioversions, and induction for Cesarean sections. *Id*. at PageID 31052.

Pertinent to Cesarean sections, Dr. Antognini cited a study which compared the effects of midazolam to thiopental during those procedures. *Id*. at PageID 31120, *citing* Michael Crawford, et al., *A Randomized Comparison Between Midazolam and Thiopental for Elective Cesarean Section Anesthesia*, DX. 76 at 1130-34. He recalled that the study concluded the two drugs were "essentially equivalent" in terms of the effects of the drugs on blood pressure, etc. *Id*. at PageID 31056. That study, however, and by Dr. Antognini's own admission, did not consider any analgesic or anesthetizing effects of midazolam or thiopental, and he did not state in his testimony what those effects were,[24] only that whatever effects were observed were equivalent or nearly so. *Id*. Dr. Antognini pointed out that during the first minute or so of the Cesarean sections given the women in the study, of those who received midazolam, it was the only anesthetic they received, although they did receive a muscle relaxant to facilitate intubation as well. *Id*. at PageID 31056, 31127. Again, however, the focus of the study was on the drugs' effect on blood pressure, heart rate, etc., not on the anesthetic effect of either drug.

In a cardioversion, an electrical shock is administered to the patient to normalize the heart rhythms. During the procedure, the patient is sedated, not anesthetized. *Id*. at PageID 31151. Dr. Antognini questioned whether the patient actually feels the pain and emotional aspects that go along with that sensation when a noxious stimulus such as the electric shock is applied and the patient wakes up without any memory of the stimulating event. *Id*. at PageID 31152. Many times, the electrical stimulation will awaken the patient from sedation, but if he or she were under general anesthesia, which is to say unarousable, the stimulation would not wake them up. *Id*. at PageID 31155, 31157. Beyond general anesthesia is coma which is a level of

[24] The article reveals that the effects measured included induction time; time until umbilical cord was clamped; duration of anesthesia; blood loss; amount of meperidine (an opioid immediately administered after delivery) needed for each group; diastolic blood pressure; perivenous tenderness, and post-operative nausea, dizziness, vomiting, incisional pain, headache, sedation, fatigue, crying, or visual difficulties. (DX 76, at 1131-32.)

consciousness Dr. Antognini would not want to induce in a normal person using anesthesia. *Id*. at PageID 31156.

Dr. Antognini identified some of the signs a patient emerging from general anesthesia may exhibit: swallowing, gagging, coughing, grimacing, defensive posturing, and the return of muscle tone. *Id*. at PageID 31157-58. Continued emergence may produce eye opening, response to verbal commands, and patterns on the electroencephalogram indicating waking. *Id*. at PageID 31158. On redirect examination, Dr. Antognini denied that these movements and responses are always indicative of emergence, however. *Id*. at PageID 31178. He explained that the patient may be shifting from a deeper level of anesthesia to a lighter level, *id*. at PageID 31178. In an attempt to clarify the distinction between that expression and the word "emergence," Dr. Antognini explained that a person exhibiting the signs mentioned above is not as deep in terms of their brain depression. *Id*. at PageID 31179.[25]

It is not clinically warranted to administer a massive dose of midazolam to determine whether it is suitable to be the sole drug used to achieve general anesthesia, but it can be used alone on temporally short procedures such as intubation. *Id*. at PageID 31057. Dr. Antognini noted, however, that general anesthesia, which he defined as "the prevention of movement during noxious stimulus," had been achieved in studies using mice. *Id*. at PageID 31058. When asked if there is any evidence that midazolam can produce anesthesia's goal of immobility, Dr. Antognini again relied upon the study that used mice, and indicated that immobility can be achieved with midazolam. *Id*. at PageID 31059.

Five hundred milligrams of midazolam, would in Dr. Antognini's opinion be sufficient to produce a level of anesthesia adequate for a variety of medical procedures. *Id*. at PageID 31060.

[25] There must be very fine lines between "emergence," "shifting to a lighter level of anesthesia," and "not as deep in terms of their brain depression," for they escape the Court's vision.

No qualification was placed by the examiner or Dr. Antognini on what specific medical procedures could be performed using only midazolam, but the doctor stated that there were studies that looked at the effects of midazolam and consciousness. *Id.* None of those studies involved human subjects. *Id.*

Ohio's execution protocol calls for 500 mg of midazolam to be administered as the first of a three-drug procedure, in two injections of 250mg each. (ECF No. 667-1, PageID 19824.) Dr. Antognini testified that with that dosage of midazolam a person would become unconscious and would not form memories of anything that happened during the action of the drug. (ECF No. 924, PageID 31061.) The risk of the person experiencing pain under such sedation would be very, very low even though the patient may exhibit some physiological responses to whatever noxious stimulus might be applied. *Id.* at PageID 31063-64.

Generally, the process of anesthetization goes something like this: the patient will have an intravenous line through which the induction drug, propofol or a something similar, is given first. *Id.* at PageID 31065. Next, a muscle relaxant, or paralytic drug, is administered through the IV line so that the patient can be intubated and his or her breathing controlled. *Id.* Rocuronium bromide, the second drug in Ohio's execution protocol, is often used as the second drug in the anesthetization process, and is irritating to the veins. *Id.* In fact, Dr. Antognini has seen patients flinch their arm as the rocuronium enters their vein despite the previous administration of propofol. *Id.* at PageID 31066. Scientists who have studied that type of movement believe it to be secondary to vein irritation, and do not view it as indicative of the patient's awakening. *Id.* Dr. Antognini testified that the constancy of the BIS monitor readings coincide with the scientists' conclusions. *Id.*

Rocuronium is not the only drug that causes vein irritation. *Id*. Propofol, etomidate, diazepam, valium, and potassium chloride all do so, propofol to the extent that lidocaine, a numbing agent, is mixed with propofol before it is administered. *Id*. at PageID 31067. Some unfortunate patients are allergic to lidocaine and must bear the discomfort from the propofol, generating significant complaints from them.. *Id*. An unconscious person would not, however, feel pain from administration of those drugs according to Dr. Antognini. *Id*. at PageID 31067. They may have a physiologic response to administration of the painful drug, but that does not necessarily mean they experience the typical emotion we generally refer to as "pain." *Id*. at PageID 31067.

Potassium chloride is the third drug in Ohio's execution protocol. Dr. Antognini testified that it can be "very painful" when injected. *Id*. at PageID 31068. Obviously, if the drug is administered slowly, the pain could last for a significant length of time. *Id*. If it is administered as a bolus and in a large enough dose, it will reach the heart fairly quickly and cause it to stop beating. *Id*. That would cause the person to become unconscious for lack of oxygen to the brain. *Id*. If a person were injected with 500 mg of midazolam, Dr. Antognini would predict that person would be unconscious and unable to experience the pain associated with an injection of potassium chloride. *Id*. at PageID 31070-71. On the other hand, if a patient were administered the usual therapeutic dose, Dr. Antognini stated the patient probably would feel pain. *Id*. at PageID 31118.

Dr. Antognini explained the term "air hunger" as "the conscious awareness that we have when we can't catch our breath" such as occurs in pneumonia, congestive heart failure, or pulmonary edema. *Id*. at PageID 31071-72. "Air hunger" can also be caused by an obstruction

in the airway.[26] *Id*. at PageID 31072. Although unquestionably uncomfortable and frightening, Dr. Antognini would not expect a person who had been injected with 500 mg of midazolam to be aroused by the sensation of air hunger. *Id*. He noted that the common anesthetics in use all produce some level of respiratory depression. *Id*.

Dr. Antognini was asked about the effect of midazolam and opiates on respiration. He testified that those drugs depress the drive to breathe and can partially collapse the airway causing a snoring-like action, but that those effects are true of anesthetics generally. *Id*. at PageID 31088. Those effects differ from the sensation of air hunger in that they actually remove the feeling of a need to breathe whereas that feeling precisely describes air hunger. *Id*. at PageID 31089. Dr. Antognini doubts that air hunger could awaken an unconscious person or cause them to spontaneously resume breathing on their own. *Id*. If it could, he postulates that there would be far fewer overdose deaths from heroin. *Id*. at PageID 31090.

Dr. Antognini familiarized himself with some of the witness reports of executions and the choking, snorting, mouthing of words, and gasping as well as prolonged periods of movement by the inmate(s) observed by those witnesses. *Id*. at PageID 31091, 31162. Since he is involved in one or two other similar cases elsewhere, he cannot remember which accounts were related to which case, nor does he recall what information he gleaned from those witness accounts or from news media. *Id*. at PageID 31162-63. Some of the reported observations of the execution witnesses he read are consistent with emergence from anesthesia. *Id*. at PageID 31164. Those observations were not related by medically trained individuals, however, and Dr. Antognini stated they may not have understood what was going on physiologically in the inmate's body

[26] There was testimony during the McGuire preliminary injunction hearing, which Judge Frost credited, that McGuire had a condition that might make him susceptible to an airway obstruction. No particularized medical testimony was offered with respect to any of the Plaintiffs whose motions for preliminary injunction are under consideration.

during the executions they witnessed. *Id*. at PageID 31091. In the clinical context, if he saw those signs in the middle of a surgical procedure, he would administer more anesthetic, an opiate, or a muscle relaxant unless such signs were observed near the end of the surgical procedure. *Id*. at PageID 31165. In that case he would not feel the need to provide more drugs, since it is desirable to have the patient wake up as soon as possible following surgery and giving more drugs to the patient would delay their return to consciousness. *Id*.

Dr. Antognini acknowledged that when drugs like midazolam and opiates are administered to a person without intervention, presumably intubation, the person may try to breathe and may emit sounds while doing so. *Id*. at PageID 31092. That does not necessarily mean the individual is experiencing pain, however. To illustrate his point, Dr. Antognini offered a hypothetical example of reaching the end of a surgical procedure. *Id*. The patient is starting to awaken, and the anesthesiologist gives a verbal command to him to open his eyes, which the patient does. *Id*. at PageID 31092-93. Then the anesthesiologist gives the patient the command to breathe, which the patient also does, but fails to continue breathing on his own and has to be commanded to do so again and again until he is breathing normally. *Id*. at PageID 31093. If that patient were not told to breathe, he would not do so and would instead just lie there without experiencing air hunger because the drugs he was given would have removed the urge to breathe. *Id*.

Dr. Antognini also expressed familiarity with (and some skepticism about) the concept of midazolam's "ceiling effect," which is the maximum effect from the administration of a drug beyond which more of the drug will not produce more benefit. *Id*. at PageID 31071-74. Dr. Antognini stated that the ceiling effect of midazolam as used in the Ohio execution protocol is not germane to the issues before the Court. *Id*. at PageID 31073. The question, as he sees it, is

does 500 mg of midazolam produce unconsciousness, and he believes it does. *Id*. at PageID 31073-74. Whether there is a ceiling effect beyond the amount of midazolam needed to produce unconsciousness, therefore, is unimportant. *Id*. Dr. Antognini criticized Dr. Stevens' testimony on the theory of the ceiling effect as "an academic exercise," but he also stated that Dr. Stevens used appropriate data and interpreted it in a reasonable way, much the way he himself would have proceeded, in spite of a mathematical error[27] Dr. Antognini noticed in Dr. Stevens' declaration. *Id*. at PageID 31074. Dr. Antognini identified some of the variables that could affect studies conducted on the ceiling effect of certain drugs as the types of cells that were used in a study, the temperature of the drugs, and the methods used to conduct the study. *Id*. at PageID 31075. Some of the studies were conducted using drugs at room temperature, but in the clinical arena drugs are administered at body temperature. *Id*. In addition, Dr. Antognini explained that conclusions drawn from studies using sampling possess some inherent variability since the sample may not be precisely representative of the population as a whole. *Id*. at PageID 31076-80. Such is the case, Dr. Antognini said, with Dr. Stevens' explanation of the ceiling effect and indeed with some of his own calculations in other circumstances. *Id*. at PageID 31079.

