

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

JOSEPH C. GARCIA,	§	
PLAINTIFF,	§	
	§	
v.	§	
	§	CASE NO. 4:18-CV-4521
BRYAN COLLIER,	§	
EXECUTIVE DIRECTOR OF TEXAS	§	
DEPARTMENT OF CRIMINAL JUSTICE	§	
	§	
LORIE DAVIS,	§	CAPITAL CASE
DIRECTOR OF THE CORRECTIONAL	§	
INSTITUTIONS DIVISION OF TEXAS	§	EXECUTION DATE
DEPARTMENT OF CRIMINAL JUSTICE	§	
	§	DECEMBER 4, 2018
JAMES L. JONES,	§	
SENIOR WARDEN OF THE HUNTSVILLE	§	
UNIT	§	
AND	§	
	§	
JOHN OR JANE DOES (UNKNOWN	§	
EXECUTIONERS) 1-50	§	
	§	
DEFENDANTS.	§	
	§	

PLAINTIFF’S MOTION FOR PRELIMINARY INJUNCTION

Plaintiff Joseph Garcia has filed a complaint pursuant to 42 U.S.C. § 1983 in the above-captioned case, in which he alleges that he the State of Texas will use a compounded lethal-injection drug that will result in him experiencing severe pain during his execution, such that his execution will violate his Eighth Amendment right to be free from cruel and unusual punishment. He now respectfully asks this

Court for a preliminary injunction under Rule 65(a) of the Federal Rules of Civil Procedure barring Defendants from executing him until it demonstrates that they have acquired a supply of pentobarbital from a reputable pharmacy, and if that pentobarbital is compounded, that it has been tested shortly before use. Garcia seeks injunctive relief barring Defendants and each of them and their agents from acting in a manner that will deprive him of his First, Eighth, and Fourteenth Amendment rights, under the United States Constitution and 42 U.S.C. § 1983.

In his Complaint filed simultaneously with this Motion, Garcia asserts four claims. First, Defendants' use of compounded pentobarbital from a pharmacy that has a history of compounding unsafe drugs demonstrates deliberate indifference and creates a substantial risk of serious harm, violating Garcia's Eighth Amendment right to be free from cruel and unusual punishment. Second, by deliberately concealing necessary information from Garcia, Defendants have violated his First Amendment right to be informed about the manner in which the State implements the most serious penalty available in the criminal-justice system. Third, Defendants' deliberate actions in hiding information regarding the source of the pentobarbital that they intend to use to execute Garcia denies him of his federal rights to due process and meaningful access to the courts. Fourth, Defendants' actions violate Garcia's right to equal protection under the law pursuant to the Fourteenth Amendment.

In light of his pending execution date of December 4, 2018, a preliminary injunction and a stay is necessary to allow Garcia to litigate his claim before he is unconstitutionally executed. Garcia also requests expedited discovery, oral argument, and an evidentiary hearing on his motion. This motion is supported by the attached memorandum.

MEMORANDUM IN SUPPORT OF MOTION

Pentobarbital is a schedule II prescription drug regulated under a complex set of federal laws that address the manufacturing, possession, distribution, labeling, and importation of controlled substances. It is the drug the State of Texas uses to execute prisoners. (See TDCJ¹ Execution Procedure (July 2012) at 8, *attached as Ex. A.*)

Texas obtains its execution-related pentobarbital from a pharmacy located in Texas. (See Decl. of Pharmacy X, *McGehee v. TDCJ*, No. 4:18-mc-01546 (S.D. Tex. June 22, 2018) ECF No. 12-4, *attached as Ex. B.*) According to a recent report by an investigative journalist, that pharmacy is Greenpark Compounding Pharmacy (“Greenpark”). (See Chris McDaniel, *Inmates said the drug burned as they died. This is how Texas gets its execution drugs.* BuzzFeed (Nov. 28, 2018 at 5:09 p.m. ET), *attached as Ex. C.*²) This pharmacy has been cited for multiple safety violations, by the Food and Drug Administration, and the Texas State Board of Pharmacy. *Id.*

Within hours of the publication of that news article, Garcia’s counsel contacted TDCJ requesting information about its source of the pentobarbital it

¹ Texas Department of Criminal Justice

² Also, *available at* https://www.buzzfeednews.com/article/chrisgcdaniel/inmates-said-the-drug-burned-as-they-died-this-is-how-texas?utm_term=.pkxy4410jP#pkxy4410jP.

intends to use in his execution. (Nov. 28, 2018 Letter to Laurie Davis, *attached as Ex. D*). TDCJ has not responded.