Aside from the later-corrected mathematical error mentioned above, Dr. Antognini identified another error in Dr. Stevens' declaration. Dr. Antognini explained that when midazolam is administered, 95% of the drug binds to the proteins coating the blood cells, but that the drug cannot enter the brain while it is so bound. *Id*. at PageID 31081. Instead, the drug must become unbound or "free" to enter the brain. *Id*. Thus, the amount of blood in the plasma is the important measurement, not the concentration of the drug in the blood. *Id*. at PageID 31081,

[27] As previously noted, Dr. Stevens acknowledged his error and corrected it in his subsequent addendum to his declaration, and Dr. Antognini stated the initial error is no longer germane to the issues before the Court. *Id*. at PageID 31080.

31084. Figure 7 in Dr. Stevens' declaration illustrates the midazolam concentrations in plasma (containing bound and unbound midazolam) and in cerebral spinal fluid (which has very little proteins in it, so contains mostly unbound midazolam.) *Id*. at PageID 31085; ECF No. 836-1, PageID 24824. According to Dr. Antognini, Dr. Stevens discounted the concentration of the midazolam in the plasma to account for the protein bound quantity of the drug, but then erroneously also discounted the concentrations in the cerebral spinal fluid, resulting in a sort of double discounting of the protein bound midazolam. (ECF No. 924, PageID 31085.) He added, however, that he did not place much significance on the error he perceived in Dr. Stevens' calculations since the variability inherent in the sampling method of conducting research could well counteract the error. *Id*. His conclusion was that the accuracy of the data on the ceiling effect of midazolam was "unclear." *Id*. at PageID 31086.

In fact, Dr. Antognini believes that the whole discussion of the ceiling effect of midazolam obfuscates the issue because .2 or .3 milligrams[28] of midazolam will render a patient unconscious, and the dosage used in the execution protocol is 500 milligrams. *Id*. at PageID 31086. Any discussion of the ceiling effect is therefore irrelevant in his opinion. *Id*.

Dr. Antognini also acknowledged an error in his own declaration which had been identified by Dr. Stevens in his rebuttal report. *Id*. at PageID 31083. Because the drug must be in the plasma to reach the brain, and the concentration of the drug in the plasma is the important measurement, not the concentration of the drug in the blood, which was the measurement Dr. Antognini used in his declaration. *Id*. at PageID 31081, 31084. Nevertheless, Dr. Antognini downplayed the significance of his error stating that "I don't personally think it's that important whether you refer to blood or plasma, but it is the same thing." *Id*. at PageID 31084.

[28] Elsewhere in his testimony, Dr. Antognini states that the typical dose of midazolam for the induction of anesthesia is 0.2 to 0.3 milligrams, or even up to 0.6 milligrams per kilogram of the patient's weight. (ECF No. 924 at PageID 31051.) The Court suspects that is what he intended to communicate here.

Consciousness, he testified, exists on a spectrum. *Id*. at PageID 31093. When one is sedated or under anesthesia, consciousness is determined by applying one or more stimuli to the patient. *Id*. The stimulus can be verbal such as commanding them to open their eyes, tactile such as touching or gently shaking them, or noxious stimulation such as a pinch. *Id*. at PageID 31094. If the patient responds to any of those stimuli, the observing individual must determine whether the patient's reaction was a conscious movement or simply reflexive, an exercise that can be somewhat arbitrary. *Id*. at PageID 31094, 31190. Later in his testimony, Dr. Antognini reiterated that "[w]here you decide whether somebody is conscious or not is arbitrary." *Id*. at PageID 31190. Different studies have used different criteria for determining consciousness and have consequently come to different conclusions about whether the patients or subjects of the study were unconscious or not. *Id*. at PageID 31192. Thus, there can be differences of opinions on when a person is or is not unconscious, but Dr. Antognini draws a rather bright line, stating that if a person responds to the verbal, tactile, or noxious stimulation, they are conscious; conversely, no reaction would mean the patient is unconscious. *Id*. at PageID 31094-95. Somewhat circularly, Dr. Antognini denied that only physicians are qualified to perform a consciousness test because the Glasgow Coma Scale, the Richmond Agitation-Sedation Scale, the Observer Assessment of Sedation Scale, all techniques for assessing consciousness, are routinely used by nonphysicians. *Id*. at PageID 31095-96. He included the caveat, however, that "[t]he way some of these scales are used, it really is an arbitrary decision about whether [the patients] are unconscious or not." *Id*. at PageID 31191.

Dr. Antognini expressed a familiarity with the bispectral index (BIS) monitor which is used to assess the depth of anesthesia by measuring brain activity. He has used the device in the operating room and in the laboratory. *Id*. at PageID 31110. There are some anesthetics the

effect of which is less reliably measured by the BIS monitor, specifically ketamine, nitrous oxide, dexmedetomidine, and some others. *Id*. at PageID 31111. Neither the BIS monitor manual nor *Miller's Anesthesia*, the most accepted textbook on the topic in Dr. Antognini's opinion, list midazolam as one of the drugs the BIS monitor is less accurate at measuring. *Id*. at PageID 31112. Dr. Antognini expressed some doubt about the accuracy of the data collected by the monitor and the interpretation of that data, however. *Id*. at PageID 31183. Different drugs affect the BIS monitor differently. *Id*. Specifically, the BIS monitor can display differing values "even at the same sedation level." *Id*. at PageID 31186. It is unclear to the Court whether Dr. Antognini means that the values may vary even when patients are given the same drug in the same amounts, or whether the monitor will record different values when the patients are in fact at the same level of consciousness or brain depression. He still uses the monitor, and has never used any other available similar devices, but believes it is not 100% sensitive and 100% accurate. *Id*. at PageID 31186, 31188.

Of course, heart rate and blood pressure monitors are commonly used during surgical procedures, as well, primarily to make sure those measurements do not get too depressed by the anesthesia, but they could also be used to measure the patient's autonomic response to noxious stimuli. *Id*. at PageID 31188-89. Other visual autonomic indications of stress resulting from the application of noxious stimuli are pupil dilation, movement, and sweating. *Id*. at PageID 31189. Dr. Antognini testified 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." *Id*. He would never rely solely on a reflex check to determine the depth of a patient's anesthesia in a clinical setting. *Id*. at PageID 31190. That said, Dr. Antognini agrees with Dr. Stevens' testimony that reflexive withdrawal from a noxious stimulus is not considered a purposeful movement. *Id*. at

PageID 31191. (See Testimony of Dr. Craig Stevens, ECF No. 923, PageID 30770.) Indeed, Dr. Antognini interprets the table from the American Society of Anesthesiologists discussed by Dr. Stevens as stating that even individuals under general anesthesia can exhibit reflexive withdrawal from a noxious stimulus and that is not considered a purposeful movement. (ECF No. 924, PageID 31191.)

Dr. Antognini believes midazolam possesses some analgesic properties. Benzodiazepines like midazolam act to produce hypnosis (sleep) and amnesia, among other things. *Id*. at PageID 31114. In his declaration, Dr. Antognini cited four studies in support of his conclusion that midazolam possesses some analgesic properties. (ECF No. 852-1, PageID 25793.) On cross-examination, it was brought out that one of the studies cited administered an analgesic drug with midazolam, and another permitted physicians to administer neuromuscular blockers at their discretion. (ECF No. 924, PageID 31114-15.) Thus, at least those two studies did not provide unequivocal support for Dr. Antognini's opinion that midazolam possesses analgesic properties, although Plaintiffs did not challenge the other two studies forming the basis for his opinion. Dr. Antognini stated, however, that his recollection was that one of those studies had provided only midazolam to at least some of the patients during endotracheal intubations. *Id*. at PageID 31181. And the second of the challenged studies, the Yegin Study, which Dr. Bergese also discussed above,[29] involved intrathecal injection of midazolam with another drug that Dr. Antognini recalled had no analgesic properties whatsoever. *Id*. at PageID 31182. The analgesic period was longer when midazolam was used which Dr. Antognini interprets as supporting his belief that midazolam seems to have some analgesic properties. *Id*. at PageID 31182. The drug administered with the midazolam in the study was bupivacaine, and his

[29] Recall that Dr. Bergese testified that it was the bupivacaine that provided the analgesic effect which midazolam synergistically extended, but did not increase.

recollection that it has no analgesic properties is perhaps medically correct, but when administered intrathecally it produces a "complete motor and sensory block." Physicians' Desk Reference, www.pdr.net/drug-summary/Marcaine-Spinal-bupivacaine-hydrochloride-1574 (last visited Jan. 23, 2017). He presumes the belief that benzodiazepines do not have an analgesic effect is born of studies using therapeutic doses of the drugs rather than massive doses. *Id*. at PageID 31144.

Dr. Antognini recognized as fair the criticism of his belief that midazolam possesses analgesic properties from his clinical and scientific colleagues. *Id*. at PageID 31145. But he explained that a categorical statement that it provides *no* analgesic effect goes too far; he believes it can provide *some* mild analgesic effect, particularly when it is administered intrathecally in conjunction with other drugs he does not name. *Id*. at PageID 31145-46. Ohio's protocol does not allow for intrathecal administration of the execution drugs.

In rebuttal to Dr. Antognini's testimony that midazolam possesses analgesic properties, Dr. Stevens testified that

> [I]n that sense, he's probably the farthest [sic] from the mainstream facts about benzodiazepines, because textbooks, and especially *Miller's Anesthesia*, shows – and I have quotes there that you guys can read, of course, and it definitely lacks analgesic properties, must be used with other anesthetic drugs to provide sufficient analgesia, and it goes on and talks about midazolam/ benzodiazepine.

(ECF No. 925, PageID 31466.) Dr. Stevens continued that based on research he had recently reviewed, including a 2013 paper by Frolich (ECF No. 900-1, PageID 30147), he found that "midazolam not only was not analgesic, it actually decreased the pain threshold. So it made them hyperalgesic. It made them more sensitive to pain." (ECF No. 925, PageID 31466-31467.)

Dr. Antognini agreed that the normal practice for the induction of anesthesia is to administer a fast-acting intravenous anesthetic followed by a neuromuscular blocking drug. *Id.* at PageID 31116. The neuromuscular blocking drug immobilizes the patient so that intubation can be achieved. *Id*. at PageID 31117. Not remembering the pain of intubation does not mean the patient did not experience the pain during the procedure. *Id*.

Dr. Antognini agreed with Dr. Stevens that benzodiazepines like midazolam act on GABA receptors, and further stated that GABA is present in both the brain and the spinal cord. *Id*. at PageID 31139. In short, no GABA equals no effect from a benzodiazepine. *Id*. Once the GABA receptors are occupied by the drug, no additional effect from the benzodiazepine can be had even with the introduction of more of the drug. *Id*. That scenario describes one of the ways that a benzodiazepine might reach its ceiling effect, but at what dosage that effect might be reached is not presently known. *Id*. at PageID 31140. Dr. Antognini recognized the existence of a ceiling effect resulting from the not-unlimited-but-variable number of GABA receptors in each person, and stated that clinically, a dosage may be anywhere from one to twenty-five milligrams, and evidence of the ceiling effect can begin to appear within that clinical range. *Id*. at PageID 31140-42. Dr. Antognini testified that when the readings on a BIS monitor begin to approach sixty, the ceiling effect can begin to be detected. *Id*. at PageID 31143. The benzodiazepines, however, cannot achieve isoelectricity (basically a flat line) on the electroencephalogram. *Id*. at PageID 31142.

Since 2010, when *Miller's Anesthesia* first included a chapter on consciousness, there has been substantial research performed on the topic, although Dr. Antognini has not participated in that research. *Id*. at PageID 31149-50. He agreed that consciousness is not the same as

responsiveness in that a patient may be unable to move after having been given a muscle relaxant, and yet remain fully awake. *Id*. at PageID 31150.