Accordingly, Garcia has filed the Complaint in this case. In light of Garcia's scheduled execution date of December 4, 2018, a preliminary injunction is necessary to allow Garcia to litigate his claims in order to ensure that Texas does not execute him in a manner that violates his constitutional rights.

I. Background

Drug compounding is “the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not FDA-approved.”³ Compounded drugs include “sterile injectables”—drugs that are intended to be injected into a person, and therefore must be sterile.

Although medical professionals sometimes recommend compounded drugs for their patients when an FDA-approved drug is not medically appropriate for them,⁴ relying on compounding pharmacies can be risky. As the FDA explains, “they do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially

³ Compounding and the FDA: Questions and Answers, <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm>.

⁴ *See, e.g., id.*

serious health risks.”⁵ Moreover, the FDA “has observed troubling conditions during many of its inspections of compounding facilities including toaster ovens used for sterilization, pet beds near sterile compounding areas, and operators handling sterile drug products with exposed skin, which sheds particles and bacteria, among many others.”⁶ Reliance on compounding pharmacies is risky, however, because regulations governing such pharmacies are lax and vary from state to state, and instances of contamination abound; American Medical Association guidelines even warn doctors that prescribing compounded medications can lead to malpractice liability. Deborah Denno, *Lethal Injection Chaos Post-Baze*, 102 Geo. L.J. 1331, 1360-68 (2014). Therefore Defendants choice to use compounded pentobarbital requires them to exercise due diligence about the safety practices of their sources.

A. Unsafe practices at compounding pharmacies create significant health crises.

Unsafe practices by compounding pharmacies have caused numerous public health crises over the years.⁷ In 2012, injectable steroids produced by the New England Compounding Center (NECC) led to a tragic fungal meningitis outbreak

⁵ *Id.*

⁶ *Id.*

⁷ A Continuing Investigation into the Fungal Meningitis Outbreak and Whether it Could Have Been Prevented Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce, 113th Cong. 2 (2013) (statement of Margaret A. Hamburg, M.D., Comm’r, FDA) [hereinafter Hamburg Statement] (reporting multiple incidences over the past twenty years where compounded drugs have caused deaths and serious injuries).

across twenty states, infecting more than 800 individuals and resulting in 64 deaths. Kurt Eichenwald, *Killer Pharmacy: Inside a Medical Mass Murder Case*, Newsweek (Apr. 16, 2015 at 7:07 AM).⁸ An FDA inspection report of NECC facilities following the outbreak noted several alarming observations, including yellow and greenish residue lining on surfaces of equipment used in producing sterile drug products, “dark, hair-like discoloration” along the edges of a “Clean Room” used to formulate and fill sterile preparations, and multiple vials of sterile injectable drugs containing “greenish black foreign matter” and “white filamentous material.” FDA, Form FDA 483 issued to Barry J. Cadden of New England Compounding Pharmacy Inc. 1, 7-8 (Oct. 26, 2012).⁹

A subsequent FDA investigation of 55 compounding pharmacies found that more than 75% of those inspected had “serious issues,” such as “lack of appropriate air filtration systems, insufficient microbiological testing, and other practices that create risk of contamination.”¹⁰

These concerns directly affect Defendants’ supply of pentobarbital: Defendants apparently obtain at least some of their pentobarbital from a

⁸ Available at <http://www.newsweek.com/2015/04/24/inside-one-most-murderous-corporate-crimes-us-history-322665.html>.

⁹ Available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAElectronicReadingRoom/UCM325980.pdf>.

¹⁰ Hamburg Statement at 5.

compounding pharmacy that has been repeatedly cited for violating safety requirements in their compounding procedures.

B. TDCJ purchases compounded drugs for use in executions.

In September 2013, the TDCJ began purchasing and using compounded pentobarbital, instead of manufactured pentobarbital, to carry out its executions.

At approximately 4:30 p.m. CST on November 28, 2018, Garcia learned from a news article that TDCJ has for the last three and half years procured the drugs it uses to carry out lethal injections from Greenpark, a compounding pharmacy that regulators have repeatedly cited for dangerous practices. (*See* Ex. C.)

Reporter McDaniel tied Greenpark to a declaration submitted to the United States District Court for the Southern District of Texas, Houston Division under the pseudonym Pharmacy X. (*See* Exs. B & C.) In the declaration, Greenpark averred that it “has supplied lethal injection chemicals to the Texas Department of Criminal Justice for use in executions of death row inmates.” (Ex. B, ¶ 3.) Greenpark stated that its decision to supply lethal-injection chemicals “was and is” contingent on its identity remaining a secret, and that it would end its business with TDCJ if its identity were revealed. (Ex. B, ¶ 4.)

C. Greenpark has a history of safety violations.

Greenpark has been cited for safety violations in recent years, related to its compounding practices, and its license has been in a probationary status since

November of 2016, when the Texas State Board of Pharmacy (“TBP”) found that it compounded the wrong drug for three children. (*See* TBP Order #H-16-006-B, *attached as* Ex. E.)

TBP found that Greenpark failed to verify or incorrectly verified the correct identity of an ingredient used in compounding a batch preparation, which resulted in the children receiving compounded lorazepam instead of lansoprazole. (*See* Ex. E.) The lansoprazole, that the children were supposed to receive, is used to treat high levels of stomach acid,¹¹ but the lorazepam that they did receive is a benzodiazepine used to treat seizures and anxiety.¹² After taking the compounded drug with lorazepam, one of the children was hospitalized after experiencing adverse effects, including drowsiness, lack of coordination and irritability. (*See* Ex. E.) In the same order, TBP also found that an employee of Greenpark forged a quality control document for the compounded batch preparation mentioned above. (*See* Ex. E.) As a result, TBP placed Greenpark’s license on probation for a period of two years, beginning thirty days after the entry of its order on November 1, 2016. (*See* Ex. E.)

TBP also issued several Warning Notices to Greenpark for violations of rules

¹¹ *See* U.S. Nat’l Library of Medicine, DailyMed: Lansoprazole, <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9cf54748-80da-428d-86f1-2a17f1160bc2>.

¹² *See* U.S. Nat’l Library of Medicine, DailyMed: Lorazepam, <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ae274b1f-27c3-483b-99f1-9a9249dc2459>.

governing practices for producing sterile drug products.

On March 27, 2017, Greenpark received three Warning Notices for, inter alia, the failure to: “conduct and document filter integrity tests on all filters used to sterilize high risk or batch preparations”; certify its hood since June 2015, compromising pre-sterilization procedures for high risk sterile compounding; conduct and document results of viable sampling to be performed at least every six months as part of the recertification of facilities and equipment; and complete and maintain documentation of initial technology training for all pharmacy technologists and technology trainees. (*See* March 27, 2017 TBP Warning Notices at 1-3, *attached* as Ex. F.)

As part of its inspection of Greenpark’s Houston facilities in March 2017, TBP also noted additional failures on its Inspection Report Checklist, and advised Greenpark to ensure that the temperature of its cleanroom was consistently 68 degrees Fahrenheit or cooler, and to ensure that antiseptic hand cleansing is performed using waterless alcohol-based surgical scrub once inside the buffer area prior to putting on sterile gloves. (*See* March 27, 2017, TBP Notice of Inspection at 5, *attached* as Ex. G.)

Additionally, Greenpark was issued two Warning Notices by TBP on June 23, 2015, for several safety issues including the “failure to remove and quarantine out of date drugs from dispensing stock until drugs can be destroyed properly,” and the

failure to have all supervising personnel involved in compounding sterile preparations do gloved fingertip and media-fill challenge tests. (*See* June 23, 2015 TBP Warning Notices at 1-2, *attached as* Ex. H.)

Greenpark was also issued two Warning Notices by TBP on May 1, 2014. Amongst the warnings were one for failing “to weigh/mix chemicals in at least ISO 8 air quality” and was ordered to “[c]ease this practice now and comply,” and the failure to indicate beyond use date (“BUD) on prescription labels. (*See* May 1, 2014 TBP Warning Notice at 1, *attached as* Ex. I.) Additionally, Greenpark was in violation for failing to calibrate and verify the accuracy of the automated compounding device, and was ordered to have it removed, replaced or repaired immediately. (*See* Ex. I at 2.)