On redirect examination, Dr. Antognini was asked about the Plaintiffs' numerous references to *Miller's Anesthesia* during cross-examination, and his opinion of the text. *Id*. at PageID 31167. He related that when he was in medical school he and his roommate approached his professor after a lecture and said, "[Y]ou said this in your lecture, but the book says that." *Id*. at PageID 31167. The professor answered, "The book is wrong." *Id*. Dr. Antognini advised that many statements in textbooks are unreferenced, chapters are written by different authors, and it is a scramble to get the chapters in on time so peer review is limited. *Id*. at PageID 31168. In fact his own chapter in *Miller's Anesthesia* did not undergo a complete peer review! *Id*. Thus, he always takes statements in textbooks with a grain of salt. *Id*. He described the validity of the statements in *Miller's* as "hit and miss" stating that textbooks are not a particularly great source of accurate information, although he allowed somewhat contradictorily that they can be, and that *Miller's Anesthesia* is possibly "the most accepted textbook in the field . . . in my estimation". *Id*. at PageID 31168-69. The text does not to his knowledge address massive doses of midazolam and it can be reasonably assumed that whenever the text discusses any drug, it contemplates therapeutic doses. *Id*. at PageID 31173.

Dr. Antognini read Ohio's current execution protocol and testified that his report "absolutely" relies on the execution protocol being carried out perfectly. *Id*. at PageID 31166. He stressed that it is critical that the drugs being administered intravenously be flowing properly through the IVs, or there would be "significant problems." *Id*.

Plaintiffs offered a Rebuttal Report, as well as rebuttal testimony, by experts Dr. Craig Stevens and Dr. Sergio Bergese. Dr. Stevens set forth a summary of his opinions in his Rebuttal Report as follows:

> Dr. Antognini disregards the scientific data from medical and pharmacological research in opining that using midazolam instead of a true general anesthetic (such as pentobarbital) as the first drug in Ohio's three-drug lethal injection protocol would render a person completely unconscious and insensate to pain and noxious stimuli.
>
> Dr. Antognini suggests that because midazolam produces an amnesic effect it therefore also produces a general anesthetic effect. This is an [sic] fundamental error in understanding drug effects; no memory of a noxious event (amnesia) is not the same as no experience of the noxious event (General Anesthesia) at the time of its occurrence.
>
> Dr. Antognini states that a therapeutic effect of IV midazolam is to relieve the patient's anxiety (by acting as a sedative), and to cause amnesia. He then states that "Midazolam can also cause unconsciousness." This is false. Loss of consciousness and awareness only occurs [sic] at the medically-defined state of General Anesthesia. Midazolam has not been shown to produce the state of General Anesthesia in clinical studies; in fact clinical studies show that midazolam can only produce a level of Deep Sedation, with no loss of consciousness or awareness.
>
> Dr. Antognini states that midazolam "possess[es] analgesic properties." This is also false. It is in contradiction to the pharmacological and clinical studies that show that midazolam and other benzodiazepines do not have analgesic properties and rather sometimes produces hyperalgesia (increased sensitivity to pain).
>
> To support his opinions, Dr. Antognini totally dismisses the basic pharmacology of midazolam, and the impact of the known pharmacological differences between benzodiazepines and barbiturates on the lethal injection protocol. This occurs when he dismisses the ceiling effect of midazolam, which is important to

> understanding why midazolam cannot produce the state of General Anesthesia.
>
> In summary, the key opinions in Dr. Antognini's report are unsupported statements, with no medical or pharmacological studies to provide evidence for the truthfulness of these assertions.
>
> In his addendum, Dr. Antognini maintains that midazolam has analgesic properties, which is incorrect. He also concedes that midazolam may not produce a state of unawareness and loss of pain sensation, but suggest [sic] that this is acceptable as the pain would only last 20-30 seconds. This suggestion is incompatible with accepted medical practice. He also attempts to dismiss midazolam's inability to sufficiently lower the BIS index by falsely suggesting the BIS methodology cannot accurately measure midazolam.

(ECF No. 900-1, PageID 30143-44.)

With respect to testimony by both Drs. Buffington and Antognini that benzodiazepine drugs such as midazolam are not safe, Dr. Stevens testified as follows:

> I find that a little disingenuous, because benzodiazepines are probably one of the largest drug classes that are used: Ambien, Xanax, diazepam, Valium. It goes on and on and the reason they are so popular and so commonly used is because they are safe. They have replaced the barbiturates because the barbiturates, not having a ceiling effect, can much more easily produce respiratory depression.

(Evid. Hrg. Tr. ECF No. 925, PageID 31471-18). Dr. Stevens reiterated that overwhelmingly, cases of midazolam-related fatalities were because there was another drug, such as an opioid, on board. (ECF No. 925, PageID 31472).

Plaintiffs offered rebuttal testimony by Dr. Bergese who began by explaining how the study of consciousness "is something that we learn more and more in the last few years," and that "clearly there's been an explosion on this topic in the last few years." (ECF No. 940,

PageID 31599-00.) On cross-examination, Dr. Bergese refused to characterize the study of consciousness as "cutting edge," or anything besides "everyday science." *Id*. at PageID 31639-40. With respect to portions of Dr. Antognini's testimony on the concepts of consciousness and awareness, Dr. Bergese opined that Dr. Antognini did not appear to go deep into those concepts, insofar as he only sometimes found there was a difference between the two. *Id*. at PageID 31601-02. When asked about a question Defendants had put to Dr. Antognini suggesting that Dr. Bergese had characterized consciousness as all or none, Dr. Bergese emphatically disputed that that was ever his testimony. "Actually I think I said two or three times," Dr. Bergese explained, "it's a spectrum." *Id*. at PageID 31603.

Dr. Bergese was next asked about his testimony that "consciousness checks" are checks on reflexes rather than checks on consciousness, and whether anything from Dr. Antognini's testimony changed Dr. Bergese's opinion in that regard. He responded:

> No. If you don't measure consciousness, you cannot check consciousness. All you can do with this if you elicit a reflex, you're checking for a reflex. If you elicit pain, you are going to check for a reflex to pain. But consciousness, you got to measure consciousness. None of those [consciousness checks to be used in Ohio's lethal injection protocol] are going to measure consciousness.
>
> Again, if you do not have reflex, it doesn't mean that you do not have awareness, right? So you can be unconscious and aware or you can be unconscious and aware. [sic] That's the problem with this kind of reflex.
>
> We use 20, 30, 40 years ago, sure we did, because it was the only thing we had. We got better tools today.

Id. at PageID 31603-04. "Which are?," the Court asked. "Brain consciousness monitor for instance," Dr. Bergese answered. "BIS monitor is one of the brain consciousness monitors," Dr. Bergese stated.

Dr. Bergese explained that a BIS monitor factors in three values: the EEG, the drug used, and the state of consciousness or level of sedation. *Id*. at PageID 31604-05. Dr. Bergese stressed the importance of knowing all three values. He proceeded to describe a slide projection of a BIS monitor screen shot that was displayed in court, after which he reminded the Court that the BIS index should register a reading between 40 and 60 (for general anesthesia) and explained that it's a very simple device which truly helps to validate what the brain is doing *Id*. at PageID 31606-07. He continued that it is very simple to attach to patients, and noted that its expense is the only reason that presently it is used in at least 50%, but not 100%, of surgeries. *Id*. at PageID 31607; *see also* PageID 31657-59. Dr. Bergese further testified that you do "not necessarily" need to be able to read EEGs to read a BIS monitor, and that most of the people who use the monitor are technicians who have very little medical training. *Id*. at PageID 31608.

Dr. Bergese did not agree with Dr. Antognini's belief that midazolam does not cause a consistent change in the BIS readings. "The science doesn't show that," Dr. Bergese testified. *Id*. at PageID 31609. "There are more than 3,000 papers where midazolam is part of the original algorithm, so the information that you get out of midazolam is no different than any information you get out of propofol or any other drugs." *Id*. When asked about Dr. Antognini's testimony that the BIS monitor does not necessarily provide accurate information, Dr. Bergese answered, "I can't disagree more." *Id*. He continued, "I don't think that today we can do an anesthetic without brain waves." *Id*. Dr. Bergese demonstrated this by describing another slide projection of a different BIS monitor screen shot that was displayed in court, testifying from it that "you

can't argue this doesn't work." *Id*. at PageID 31610. After describing all of the information that a BIS monitor can provide to an anesthesiologist trying to administer the right amount of anesthetics to maintain the optimal level of general anesthesia, *id*. at PageID 31610-14, Dr. Bergese reiterated that he disagreed with Dr. Antognini's statement about midazolam having different values vis-à-vis BIS readings than other anesthetics have. *Id*. at PageID 31614. Dr. Bergese later explained on cross-examination that the fact that every drug impacts EEG differently does not diminish the value of a BIS monitor because the algorithm that helps generate a BIS number accounts for how each drug impacts EEG. *Id*. at PageID 31660.

Dr. Bergese agreed on cross-examination that there are no studies demonstrating how an IV administration of 500 mg of midazolam would affect BIS measurements. *Id*. at PageID 31641. When later asked on cross-examination whether all expert opinions about the effects of the massive doses of drugs used in executions were based on conjecture and extrapolations, Dr. Bergese agreed, but also reiterated that what made him reconsider those extrapolations "was to see some of the inmates do certain things that I would not expect that if I truly extrapolate those doses." *Id*. at PageID 31655.

Dr. Bergese next disputed Defendants' questions to Dr. Antognini suggesting Dr. Bergese had testified that only a neurologist or doctor should perform consciousness checks. *Id*. at PageID 31615-16. "I don't think that's what I said," he explained, "or at least for sure that's not what I meant to say." *Id*. at PageID 31615. Dr. Bergese then clarified, "So I said that reflex, you got to understand the pathway of the reflex, and the more that you understand it, the better you will interpret the results." *Id*. Dr. Bergese reiterated this explanation on cross-examination, testifying that "there is a finesse on a reflex and that finesse may be picked up better by an expert." *Id*. at PageID 31644.

When asked during cross-examination if using a BIS monitor is better at gauging actual consciousness than "consciousness checks," why paramedics do not take BIS monitors to trauma scenes, Dr. Bergese answered, "The question is do you really need it. I mean war medicine is war medicine." *Id*. at PageID 31645. To this point, and specifically with respect the level of sophistication for assessing consciousness required for medical procedures versus traumas, Dr. Bergese agreed that executions are not medical procedures. *Id*. at PageID 31646-47.

Dr. Bergese was next asked what he would expect to see of someone who was administered 1000 mg of midazolam. He answered:

> You're going to depress the consciousness, that's no question. I think our argument when you were asking me is that it's going to depress the consciousness. Not going to depress to the point that you need it. So that's my concern. There's some people who get depressed more and people who was depressed less. Are they going to be talking fluently? No, I don't expect that.

Id. at PageID 31617. He doubted that anyone would survive that dose, unless they were given respiratory support and other medical intervention. *Id*. at PageID 31617-18. Even so, Dr. Bergese insisted that midazolam is a safe drug, with the caveat that a massive dose of any drug is unsafe. *Id*. at PageID 31647-48. He agreed 500 mg or 1000 mg of midazolam would unquestionably be an overdose. *Id*. at PageID 31648-49. Later during cross-examination, Dr. Bergese agreed again that a 500 mg dose of midazolam is dangerous, and that it can cause respiratory depression and respiratory arrest. *Id*. at PageID 31663-64.

But Dr. Bergese also doubted whether it would be advisable to administer a reversal agent for that high dosage, characterizing the very proposition as "experimental pharmacology." *Id*. at PageID 31618. Dr. Bergese explained that the reversal agent in this case is a competitive reversal agent, which means that it does not bond to midazolam to flush it out; rather, the reversal agent competes with midazolam for the receptor. *Id*. at PageID 31618, 31619.

"Personally if I'm in there," he explained, "just don't give it to me. Just leave me alone," but he later agreed that the reversal agent might be more effective if given before the whole dose of midazolam were given, for instance in the case of a venous blow. *Id*. at PageID 31619, 31621. Dr. Bergese agreed that his research and experience deal with therapeutic doses of drugs, not massive doses of drugs such as the 500 mg of midazolam called for in Ohio's execution protocol. *Id*. at PageID 31640.

Dr. Bergese appeared to disagree with Dr. Antognini's testimony that opioids administered with benzodiazepines can result in a patient forgetting to breathe, so it is important to maintain a sufficient level of consciousness for the patient to remember to breathe. *Id*. at PageID 31620. Dr. Bergese distinguished opioids from benzodiazepines stating that the action of opioids allows a patient to follow a command to breathe, but that benzodiazepines' action does not; they are simply unable to breathe. *Id*.

Dr. Bergese was next asked about portions of Dr. Antognini's testimony expressing a belief that benzodiazepines possess analgesic properties, and discounting texts, such as *Miller's Anesthesia* which states that they do not. *Id*. at PageID 31621-22. Dr. Bergese essentially stated that for a patient who is in pain, "I will treat [him] with an opioid or any other pain medication but I would not give benzodiazepine." *Id*. at PageID 31623.

With respect to whether he disagreed with Dr. Antognini's distinction between pain and noxious stimuli, Dr. Bergese answered, "[n]ot that I disagree. We were trying to split a hair here." *Id*. at PageID 31623. In explaining his answer, Dr. Bergese reminded that "you can be unconscious and feel pain." *Id*. at PageID 31624. He testified:

> And I think I said previously, put a patient to sleep, the surgeon take 20 minutes until they paint the abdomen so I can give very little anesthetic because the patient doesn't have any noxious

> stimuli, all of a sudden I get distracted and the surgeon without telling me make incisions, guess what?
>
> The patient is unconscious but the patient is sensat[e] and all of a sudden the patient moves, hypertension, have tachycardia, start to sweat. Even though he's unconscious he's sensate and he may be aware as well.

Id. at PageID 31624. Dr. Bergese testified that in such a situation, he would agree with Dr. Antognini's approach of administering more anesthesia to the patient and/or give the patient pain medication, even if the patient were unconscious. *Id*. at PageID 31624-25.

Dr. Bergese was next asked about Dr. Antognini's explanation of the concepts of having a memory of pain and actually experiencing pain. *Id*. at PageID 31625. Specifically, Dr. Bergese was asked whether he agreed with testimony suggesting that if a patient has trouble recalling the procedure, it is as if that patient never experienced that pain. *Id*. Dr. Bergese responded that they are difficult terms, and proceeded to explain his understanding of the distinction between memory and awareness.

> So memory is I get the information, I process the information, I save it in my hard drive, and I'm able to use it later. Unfortunately in this case you're not going to be able to use the memory later. So memory information, I think it's kind of inconsequential for this kind of execution because even if they are forming memory, they're not going to be able to tell you later.
>
> So memory is important for that point of view. Actually I want my patients to keep forming some memories because I don't want them to decline further. But that's different than awareness. Awareness is feeling what's going on during the unconscious and when you can't move and express. So you're aware what's going on to you at that specific point of time.

Id. at PageID 31627.

Relating these concepts to the lethal injection context, as well as to Dr. Antognini's testimony, Dr. Bergese explained that his concern with the use of midazolam is that although

midazolam can have the effect of blunting memory formation of the procedure, it does not follow that midazolam abates the experiencing of the procedure. *Id*. at PageID 31627-28. When asked whether it is generally accepted in his field that if a patient does not recall the pain of a procedure, that patient did not experience it, Dr. Bergese appeared to disagree: "I'm going to give the same answer that I gave before, colonoscopy. You get a colonoscopy, you may not remember but you're suffering pain through it. If they don't treat you [with a pain-blocking drug]." *Id*. at PageID 31628.

To this point, Dr. Bergese disagreed with Dr. Antognini's opinion that benzodiazepines, including midazolam, may possess analgesic properties. *Id*. at PageID 31628. Dr. Bergese took issue with one of the studies upon which Dr. Antognini relied, the 2004 Yegin study, to support the opinion that midazolam possesses pain-blocking properties.[30] Dr. Bergese explained that that study involved the administration of midazolam *along with* bupivacaine—a drug that blocks transmission of pain—and that the analgesic effect was due *not* to midazolam *but* to bupivacaine. *Id*. at PageID 31629. Dr. Bergese cautioned against making conclusions that the paper did not intend, and explained that the intent of the Yegin study was to demonstrate what bupivacaine accomplishes alone (short-acting pain blocking), and what bupivacaine and midazolam accomplish (longer lasting effect). *Id*. at PageID 31629-30.

Dr. Bergese likewise took issue with another study upon which Dr. Antognini relied, the Crawford study on the use of midazolam in Caesarian sections, to support Dr. Antognini's opinion that midazolam has analgesic properties. Dr. Antognini testified on direct examination that the Crawford Study involved elective C-sections during which some expectant mothers were administered thiopental and nitrous oxide, while others were administered midazolam and

[30] The portions of Dr. Antognini's testimony during which he discussed the Yegin Study may be found at ECF No. 924, PageID 31114; 31145; 31147-31148; 31182; and 31194-31196.

nitrous oxide. (ECF No. 924, PageID 31053-56.) With respect to Dr. Antognini's testimony that the nitrous oxide administered could take as long as 30 to 60 seconds to take effect, meaning that for those 30 to 60 seconds, midazolam was the only acting drug the expectant mothers would have, Dr. Bergese expressed disagreement, or at least skepticism. (ECF No. 940, PageID 31630.) He explained that nitrous oxide, delivered at a very high flow, will affect the brain immediately, but if it is administered at a very low flow, might take a minute or so to take effect. *Id*. at PageID 31630. On cross-examination, Dr. Bergese reiterated that if the nitrous oxide flows were low, Dr. Antognini may be right; but that if the flows were medium high, Dr. Antognini is actually wrong. *Id*. at PageID 31654.

Plaintiffs next asked Dr. Bergese about Dr. Antognini's opinion that midazolam has a ceiling effect at the receptor level. He answered:

> I don't think you can define "ceiling effect" and I think the pharmacology talks about it quite a bit. I think all I'm going to say, if I may, is that he said it has a maximum affect [sic] to the EEG and then you cannot go further. So I think that's my concern.
>
> My concern is this [midazolam] is the wrong drug and it's going to depress the EEG up to a point and you can give more and more and more and it's not going to change. So he defined it as a ceiling effect on the EEG; I can go up to here and I cannot go further. That's what he said on that, my interpretation of what he said on that statement.

Id. at PageID 31631-32.

Dr. Bergese was asked about Dr. Antognini's application of graphs demonstrating how the concentration of inhaled anesthetic relates to a patient's tendency to move during surgery to IV-administered anesthetics. Applying the inhaled anesthetics concept to other non-inhaled anesthetics is "[a]pples and oranges. I would not make that correlation with this graph." *Id*. at PageID 31632-33.

Dr. Bergese proceeded to describe his analogy of "general anesthesia" to a "black box" warning required by the FDA to appear on the package insert of certain drugs. He explained:

> Yeah, I said a black box because over the years I designed studies for general anesthesia and so when you do sedation studies, they're really easy because you are a little sedated or a lot sedated. Doesn't matter what scale you use, you can use different things: Answer questions, answer to pain, easy.
>
> Now when you're getting into the box, I say "black box," then you don't know. Because how can you ask those questions? And again, unless the patient then is aware or the patient has any interpretive [sic] pain, it's very difficult to ask those questions.
>
> So I go further. I mean I have reviewed papers like Dr. Antognini says he reviews, also I'm on the editorial board of the Journal of Neuro[a]nesthesia and again if I get a paper and trying to definite consciousness and it doesn't have a brain consciousness monitor, probably would reject it immediately because there is no way to validate it.
>
> . . .
>
> So clearly that's what I mean by a box is that you got to get other tools to do it and we are going further. I mentioned now there are pain monitors like the BIS monitor for when [a patient is] asleep. Not only now [the monitor] can [indicate] how deep [the patient is] but [it] can [indicate] how much pain [the patient is] suffering when [he or she is] asleep.

Id. at PageID 31635-37. Dr. Bergese testified that he could not achieve general anesthesia with midazolam alone. *Id*. at PageID 31637. He also confirmed his understanding that while Dr. Antongini's research focus and expertise were in the area of immobility, the focus of his own research and expertise were in the area of pain and consciousness. *Id*. at PageID 31638-39. Dr. Bergese explained:

> Well, he's an expert in mobility. So animal data, no animal data, an expert in mobility at the end of the day. Now the problem, ten years ago when he was doing his research to analyze mobility, you got to take the consciousness away. There's no way to do it with

> the consciousness. So he has to ignore the consciousness to do his [work].
>
> So he's working in a very primitive reflex part of the brain. He's not working on the cortex so he had to take the cortex away to understand what those movements mean[]. So I respect his research.

Id. at PageID 31638. Dr. Bergese, by contrast, focuses his clinical research on sedation, abating pain, cognitive decline, and the impact of the anesthetic on consciousness. *Id*. at PageID 31638-39.

When asked on cross-examination whether a patient would lose memory and consciousness before mobility during the induction of anesthesia, Dr. Bergese stated that the time that elapses between those events is not presently known. *Id*. at PageID 31649. He stressed, however, that any movement means the patient is immediately regaining consciousness. *Id*. at PageID 31650. Dr. Bergese did qualify his opinions by saying that there could be a difference in these events (mobility and consciousness) depending on whether the anesthetics are inhaled or IV-administered. *Id*. He also agreed that the endpoints of unconsciousness, amnesia, and immobility probably occur simultaneously with IV-administered anesthetics, while again denying that you can meaningfully compare graphs demonstrating the effects of inhaled to the IV administration of anesthetics. *Id*. at PageID 31650-51.

Daniel Buffington Pharm.D.

Dr. Daniel Buffington was called as an expert witness by the Defendants. He studied biology and biochemistry at the University of South Florida and obtained his Doctorate of Pharmacy degree at Mercer University in Atlanta, Georgia. (Evid. Hrg. Tr., Doc. No. 925,

PageID 31384.) He completed his residency and clinical pharmacology fellowship at Emory University in Indiana, before returning to Mercer University to obtain his Master of Business Administration[31] degree with a healthcare focus. *Id.*

Dr. Buffington was asked to explain the difference between a Doctor of Pharmacy degree and a Ph.D in pharmacology, and responded that the Doctor of Pharmacy degree is the highest clinical pharmacology degree, whereas the Ph.D in pharmacology is focused on research design. *Id*. at PageID 31385. He later agreed that the Doctor of Pharmacy degree is a professional degree and the Ph.D in pharmacy is an academic degree. *Id*. at PageID 31443. Dr. Buffington defined pharmacology as "the study of medications and natural substances . . . and what pharmacologic effects they have on the body to guide or direct treatment or therapy." *Id*. at PageID 31384-85. His employment history includes academic endeavors, presumably research, and teaching medical students, practicing physicians of various specialties, pharmacists, nursing students, and anesthesiologists. *Id*. at PageID 31384, 31388. He has a clinical practice and also provides forensic consultation services to physicians, health plans, the federal government, and law enforcement. *Id.* He is also currently a clinical assistant professor of medicine at the University of South Florida College of Medicine, College of Pharmacy. *Id*. at PageID 31426. He has testified or been deposed in other States' execution protocol cases and has been consulted by other states on technical issues of their execution protocols. *Id*. at PageID 31386, 31437-38.