In its Notice of Inspection from May 1, 2014, TBP noted additional failures on its Inspection Report Checklist, including the fact that the balance could not be calibrated to verify accuracy during inspection, and that the law book, general reference and handbook on injectable drugs were all outdated. (*See* May 1, 2014 TBP Notice of Inspection at 4, *attached as* Ex. J). TBP also advised Greenpark to “[r]emove all expired/improperly labeled drugs, compounds, chemicals from the dispensing stock,” and to “make all quantities clear on controlled substance inventory.” *Id.*

On October 26, 2018, Greenpark was also the subject of a Warning Letter

from the United States Food & Drug Administration (“FDA”). (*See* Oct. 26, 2018 FDA Warning Letter, *attached as* Ex. K.) From October 16, 2017 to October 27, 2017, an FDA investigator inspected Greenpark’s facilities in Houston and noted serious deficiencies in their practices for producing sterile drug products, putting patients at risk. (*See id.* at 2.)

The FDA investigator noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing Greenpark’s drug products to be adulterated according to statute. *Id.* at 2 (citing FDCA § 501(a)(2)(A); 21 U.S.C § 351(a)(2)(A).)

Specifically, the FDA investigator noted problems with sterility such as “personnel were engaged in aseptic processing” had “partially exposed skin and wearing non-sterile garb,” “personnel were observed re-sanitizing gloved hands with non-sterile [redacted] before resuming aseptic processing,” and “wipes used for disinfecting” sterile preparation areas “were not sterile.” (Ex. K at 2.)

D. Improperly compounded pentobarbital creates a variety of significant health risks.

Substandard compounded pentobarbital has a risk of forming visible, solid precipitate. Visible chemical precipitates, when injected into the vasculature, can travel rapidly through the heart and into the pulmonary capillary vasculature. Given the size of the particles, they could occlude these capillaries and lead to rupture and

hemorrhage of blood into the lungs. This is clinically referred to as pulmonary embolus and pulmonary hemorrhage. A person experiencing this condition is substantially likely to feel exceptional physical pain. (Report of James H. Ruble R.Ph., Pharm.D., J.D., at 6, *Whitaker v. Livingston*, No. 4:13-cv-02901 (S.D. Tex. Aug. 26, 2015), ECF No. 93-1, at , *attached at Ex. L* (citing Gupta, VD, Stability of pentobarbital sodium after reconstitution in 0.09% sodium chloride injection and repackaging in glass and polypropylene syringes, *Int. J. Pharm. Comp.* 2001, 5(6): 482-4).)

Additionally, impurities or particulates in the injectable solution would lead to extreme venous irritation. Chemical imbalances in compounded pentobarbital leading to pH levels outside human blood parameters would also cause extreme pain upon injection. Moreover, the administration of sub-potent drugs, such as those used after their BUDs could also prolong the procedure and lead to suffering at the time of an execution. *Id.*

TDCJ refuses to disclose information regarding the provenance of the pentobarbital it uses to execute people, and plans to use to execute Garcia. TDCJ has gone to great lengths to keep information about the source of its execution drugs a secret. Jolie McCullough, *After loss at state Supreme Court, Texas keeps fighting to*

conceal its execution drug supplier, Texas Trib., (Jul. 23, 2018).¹³ The source of Texas's pentobarbital has only come to light recently, due to a news outlet investigation (*See Ex. C.*)

Given that compounding pharmacies are not subject to the same stringent standards as large pharmaceutical manufacturers, the shorter shelf life and higher failure rate of compounded drugs, and the known pain experienced by multiple people recently executed in Texas (Ex. C), attorneys representing prisoners on death row in Texas have sought to determine the provenance of the drugs the State uses to execute people, *see, e.g.*, Second Am. Compl., *Whitaker v. Livingston*, CV No. H-13-2901, at 6-7 (S.D. Tex. Sept. 11, 2015), ECF 109. However, the State has refused to disclose this information, as well as other information about the pentobarbital it uses. Keri Blakinger, *As lethal injection lawsuit continues, Texas replenishes execution drug supplies*, Houston Chronicle (Aug. 18, 2018).¹⁴

As a result, prisoners, including Garcia, have been unable to obtain information regarding the quality (or lack thereof) of the drugs being used to execute them, and the serious constitutional risks they pose. This refusal prevents Garcia from discovering that the source of the drug, which he believes to be Greenpark, has

¹³ Available at <https://www.texastribune.org/2018/07/23/texas-supreme-court-execution-drug-rehearing/>.