Plaintiffs objected to Dr. Buffington's being accepted as an expert in toxicology and pharmacology on the ground that he is a pharmacist, not a pharmacologist. *Id*. at PageID 31388. After a full discussion, the Court found the Plaintiffs' had waived the objection by failing to file a motion in limine challenging Dr. Buffington's qualifications by the previously set deadline for

[31] The transcript identifies this degree as an MDA, but Dr. Buffington's Curriculum Vitae states the degree is an MBA. (*See* Curriculum Vitae of Daniel E. Buffington, ECF No. 870-1, PageID 28177.)

such motions. *Id*. at PageID 31393. He also qualifies under the test adopted by the Supreme Court in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Dr. Buffington was permitted to provide expert opinions in the case. In cross-examination, he acknowledged that he has never authored any papers or book chapters specific to midazolam, and never conducted any scientific studies of midazolam. *Id*. at PageID 31424-25.

Dr. Buffington explained that the term "anesthesia" is a broad term that covers a category of drugs which may be topical, ingestible, or injectable and may have local or global effect in the body. *Id*. at PageID 31396. He described it as "the entire continuum of all attempts to block awareness based on levels of sedation." *Id*. at PageID 31408. He heard testimony in this hearing[32] and saw graphs and charts that he stated did an excellent job of explaining the spectrum of anesthesia and sedation, progressing through low, minimal, moderate, and deep sedation, and ending with general anesthesia. *Id*. at PageID 31396-97.

"Noxious stimulus" was defined by Dr. Buffington as "something that is offensive or disturbing or painful to an individual . . . [that could be] of a verbal nature[,] . . . shaking the patient to alert them[,] . . . [or] something of a painful nature." *Id*. at PageID 31397. Anesthesiologists must tailor the types and amounts of medication to the expected noxious stimuli to achieve the desired level of sedation. *Id*. It is possible that a patient could be sedated to a level short of general anesthesia, and yet be unaware of a noxious stimulus, which in *Miller's Anesthesia* is acknowledged to be the emotional experience of pain, whether it is a pinprick, a pinch, a pressure, a temperature applied to the patient. *Id*. at PageID 31397-98.

Dr. Buffington testified that midazolam is a benzodiazepine drug which is a central nervous system depressant. *Id*. at PageID 31394. Benzodiazepines vary as to their duration and effect, some lasting longer and more potent than others. *Id*. They are used for treating seizures,

[32] Without objection, the respective parties' experts were exempted from the usual separation of witnesses order.

anxiety, or sedation. *Id*. The Federal Drug Administration has approved midazolam for the induction and maintenance of anesthesia, sedation for intubated or ventilated patients, and the treatment of different types of seizures. *Id*. at PageID 31395. Midazolam has been used for several years in medical offices, surgical centers, ambulatory surgery centers, plastic surgery suites, and operating rooms or suites. *Id*. at PageID 31398. Since December 2015, he himself has both prescribed and administered midazolam. *Id*. at PageID 31421-22. It produces sedation of short duration and can be used for a variety of procedures, including in combination with other medications for induction and maintenance of general anesthesia for some procedures. *Id*. at PageID 31399. It can also be used in very high doses in a controlled setting for treatment of life-threatening seizures. *Id*. The drug is capable of rendering a patient to a level of sedation sufficient to produce BIS levels between forty and sixty in doses from five to twenty milligrams. *Id*. at PageID 31400. Dr. Buffington testified that "midazolam is pharmacologically capable of inducing deep respiratory depression and sedation." *Id*. at PageID 31400-01.

In his experience, Dr. Buffington testified that using midazolam alone rather than in conjunction with another drug such as an analgesic, would be preferable in some circumstances. *Id*. at PageID 31413. He explained that the majority of times when midazolam is used alone, it is in cases in which general anesthesia is not required, such as in vasectomies, resetting bones, bone marrow aspiration, or placement of tubes or implanted devices. *Id*. at PageID 31415-16. In such cases, the patient does not need to be "fully asleep," but rather insensate to the pain of the procedure and unable to remember the experience. *Id*. at PageID 31416.

As to the ceiling effect of midazolam, Dr. Buffington stated that comparing midazolam to other drugs such as barbiturates as Dr. Stevens did, would reveal a difference in potency, not the existence of a ceiling effect. *Id*. at PageID 31401. He denied that there is any literature or

scientific study to support the contention that there is a ceiling effect for midazolam at all, let alone at what dosage that effect might occur. *Id*. He stated that other expert witnesses in this case who have testified about the ceiling effect of midazolam had put forth only a theory that it has a ceiling effect. *Id*.

> What we know in a dose-dependent increase is that midazolam produces small effects at low doses and increasing effects of depths of sedation and depth in intensity of respiratory depression. If there were a ceiling dose to be defined or an outcome, it would be death because we now that midazolam is considered lethal at large doses.

Id. at PageID 31401-02. He discounted the value of the prior testimony on the ceiling effect of midazolam stating that "it is inappropriate to attempt to opine human pharmacologic effect from animal or laboratory data that hasn't been tested or validated in humans." *Id*. at PageID 31402. Dr. Buffington disputed the existence of a ceiling effect, testifying that "[w]e do not see a ceiling effect in humans." *Id*. Instead, "what we actually see is a capacity to produce deep sedation to the equivalent level of general anesthesia and the capacity to render death. *Id*. at PageID 31402-03. Even if assuming a ceiling effect at some point, there is no evidence that it would come into play before midazolam produced deep sedation and amnesia in an individual. *Id*. at PageID 31414. Dr. Buffington stated that larger doses of midazolam can produce death, so that is where the ceiling effect would be in that case. *Id*.

In apparent disagreement with Dr. Stevens' testimony respecting the interaction between midazolam and GABA receptors, Dr. Buffington stated that there are various types of GABA receptors: $GABA_A$, $GABA_B$, and $GABA_C$, each of which has many subunits. *Id*. at PageID 31414-15. He testified that any ceiling effect could not be reached until all of those receptors on all of those types of GABA were occupied by midazolam such that there were no more receptors to accommodate more of the drug. *Id*. at PageID 31414. In his rebuttal testimony, Dr. Stevens

agreed with Dr. Buffington that there are different types of GABA, but disagreed that all three receptors would need to be occupied for the ceiling effect to be reached because the only GABA benzodiazepines interact with is $GABA_A$. *Id*. at PageID 31454.

Dr. Buffington expressed his expert opinion to a reasonable degree of scientific certainty that if 500 mg of midazolam is given as required by Ohio's execution protocol, and it is effectively administered, it will render the inmate sufficiently insensate to the noxious stimuli that may result from the administration of the paralytic drug and the potassium chloride, the second and third drugs in the protocol. *Id*. at PageID 31403-04. He added that in addition to the sedative effect of midazolam, its amnestic properties also prevent the patient from actually experiencing pain from noxious stimuli because it interferes with the brain's capacity to understand and react to pain. *Id*. at PageID 31404. Furthermore, he has seen no evidence that has attempted to discern, graduate, or grade any presence of pain from the administration of the second or third drug in the protocol. *Id*. at PageID 31404. In fact, Dr. Buffington stated that "there is not even a foundation in this case that an individual would more likely than not have any pain from either drug two or drug three." *Id*. at PageID 31415.

Dr. Buffington testified that autonomic responses from a patient, such as a muscle twitch, a change in blood pressure or heart rate, perspiration, or guttural sounds could be signs of emergence from deep sedation or anesthesia, but that emergence is a continuum, not like an on-off light switch. *Id*. There are three phases of emergence from anesthesia with full consciousness being the third phase. *Id*. at PageID 31410-11. Thus, noxious stimuli may be applied to a patient at some level of anesthesia and that person could remain unaware even as their body exhibits autonomic responses to the stimuli such as movement or changes in blood pressure. *Id*. at PageID 31410.

In cross-examination, Dr. Buffington acknowledged that he served as a consultant to the Ohio Attorney General's Office and the ODRC with regard to development of the current three-drug lethal injection protocol. *Id*. at PageID 31417. He also testified that during his involvement in an Alabama case, he contacted approximately fifteen compounding pharmacies to ask if they would be willing to provide compounded pentobarbital to the Alabama Department of Corrections. *Id*. at PageID 31438-40. He found none were willing to do so without additional information, but he 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. *Id*. at PageID 31440-41.

Plaintiffs offered a rebuttal report to Dr. Buffington, as well as rebuttal testimony, by experts Dr. Craig Stevens and Dr. Sergio Bergese. As to Dr. Buffington, Dr. Stevens set forth a summary of his opinions in his Rebuttal Report as follows:

> Dr. Buffington disregards the scientific data from medical and pharmacological research in opining that using midazolam instead of a true general anesthetic (such as pentobarbital) as the first drug in Ohio's three-drug lethal injection protocol will render a person unconscious and insensible to noxious stimuli.
>
> Dr. Buffington states that midazolam at a dose of 500 mg IV will "render an individual unconscious." Dr. Buffington does not further elaborate on this statement nor provide any data to support his bold assertion, and I am not aware of any which could support it. Further, in contradiction to this statement, his report consistently notes that midazolam produces sedation, which is not equivalent to loss of consciousness.
>
> Dr. Buffington states that "Observations of physical activity or motor response during the administration of midazolam should not be presumed to indicate that an individual is conscious." This statement is not supported by any further elaboration of citation of clinical studies, and I am not aware of any which could support it. Further, this statement is made in spite of Dr. Buffington

> consistently noting that midazolam produces a sedative effect, which is not equivalent to rendering someone unconscious.
>
> Dr. Buffington cites a paper that lists the toxic range of blood levels for midazolam and calculates that after a 500 mg IV dose of midazolam the blood concentration would be 2 to 7 times this toxic range. He does not provide any information of how he arrived at this number, and I am not aware of any scientifically acceptable methodology for doing so. Additionally, the paper that Dr. Buffington cites clearly shows that there is no fatal concentration for midazolam listed, contrary to the conclusion he attempts to support with this unexplained calculation.
>
> Dr. Buffington states that sedation is the same as loss of consciousness. This is false. The American Society for Anesthesiology (ASA)'s table of definitions shows sedation (with reduced awareness, but still response to pain) is a different stage than General Anesthesia (lack of awareness and loss of consciousness and no response to pain).
>
> Dr. Buffington disregards data that show midazolam is limited in its effects in producing depression of brain activity as reflected on the BIS index. He erroneously concludes that midazolam can produce a greater depression of brain activity, even though he cites studies that show a limit in midazolam's depression of brain activity.
>
> In summary, the key opinions in Dr. Buffington's report are unsupported statements, with no medical or pharmacological studies to provide evidence for the truthfulness of these assertions.

(ECF No. 900-1, PageID 30144-45.)

With respect to Dr. Buffington's testimony that benzodiazepines can be used for the induction *and* maintenance of general anesthesia, Dr. Stevens testified, "I believe under the FDA indications it says for the induction of anesthesia. I don't believe under the actual indications it says for the maintenance." (ECF No. 925, PageID 31447.) Dr. Stevens agreed that midazolam might be used during anesthesia in conjunction with something else, but alone could not be used

to maintain general anesthesia. *Id*. To this point, Dr. Stevens referred to a table he created in his original declaration setting forth the FDA indications of midazolam and pentobarbital. *Id*. at PageID 31448, referencing ECF No. 836-1, PageID 24812. That table, he continued, demonstrates that while midazolam is approved for "preoperative sedation, outpatient sedation, anesthesia inductions, sedation for intubated patients, and as a co-anesthetic," it is not approved as a sole anesthetic. (ECF No. 925, PageID 31449.)

With respect to Dr. Buffington's testimony that noxious stimuli could be anything, including verbal stimulation or shaking, Dr. Stevens testified, "He was incorrect about that." *Id*. at PageID 31449. Dr. Stevens explained that "pain fibers have to be activated for a stimulus to be noxious." *Id*. He agreed with other testimony in this case defining noxious stimuli as something that could cause tissue damage. *Id*. at PageID 31449-50. He disagreed with Dr. Buffington's testimony that midazolam could sufficiently sedate someone to the point of being unaware of noxious stimuli, and thus disagreed that midazolam can be effective as a first drug in Ohio's three-drug protocol. *Id*. at PageID 31450-51. According to Dr. Stevens, Dr. Buffington described *sedation* as capable of producing unawareness to pain, when anesthesiologist experts and the ASA table maintain that unawareness of pain occurs *only* at the state of general anesthesia which, according to Dr. Stevens' initial testimony during Plaintiffs' case-in-chief, is deeper than the deepest level of sedation. Asked why midazolam would not be effective as a first drug in Ohio's three-drug protocol, Dr. Stevens answered, "[b]ecause we're not talking about a verbal stimulus here with the second and third drugs. We're talking about known discomfort, pain, intolerable pain in some cases." *Id*. at PageID 31451.

With respect to Dr. Buffington's opinion that Dr. Stevens had confused "ceiling effect" with "potency," referring to a figure in Dr. Stevens' original report (ECF No. 836-1, PageID

24808), Dr. Stevens disagreed. "Potency is different," Dr. Stevens explained. "Potency just depends on how much of a drug you need to reach a given effect." (ECF No. 925, PageID 31453.) Dr. Stevens continued, "In this case, it doesn't matter the potency of a benzodiazepine because it has to have GABA present to work, it will always tail off because there is not an infinite amount of GABA." (ECF No. 925, at PageID 31454.) Dr. Stevens discounted Dr. Buffington's testimony that there is more than one type of GABA that can act as a receptor for midazolam as a "false red herring," insisting that it is only the $GABA_A$ receptor on which benzodiazepines produce their inhibiting effect. *Id*. at PageID 31454. With respect to Dr. Buffington's testimony that there is only a "theory" of a ceiling effect to midazolam, insofar as there are no studies on humans establishing such an effect, Dr. Stevens pointed to paragraphs in his Expert Declaration listing scientific literature and data about midazolam's ceiling effect in humans. *Id*. at PageID 31455-56 (referencing ECF No. 836-1, PageID 24827).

Turning next to Dr. Buffington's opinion that midazolam can be lethal, Dr. Stevens referred to a table set forth in his Rebuttal Report (ECF No. 900-1, PageID 30152). Dr. Stevens testified that what is "fairly amazing" from the chart is that "what you see for both of the benzodiazepines" is there is no comatose-lethal dose range. (ECF No. 925, PageID 31459-60.) "There are very few drug classes," Dr. Stevens explained, "that do not have a lethal range." *Id*. at PageID 31460.) As to cases in which people died from midazolam, Dr. Stevens reiterated that "the overwhelming majority of those are when there is another drug on board, namely an opioid. That's the number one death-producing combination." *Id*. at PageID 31460.

On cross-examination, Dr. Stevens agreed that it was possible to overdose on midazolam, but attempted to qualify that by distinguishing between an overdose that results in death and an overdose that sends someone to an emergency room but from which they recover. *Id*. at PageID

31485. When asked on cross-examination whether midazolam's black box warning that the drug is dangerous is exclusive to midazolam combined with another drug, Dr. Stevens simply answered, "It doesn't say the drug is dangerous. It says you have to be careful and watch out for these things basically." Defendants proceeded to read aloud the following IV midazolam black box warning from an Akorn Laboratories label:

> Adult and pediatric. Intravenous midazolam has been associated with respiratory depression and respiratory arrest, especially when used for sedation in non-critical care settings. In some cases, where this was not recognized promptly and treated effectively death and hypoxic [encephalopathy] has resulted."

Id. at PageID 31486-87. Dr. Stevens agreed that Defendants had read that accurately. *Id*. at PageID 31487.

When asked about Dr. Buffington's testimony that midazolam is often used alone for procedures such as vasectomies, resetting a bone fracture, respiration having to do with bone barrow transplants, and placements of tubes and devices, Dr. Stevens answered "I would think not." *Id*. at PageID 31460-61. On cross-examination, Dr. Stevens could not offer an opinion as to whether or under what circumstances midazolam would be used as the sole anesthetic prior to intubation, though he agreed with other testimony characterizing intubation as "very noxious." *Id*. at PageID 31483-84.

Returning to the concepts of sedation and general anesthesia, Dr. Stevens was asked to elaborate on why he found Dr. Buffington's testimony in this respect confusing. Dr. Stevens testified:

> I think we've made clear on the previous time I was here that the ASA, very authoritative organization, American Society of Anesthesiology, has a very nice table that shows mild sedation, moderate, deep sedation. Then you don't talk about sedation. Then you talk about general anesthesia.

> So to say sedation can cause general anesthesia, totally confusing and not consistent.

(ECF No. 925, PageID 31462.) Relating that to the concept of "consciousness," and specifically to the criticism that Plaintiffs referred to consciousness as all or not, Dr. Stevens explained:

> I think there is more of a gradation. In other words, harder to tell going from mild to moderate to deep sedation. But I think once you hit that general anesthesia, there is a bright line. That's a legal term, I think. I've learned that.
>
> But – and so that in that case, you do have unconsciousness. And once you get there, I think we've had testimony earlier saying by the EEG pattern or other signs that anesthesiologists know. So, yes, once you cross that bright line of unconsciousness, there may be different levels going deeper.

Id. at PageID 31463. Referring to the ASA table set forth in his original Expert Declaration (ECF No. 836-1, PageID 24810), Dr. Stevens continued that it is only at the level of general anesthesia that you achieve the most important end points: unarousable to painful stimulus and loss of consciousness. *Id*. at PageID 31463-64.

When next asked what he thought about Dr. Buffington's assertion that he had recently prescribed and administered midazolam, Dr. Stevens answered, "[w]ell, I was shocked because my understanding is only physicians can prescribe and administer drugs." *Id*. at PageID 31465.

Dr. Stevens next returned to Dr. Buffington's testimony that midazolam can achieve the level of general anesthesia. Specifically, Dr. Stevens was asked to explain his critique of the supporting data that Dr. Buffington used. *Id*. at PageID 31468. Referring to portions of his Rebuttal Report (ECF No. 900-1, PageID 30153), Dr. Stevens testified that Dr. Buffington's own source (the Liu study) demonstrates that midazolam only brought the BIS value down to sixty-nine and produced sedation, which is not general anesthesia. (ECF No. 925, PageID 31468-69.) Relating that to the use of midazolam as the first drug in Ohio's three-drug protocol, Dr. Stevens

agreed that mild prodding or shaking are not the kind of noxious stimuli that would be relevant to the use of midazolam as the first drug. *Id*. at PageID 31469.

Continuing with the data upon which Dr. Buffington relied to support his opinion that midazolam can achieve general anesthesia, Dr. Stevens discounted the 2005 Buloch study because although there were some individuals with BIS levels as low as sixty-six, that was not the mean value, which was seventy-one. Dr. Stevens essentially critiqued the reliance on the outlier BIS number of sixty-six as evidence that midazolam can achieve something close to unconsciousness or general anesthesia, when the mean was seventy-one, and, as Dr. Stevens noted, it could have been pointed out that one BIS number was only ninety-five. *Id*. at PageID 31469-70 (referencing ECF No. 900-1, at PageID 30153). Dr. Stevens emphasized, "[s]o this is not supportive of midazolam being able to produce the BIS levels that are associated with general anesthesia or, therefore, unconsciousness." *Id*. at PageID 31470. Dr. Stevens agreed that Dr. Buffington had not provided any study in which the BIS level hit the desirable reading of 60 or below. *Id*.

Dr. Stevens agreed on cross-examination that the ASA "Continuum of Depth of Sedation" table to which he referred in his original Expert Declaration (ECF No. 836-1, PageID 24810) speaks exclusively in terms of therapeutic doses of drugs, not massive doses, and does not speak to combinations of drugs, such as a combination of midazolam and hydromorphone. (ECF No. 925, PageID 31482-83.) Dr. Stevens would not necessarily agree that midazolam used with hydromorphone causes anesthesia. *Id*. at PageID 31482.

With respect to testimony by both Drs. Buffington and Antognini that benzodiazepine drugs, such as midazolam, are not safe, Dr. Stevens testified,

> I find that a little disingenuous, because benzodiazepines are probably one of the largest drug classes that are used: Ambien,

> Xanax, diazepam, Valium. It goes on and on and the reason they are so popular and so commonly used is because they are safe. They have replaced the barbiturates because the barbiturates, not having a ceiling effect, can much more easily produce respiratory depression.

(ECF No. 925, PageID 31471-18.) Dr. Stevens reiterated that overwhelmingly, cases of midazolam-related fatalities were because there was another drug, such as an opioid, on board. *Id*. at PageID 31472.

Dr. Stevens was next asked to explain his criticism of Dr. Buffington's "three-part" opinion that "it is more likely than not that doses of 500 mg or greater would render BIS values progressively lower than 69." *Id*. at PageID 31473 (referencing ECF No. 900-1, PageID 30154). According to Dr. Stevens, the first "fact" upon which Dr. Buffington relied—that midazolam has never been demonstrated to have a ceiling effect in humans—is false. (ECF No. 925, PageID 31473.) Dr. Stevens dismissed the second "fact" upon which Dr. Buffington relied, namely that midazolam's pharmacological effects are known to be dose related, because although you get more sedation with a greater dose, that fact is not pertinent to the issue at hand "[b]ecause we don't know anything about doses above the therapeutic range. And there is a ceiling effect." *Id*. at PageID 31473. Dr. Stevens reiterated that "once you get to a certain point, you are not going to get any greater effect because you need GABA present to work [and] GABA's limited." *Id*. at PageID 31474.

The third "fact" upon which Dr. Buffington premised his opinion is that midazolam is highly lipophilic. Dr. Stevens explained, "[t]hat just means that it crosses the blood-brain barrier quickly." *Id*. at PageID 31474. Dr. Stevens essentially disputed that that has any bearing on the "ultimate pharmacological effect of midazolam, which is sedation and not General Anesthesia." (ECF No. 900-1, PageID 30154; *see also* ECF No. 925, PageID 31475). And so as to Dr.

Buffington's "three-part" opinion, Dr. Stevens concluded, "Well, I just think it's false. It's contrary to any of the clinical studies that we have. And we don't have a lot, but we've got enough to at least say midazolam has shown clinically not to produce a level of general anesthesia. There is no indication of it." *Id*. at PageID 31476.

Dr. Stevens concluded the direct examination portion of his rebuttal testimony by reiterating that although counterintuitive, the fact remains that because midazolam requires GABA receptors to work, and GABA receptors are limited, you cannot just give more midazolam and get a greater effect. *Id*. at PageID 31476.

Evaluation of the *Baze/Glossip* Claim in Light of the Evidence

Although the debate among the experts on the pharmacologic effects of midazolam was robust and even spirited, a number of factual conclusions are supported by their testimony and the lay observations of midazolam-involved executions.

First of all, there appears to be consensus and the Court finds that administration of a paralytic drug and potassium chloride will cause a person severe pain. There is nothing in the testimony to suggest this pain would be limited to persons with particular physical characteristics, such as those testified to in McGuire's case and found by Judge Frost to be credible.

There is no objective measure of pain that can be applied interpersonally. Although medical personnel have in recent years become more attentive to patients reported pain levels,[33] there is not yet any way of telling that what one person counts as a "7" is the same as what

[33] For an enlightening account of that shift in medical attention and how it led to the current opiod epidemic, see Dreamland: The True Tale of America's Opiate Epidemic by Sam Quinones.

someone else counts as a "7' in ranking their pain on a scale of 1 to 10. The Supreme Court in *Baze* and *Glossip* does not attempt to quantify what is meant by severe pain. The argument of Plaintiffs that realizing one is unable to breathe and is therefore likely to be terrified and equating that phenomenon with severe suffering has not been refuted.