¹⁴ Available at <http://www.houstonchronicle.com/news/houston-texas/article/As-lethal-injection-lawsuit-continues-Texas-11943467.php>.

committed a host of safety violations and as a result, is on probation, as discussed above. Defendants have prevented Garcia from determining whether the drug it uses are degraded or contaminated, which would cause intolerable pain. The lack of transparency has impeded Garcia's ability to exercise his constitutional right not to be put to death by in a manner that has a substantial risk of serious harm.

The integrity, potency, and sterility of compounded pentobarbital are affected by: the quality of the "Active Pharmaceutical Ingredient" (API) used to make the drug; the quality of the compounder and the conditions of the laboratory in which the drug is compounded; the time between compounding and use; the assigned BUD and the qualifications of the person assigning same; and the conditions under which the drug is stored after compounding.

Given the nature of compounded pentobarbital, its source—and the safety standards of that source—is essential information. Compounded pentobarbital is classified as a high-risk sterile injectable. *See* United States Pharmacopeia ("USP") General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations. Compounded preparations are assigned a BUD intended to prevent degradation of a compound that the USP has calculated is likely to occur after a set timeframe. Absent extended sterility testing, USP <797> sets the BUD for high-risk compounded sterile preparations at a short timeframe.

E. Texas has a history of obtaining execution drugs from illicit and unsafe sources.

Past actions on the part of Texas and its supplier have raised concerns about the sanitation practices of the source of Texas's pentobarbital. For example, Texas had eight doses of pentobarbital that were set to expire on July 20, 2017. State logs list eight doses received that day as "return from supplier" and set to expire a year out, July 20, 2018. *See* Keri Blakinger, *As lethal injection lawsuit continues, Texas replenishes execution drug supplies*, Houston Chronicle (Aug. 18, 2018).¹⁵ TDCJ's spokesperson would not clarify whether those were new drugs, or merely a new expiration date. *Id.*

Additionally, a series of public information requests have revealed that the drugs that Texas uses to execute people do not meet safety and sanitation regulations. USP <797> says that compounded injectible sterile preparations (CSPs) should maintain their labeled strength within monograph limits, and the monograph for pentobarbital allows for 2% standard deviation, meaning, that pentobarbital has to be between 98% and 102%. (*See* Pentobarbital monograph at 1, *attached as* Ex. M.) Public records produced by TDCJ have revealed that the pentobarbital used by Texas to execute people often fell outside this range, including 109%, 103%, 94.6%, and 97%. (*See* TDCJ Lab Reports, *attached as* Ex. N.)

¹⁵ Available at <http://www.houstonchronicle.com/news/houston-texas/article/As-lethal-injection-lawsuit-continues-Texas-11943467.php>.

Texas has a history of obtaining execution drugs from unreliable and likely dangerous sources. In 2015, the FDA seized an imported shipment of execution drugs that TDCJ purchased because the drugs were not approved for human use and were misbranded. Mike Tolson, *FDA will not give seized execution drugs back to Texas*, Houston Chron. (Apr. 21, 2017).¹⁶

Moreover, once Defendants obtain their drugs, they often fail to use them according to their execution protocol. Defendants' protocol requires the use of "100 milliliters of solution containing 5 grams of Pentobarbital," which translates to a solution concentration of 50mg/mL. (*See Ex. A at 8.*)

Despite this requirement, Defendants have used two different concentrations of pentobarbital in its executions over the past several years. (*See Huntsville Unit Storage Inventory for Pentobarbital, attached as Ex. O.*) TDCJ's own logs reveal that in some executions, *e.g.*, Christopher Young's on July 17, 2018, Defendants used the correct concentration, but in others, such as those of Erick Davila on April 25, 2018, and Juan Castillo on May 16, 2018, Defendants used a solution of pentobarbital at a concentration of 100 mg/mL, in violation of the protocol. (*See Ex. O.*) The logs contain no explanation of why the 100 mg/mL was chosen for certain executions. (*See id.*)

¹⁶ Available at <https://www.houstonchronicle.com/news/houston-texas/houston/article/FDA-will-not-give-seized-execution-drugs-back-to-11090050.php>.