Plainly, midazolam does not have the same pharmacologic effect on persons being executed as the barbiturates thiopental sodium and pentobarbital. The Plaintiffs' experts explained at great length why this was likely to be so. The Court finds 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 produce the same effects in those being executed. Without knowing precisely why, the Court finds that those administered midazolam (whether in a one injection combination with hydromorphone or in sequence with a paralytic and potassium chloride) take longer to die and exhibit different bodily behaviors in the process. In terms of their respective effects on the human body, deep sedation and general anesthesia are distinct.

Defendants' argument as the Court understands it is that that is a distinction without a legally significant difference. That is, if a person is so deeply sedated as to have no awareness of what is happening or is unable to form memories of the "noxious stimuli," he has not "experienced" the pain. The testimony is consistent that the effect of midazolam as an anterograde amnesic is to prevent the formation of those memories. That does not mean the pain was not inflicted and the Supreme Court has yet to tell us that inflicted pain that is not remembered does not count as severe pain for Eighth Amendment purposes.

For obvious reasons, there are not now and never will be clinical studies of the effect of injecting 500 mg of midazolam into a person. Testimony established that 500 mg was

approximately one hundred times the usually indicated therapeutic dose and no institutional review board[34] would ever approve such an experiment. And we certainly cannot ask the executed whether or not they experienced pain after the injection of midazolam from the ordinarily painful injections of the second and third drugs they received after the midazolam. We can ask those questions of post-surgery patients, but none of them would be subjected to use of that level of midazolam and there was little support in the testimony for the idea that midazolam would be used alone for surgeries other than those performed on an outpatient basis.

The Court also cannot ignore reasonable inferences to be drawn from the practice of executing States. Use of the midazolam-hydromorphone combination with which Dennis McGuire was executed caused ODRC Director Mohr to call a medical team consultation in the middle of that execution; after that execution, Ohio abandoned that protocol. Florida, despite having conducted many executions using midazolam, abandoned the drug while this case was in hearing. Arizona also abandoned midazolam shortly before the hearing as a result of settling litigation over its use.

The Court concludes that use of midazolam as the first drug in Ohio's present three-drug protocol will create a "substantial risk of serious harm" or an "objectively intolerable risk of harm" as required by *Baze* and *Glossip.*

To prevail, Plaintiffs must also identify "a known and available alternative method of execution that entails a lesser risk of pain." *Glossip, supra,* at 2731 citing *Baze*. The Ohio General Assembly has limited available methods of execution in Ohio to those employing lethal injection. Ohio Revised Code § 2949.22. The Court does not believe that Plaintiffs are required to ignore that limitation in identifying alternatives. That is to say, a method of execution that

[34] Institutional review boards are the entities which must approve experiments on human subjects.

would require legislation, e.g., to adopt the firing squad as an alternative, need not be proposed by Eighth Amendment plaintiffs as an available alternative.

The Court is also aware that McGuire as a plaintiff in this case effectively presented the 500 mg midazolam Florida method as an alternative. But McGuire's was the first American midazolam-involved execution and evidence has accumulated since then.[35]

All the parties and witnesses in this case agree that use of a barbiturate, either as the first drug in a three-drug protocol or as the sole drug, would be preferable to the current Ohio protocol in that it would eliminate the side effects observed in midazolam-involved executions identified in the lay testimony and would also eliminate (or at least reduce to a constitutionally acceptable level) the risk of subjecting the inmate to severe pain.

The question, then, is the availability of barbiturates. Justice Alito in *Glossip* reported the demise of the supplies of barbiturates for execution purposes and explained the reasons in terms not likely to be overcome by Ohio, to wit, the manufacturer of thiopental sodium ceasing production and the manufacturer of pentobarbital refusing to permit its export to the United States for execution purposes. Although apparently some States have been able to obtain pentobarbital for executions, Ohio's efforts to obtain the drug from other States and from non-State sources have not met with success.

There remains the possibility that Ohio can obtain the active pharmaceutical ingredient of pentobarbital and have it made into injectable form by a compounding pharmacy. Deposition testimony established that, to do so, Ohio requires an import license from the federal Drug Enforcement Administration and that it has an application for such a license pending, but that it has no indication when a decision on that application might be made.

[35] The Court puts to one side these three Plaintiffs' point that they are not bound by McGuire's position, although that is certainly true.

In *Baze* and *Glossip*, the Supreme Court did not attempt to quantify how available the alternative method must be to qualify. At the time *Baze* was decided, obtaining barbiturates was not the difficulty it had become by 2015 when *Glossip* was decided. But even recognizing the problem in *Glossip*, the Court did not essay a rule about availability.

Compounded pentobarbital would be preferable to midazolam to all parties in this case. The Ohio General Assembly has taken steps to protect the anonymity of potential suppliers and compounders in Ohio Revised Code § 2949.221 and 2949.222, indicating that approach is not unacceptable to a majority of the legislature. This Court and the Sixth Circuit have upheld and applied the confidentiality provisions of those statues which were represented to Judge Frost as necessary to obtain possible suppliers of execution drugs. While compounded pentobarbital will not be available to Ohio to permit it to execute the above Plaintiffs on the dates now set, the Court finds Plaintiffs have met their burden to identify a sufficiently available alternative method of execution to satisfy *Baze* and *Glossip*.

The Supreme Court reminds us in *Glossip* that because capital punishment is not unconstitutional, there must be a constitutional way to accomplish it. But that does not imply that an identified alternative to a problematic method must be available immediately.

Equal Protection Claims

Much of the prior preliminary injunction litigation in this case has focused on the Equal Protection Clause. Judge Frost discussed the standards for evaluating such a claim in *In re: Ohio Execution Protocol Litig. (Lorraine)*, 840 F. Supp. 2d 1044 (S.D. Ohio 2012):

> "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.' U.S. Const. amend. XIV, § 1. The Supreme Court has stated that this language 'embodies the general rule that States must treat like cases alike but may treat unlike cases accordingly.'" *Radvansky v. City of Olmsted Falls*, 395 F.3d 291, 312 (6th Cir. 2005) (quoting *Vacco*, 521 U.S. at 799, 117 S.Ct. 2293). To establish a claim for relief under the Equal Protection Clause, a plaintiff must demonstrate that the government treated the plaintiff disparately as compared to similarly situated persons and that such disparate treatment either burdens a fundamental right, targets a suspect class, or has no rational basis. *Id.; see also TriHealth, Inc*., 430 F.3d at 788.

Id. at 1053-54, quoting *Club Italia Soccer & Sports Org., Inc. v. Charter Twp. of Shelby, Mich.*, 470 F.3d 286, 298 (6th Cir. 2006). He continued:

> When the disparate treatment burdens a fundamental right, strict scrutiny applies. *Miller v. City of Cincinnati*, 622 F.3d 524, 538 (6th Cir. 2010). What this means is that any core deviation from the protocol is permissible only if it is narrowly tailored to a compelling governmental interest. *Cf. Does v. Munoz*, 507 F.3d 961, 964 (6th Cir. 2007).

Id. Lorraine also repeats *Club Italia*'s explanation of the Equal Protection class-of-one approach which is applicable to Plaintiffs' claims. *Id.*

The core of this Court's prior holdings on the Equal Protection claims has been that the execution protocol, adopted as binding on itself by the State of Ohio, must be followed. See, e.g., *Cooey v. Kasich (Smith)*, 801 F. Supp. 2d 623 (S.D. Ohio 2011). There can be no deviations from the five core components and any deviations from non-core components must be personally approved by the ODRC Director. The five core components are

> 1. At least three Medical Team Members, two of whom are authorized to administer drugs under Ohio law, shall be used in the conduct of court-ordered executions.
>
> 2. The drugs required by this policy shall be used.

> 3. Functions required to be performed by medically-qualified persons, as described in this policy, shall be performed by Medical Team Members.
>
> 4. All Execution Team functions shall be performed by appropriately trained and qualified members of the Execution Team.
>
> 5. Only the Director can authorize a variation from the procedures stated in this policy but not a variation from the four requirements listed immediately above in subsection V.1.2.3. and 4. of this policy.

October 7, 2016, 01-COM-11, V. 1–5. (DX 1).

In their Proposed Findings of Fact, Plaintiffs make the following claims of deviation from the Protocol:

1. Return to the use of a paralytic drug and potassium chloride after their abandonment in November 2009 (¶¶5-11, ECF No. 895-1, PageID 30107-08);

2. Use of 41.2 mg of hydromorphone in the McGuire execution instead of the 40 mg required by the Protocol then in effect. *Id.* at ¶¶ 12-15;

3. Deviations from required training. *Id.* at ¶¶'s 16-32; and

4. Inadequacy of the consciousness checks provided for in the current protocol. *Id.* at ¶¶ 33-44.

Plaintiffs have pointed to no requirement of prior Orders of this Court or of Ohio or federal law which suggest that an Execution Protocol, once adopted, cannot be amended by the same process by which it was adopted in the first place, to wit, action by the ODRC Director. Although the Court finds the ODRC cannot reintroduce the paralytic and potassium chloride (See Judicial Estoppel Claim, infra), that is as a result of judicial estoppel, not the Equal Protection Clause. Put more abstractly, an amendment is not a deviation. Defendants have

undertaken to give Plaintiffs at least thirty days' notice of a change in execution drugs, but that does not imply a prohibition on amendment.

There was no oral testimony about the hydromorphone overdose in the McGuire execution. Assuming that fact is supported somewhere in the mountain of paper filed in the case, no one has explained to the Court how this deviation is material. Hydromorphone is an opioid. Defendants' expert in the McGuire hearing, Dr. Dershwitz, whom Judge Frost credited over Plaintiffs' expert, testified the effect of the hydromorphone would be to prevent any ill effects from the air hunger Dr. Waisel expected to occur from the midazolam. It seems very unlikely to the Court that 1.2 mg additional hydromorphone would decrease the effects of that drug; in the absence of any testimony, the Court declines to make any such finding. If this deviation occurred, it would have had the effect of better protecting McGuire from severe pain than the 40 mg dose. *De minimis non curat lex.*

With respect to training, Plaintiffs' principal claim seems to be that Richard Theodore trains execution team members on the "therapeutic effects of the drugs," rather than their "general nature and effects." (ECF No. 895-1, PageID 30110). The Court does not find this to be a deviation, even without examining the content of the training in detail. As was evident throughout expert testimony in the hearing and also in Judge Frost's opinion in *M*cGuire, using particular drugs for the first time, especially in doses that are never used therapeutically and therefore have no clinical testing can cause results that are unexpected. Witness the ample anecdotal testimony about midazolam-involved executions above. Training cannot be done to advise personnel of results that have not been studied.

Plaintiffs are also concerned about the requirement for training for contingencies and the fact that the McGuire execution team was not trained to deal with the contingencies that Dr.

Waisel predicted would occur with the protocol used with McGuire (ECF No. 895-1, ¶¶ 25-28, PageID 30110). His testimony was heard in a preliminary injunction hearing on January 10 and 12, 2014. *In re: Ohio Execution Protocol Litig. (McGuire)*, 994 F. Supp. 2d . 906, 908 (S.D. Ohio 2014). McGuire's execution was scheduled for and conducted on January 16, 2014; Judge Frost denied an injunction in part because he credited Dr. Dershwitz over Dr. Waisel. *Id.* at 913. To find a deviation from the core component of training occurred with the McGuire execution, the Court would have to find that Ohio was required to accept Waissel's opinion hypothetically and postpone the McGuire execution so that the execution teamed could be trained to deal with what might happen if Dr. Waisel were correct. The Equal Protection Clause does not require a State's execution protocol to be written such that a "contingency" of this sort must be trained for. If that were the case, any execution could be postponed indefinitely by proposing new hypothetical contingencies shortly before an imminent execution. This would likely create the situation repeatedly warned against by the Supreme Court and the Sixth Circuit of this Court's becoming a micro-manager or best-practices board for executions.

The last Equal Protection claim fares no better. It is that the consciousness checks intended to be used for the Phillips' execution will not perform their intended task of reliably determining whether the inmate to be executed is "unaware and insensate to pain." For this Court to attempt to prescribe what consciousness checks must be performed and what results must be obtained from them would have us back in the micro-management arena.

The Court concludes that Plaintiffs are unlikely to prevail on their Equal Protection claims.

Judicial Estoppel Claim

In his Sixth Claim for Relief, Plaintiff Phillips alleges that the State of Ohio permanently renounced the use of pancuronium bromide and potassium chloride in lethal injection executions (Fourth Amended Complaint, ECF No. 692, PageID 20637-43). Plaintiffs Tibbetts and Otte raise the same claims (ECF No. 691, PageID 20496-500; ECF No. 695, PageID 21143-47).

The October 7, 2016, Execution Protocol adds a paralytic agent (vecuronium bromide, pancuronium bromide, or rocuronium bromide[36]) as the second drug and potassium chloride as the third drug in the three-drug protocol Ohio has announced it intends to use to execute Plaintiffs Phillips, Tibbetts, and Otte; on January 13, 2017, Defendants added Plaintiff Alva Campbell to the list of those it intends to execute using this protocol and for whom it has sufficient drugs available (ECF No. 919).

In December 2016 the Court stayed the executions of Plaintiffs Phillips, Tibbetts, and Otte to allow the Sixth Circuit sufficient time to decide the interlocutory appeal in this case. Given Defendants' insistence that any such stay order had to meet the preliminary injunction standard, the Court found that Plaintiffs were likely to succeed on their judicial estoppel claim. (ECF No. 834, reported at *In re: Ohio Execution Protocol Litig*., 2016 U.S. Dist. LEXIS 174933 (S. D. Ohio Dec. 19, 2016). The parties' Proposed Findings of Fact and Conclusions of Law, filed after that decision, presumably take it into account.

In 2009 death-row inmate Ronald Biros was scheduled to be executed under a three-drug protocol in which thiopental sodium was the first drug, followed by pancuronium bromide and

[36] Since each of these drugs is apparently intended to and capable of achieving the same result, the Court makes no distinction among them in this Decision, No evidence distinguishing among them was offered at the preliminary injunction hearing.

potassium chloride. Ohio had set his execution date for December 8, 2009. *Cooey (Biros) v. Strickland*, 588 F.3d 921 (6th Cir. 2009). On October 19, 2009, Judge Frost stayed Biros' execution pending further order of this Court (Case No. 2:04-cv-1156, ECF No. 590). However, on November 13, 2009, the State changed its protocol to shift to a one-drug procedsure: a single dose of five grams of thiopental sodium administered intravenously. *Id.* The State then moved to vacate the stay, Judge Frost refused, and the State appealed.

Although Ohio had ceased to use the method Biros contended was unconstitutional, he argued that voluntary cessation did not prevent a later return to that method.

> Biros rejoins that Ohio has not met its "heavy" burden of showing that this voluntary change in procedure has defeated any "'reasonable expectation . . .' that the alleged violation will recur." *Los Angeles County v. Davis*, 440 U.S. 625, 631, 99 S. Ct. 1379, 59 L. Ed. 2d 642 (1979). Biros suggests that "there is no assurance that defendants will not revert to [the three-drug procedure] whenever they want to do so." Biros Reply Br. at 14. As an initial matter, it is by no means clear that the prior procedure was unconstitutional, and it thus is by no means clear that a "rever[sion]" will lead to "recur[ring]" constitutional violations. *See Baze*, 128 S. Ct. at 1537. Be that as it may, the question at hand is whether Ohio will use the old procedure, or the new one, in executing Biros. There 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 execution protocol, and it intends to apply the substantially modified protocol to Biros. Both of the key changes to the protocol, it bears adding, grew out of--and were direct responses to--the underlying litigation of which Biros was a part. Under these circumstances, we see no reasonable basis for refusing to take the State at its word.

588 F.3d 921, 923 (6th Cir. 2009). Thus the Sixth Circuit found Biros' challenges to the old protocol moot, vacated the stay, and allowed Biros to be executed. The State of Ohio thereby

achieved two important litigation goals: the then-pending appeal was dismissed as moot and the Biros sentence was carried out.

The doctrine of judicial estoppel forbids a party from taking a position inconsistent with one successfully and unequivocally asserted by that same party in an earlier proceeding. *Mirando v. U.S. Dept. of the Treasury*, 766 F.3d 540, 545 (6th Cir. 2014), *citing New Hampshire v. Maine*, 532 U.S. 742, 748 (2001); *Warda v. Commissioner of Internal Revenue*, 15 F.3d 533, 538 (6th Cir. 1994).

> The doctrine of judicial estoppel "forbids a party 'from taking a position inconsistent with one successfully and unequivocally asserted by the same party in a prior proceeding.'" *Griffith v. Wal-Mart Stores*, 135 F.3d 376, 380 (6th Cir. 1998), quoting *Teledyne Indus., Inc. v. Nat'l Labor Relations Bd.*, 911 F.2d 1214, 1217 (6th Cir. 1990). Courts apply judicial estoppel in order to "preserve[] the integrity of the courts by preventing a party from abusing the judicial process through cynical gamesmanship, achieving success on one position, then arguing the opposing to suit an exigency of the moment." *Id. quoting Teledyne*, 911 F.2d at 1218. The doctrine applies only when a party shows that his opponent: (1) took a contrary position; (2) under oath in a prior proceeding; and (3) the prior position was accepted by the court. *Id*.

Wells Fargo Bank, N.A. v. La Salle Bank, N.A., 643 F. Supp. 2d 1014, 1029 (S.D. Ohio 2009)(Merz, M.J.).

The position the State of Ohio now takes – that it will execute Phillips, Tibbetts, and Otte under a three-drug protocol using a paralytic agent and potassium chloride -- is completely inconsistent with the position it took on appeal in *Cooey* (*Biros*) and on remand from that decision before Judge Frost. Ohio prevailed on its contrary position and is now judicially estopped from re-adopting a paralytic agent and potassium chloride as part of the Execution Protocol.

Judicial Admissions Claim

Plaintiffs also claim they are entitled to a preliminary injunction on a theory that Defendants have made binding judicial admissions to which they must be held. Plaintiffs rely on the same facts use for their judicial estoppel claim to support their position (Plaintiffs' Amended Proposed Findings of Fact and Conclusions of Law, ECF No. 895-1, PageID 30050).

The Court believes Plaintiffs misconceived the nature of a judicial admission. As the authorities they cite explain, a judicial admission is an unequivocal position taken on a question of fact, often in a pleading or stipulation. The effect of a judicial admission is to withdraw the admitted fact from further contest in the case.

However, the instances of statements relied on by Plaintiffs for this claim are not statements of fact, but promises of future conduct. For example, Ohio told this Court and the Sixth Circuit in *Cooey* (*Biros*) that "neither pancuronium bromide nor potassium chloride **will be used** as part of the lethal injection process." (quoted at ECF No. 895-1, PageID 30060; emphasis supplied.) The distinction is parallel to that made in pleading common law causes of action for fraud: language about what a party will do in the future may create a binding contract, but such language only constitutes fraud if it misrepresents a party's present intention.

While statements of promised future conduct are sufficient to support the judicial estoppel claim, they do not constitute judicial admissions and Plaintiffs are not entitled to preliminary injunctive relief on a judicial admissions theory.

II. Irreparable Harm

The irreparable harm to the named Plaintiffs if temporary injunctive relief is not granted is patent. Ohio's plan to execute these three men on the dates presently set is firm, as witnessed by Defendant's counsel's representations to the Court and by the Governor's having granted only short reprieves to Messrs. Phillips and Tibbetts in light of this revived litigation. Whether or not Plaintiffs' claims survive their deaths, the injury would be irreparable. This is consistent with earlier findings of irreparability by Judge Frost. See, e.g., *In re: Ohio Execution Protocol Litig (Lorraine)*, 840 F. Supp. 2d 1044, 1059 (S.D. Ohio 2012), aff'd., 673 F.3d 601 (6th Cir. 2012). Defendants do not contest this element.

IIII. Balance of Equities

In some cases seeking preliminary injunctive relief from execution, the courts have emphasized the lack of diligence on an inmate's part as a reason for denying relief. For example, in *Workman v. Bredesen, supra*, Workman filed his motion for temporary injunctive relief on May 4, 2007, only five days before his scheduled execution. 486 F.3d at 899. The Sixth Circuit vacated the temporary restraining order granted by the District Court, holding "[a]t no point until last Friday, May 4, 2007, did Workman challenge the State's method of execution, even though the components of the procedure that Workman challenges today have been in existence in the main since 1998." *Id.* See also

In contrast, the State announced its new lethal injection protocol here on October 7, 2016, and all three Plaintiffs filed their preliminary injunction motions within a month and on a

schedule approved by the Court. They were in no way dilatory in raising the challenges they make.

IV. The Public Interest

Both the Sixth Circuit and the Supreme Court have recognized the interest of the State in the carrying out of criminal judgments. In the case of prison sentences, this interest is protected by requiring an inmate to exhaust all available state court remedies before filing federal habeas corpus and by making the standard for bail pending a habeas decision on the merits all but impossible to meet. In other words, the State gets the benefit of the conviction until and unless a federal court decides the conviction is unconstitutional and even a conditional writ may not bring release if a retrial is possible. In a non-capital habeas corpus case, the petitioner has great interest in a speedy resolution because until he wins, he is being completely deprived of his liberty, the very interest at stake in the case.

"Death is different." *Woodson v. North Carolina*, 428 U.S. 280, 305 (1976). With a death sentence, the State gets no part of that sentence carried out until the federal courts have finished their work, often with a last-minute denial of stay of execution by the Supreme Court. Unless his case is a "dead bang winner," the death row inmate benefits from delay.

Consideration of the public interest in a case such as this requires balancing between those two poles. Assuming first that the State has an interest in retributive justice on behalf of families of murder victims, that interest is disserved by further delay. Assuming that the public has a deterrence interest in capital punishment as a practice, that interest is also served by speedy executions. It is a truism of penology that delay in punishment diminishes the deterrent effect of

punishment. However, when executions are routinely delayed decades in Ohio, it is very debatable how much loss in deterrence there is from waiting until a case can be tried on the merits.

The public interest is also served by the rule of law which in cases such as this demand that persons not be executed unconstitutionally and that the federal courts have ample time to decide whether the intended execution is constitutional or not. Enforcing the Constitution is the highest rule of law value for all American courts, since all judges take an oath to treat it as the supreme law of the land. Judge Frost's earlier decisions reached the same conclusion. See e.g., *In re: Ohio Execution Protocol Litig (Lorraine)*, 840 F. Supp. 2d 1044, 1059 (S.D. Ohio 2012), *aff'd.*, 673 F.3d 601 (6th Cir. 2012).

On balance, the public interest weighs in favor of granting temporary injunctive relief, but maintaining a fast track approach to adjudicating Plaintiffs' claims on the merits.

Conclusion

Based on the foregoing analysis, the Plaintiffs' Motions for Preliminary Injunction are GRANTED IN PART AND DENIED IN PART. Defendants and all persons in active concert with them are ENJOINED during the pendency of this action from carrying into execution the death sentences of Plaintiffs Phillips, Tibbetts, and/or Otte by using (1) the three-drug protocol embodied in the October 7, 2016, version of 01 COM 11 or (2) any lethal injection method which employs either a paralytic agent or potassium chloride.

No bond will be required.

January 26, 2017.

s/ *Michael R. Merz*
United States Magistrate Judge