And in addition to Defendants' inconsistent approaches to dosage strengths of the drugs, Defendants also have a haphazard approach to attempting to ensure the safety of its pentobarbital. For example, Defendants agreed to test the compounded pentobarbital intended for use in the executions of Thomas Whitaker and Perry Williams for potency, purity and sterility shortly before those executions. *Whitaker v. Livingston*, No. H-13-2901, 2016 WL 3199532, at *3 (S.D. Tex. June 6, 2016). But TDCJ has refused to do the same testing shortly before the executions of other condemned prisoners, including Garcia.

II. This Court should grant Garcia a preliminary injunction because he meets the four requirements necessary to secure a preliminary injunction.

Garcia seeks a preliminary injunction barring the Defendants from executing him with supplies of pentobarbital obtained from an unsafe compounding pharmacy. *See* Fed. R. Civ. Proc. 65. The purpose of a preliminary injunction is to preserve the status quo until the rights of the parties can be fully and fairly litigated. *Janvey v. Alguire*, 647 F.3d 585, 600 (5th Cir. 2011) (“We have previously stated that where a district court has determined that a meaningful decision on the merits would be impossible without an injunction, the district court may maintain the status quo and issue a preliminary injunction to protect a remedy . . .”).

A plaintiff may secure a preliminary injunction when he can show:

- (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is

not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.

Alguire, 647 F.3d at 595; *see also Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008).

For the reasons outlined below, Garcia is able to show: a likelihood of success on the merits of his four claims; that he faces a substantial threat of irreparable injury (death) in the absence of an injunction; that the threatened injury in the absence of an injunction outweighs the harm of preventing an execution for a time sufficient to allow Defendants to obtain a constitutionally appropriate supply of pentobarbital; and that the grant of an injunction would serve the public interest by allowing Defendants the time to comply with the Constitution. *Alguire*, 647 F.3d at 595.

A. Garcia can show a substantial likelihood of success on the merits on his claims.

In order to evaluate the likelihood that Garcia will succeed on the merits of his claims, the Court looks to ““standards provided by the substantive law.”” *Alguire*, 647 F.3d at 596 (quoting *Roho, Inc. v. Marquis*, 902 F.2d 356, 358 (5th Cir. 1990)). Garcia “must present a prima facie case but need not show that he is certain to win.” *Alguire*, 647 F.3d at 596 (internal quotations omitted).

The substantive law at issue here relate to the First, Eighth, and Fourteenth Amendments to the Constitution. The First Amendment is implicated because Defendants fail to provide him with information relating to his execution, thus

preventing him from exercising his First Amendment rights to speech, as well as his right to petition the government for redress. The Eighth Amendment is implicated because Garcia alleges that Defendants will execute him in a manner that violates his right to be free from cruel and unusual punishment, and that they will do so with deliberate indifference to the risk of a cruel and unusual execution. The Fourteenth Amendment is implicated because Garcia alleges that Defendants violate his due-process rights to notice and an opportunity to be heard, and that Defendants violate his right to Equal Protection.

1. Claim One: Defendants' use of compounded pentobarbital from a pharmacy that has a history of compounding unsafe drugs demonstrates deliberate indifference. This indifference violates Garcia's right to be free from cruel and unusual punishment.

The Eighth Amendment prohibits the unnecessary and wanton infliction of pain. *Gregg v. Georgia*, 428 U.S. 153, 173 (1976). Specifically, it forbids the infliction of unnecessary pain in the execution of a death sentence. *In re Kemmler*, 136 U.S. 436, 447 (1890). A condemned prisoner is entitled to a humane death that does not cause “needless suffering,” prolonged lingering, or deliberate infliction of pain. *See Farmer v. Brennan*, 511 U.S. 825, 846 & n.9 (1994); *id.* (defining “deliberate indifference” as “requiring a showing that the official was subjectively aware of the risk”). A condemned person cannot be subjected to a method of execution that is “sure or very likely to cause serious illness and needless suffering.”

Glossip v. Gross, 135 S. Ct. 2726, 2737 (2015) (quoting *Baze, v. Rees*, 553 U.S. 35, 50 (2008)).

Here, Garcia is likely to succeed on the merits of showing that Defendants are deliberately indifferent to the suffering that he will be subjected to if they use compounded pentobarbital from a pharmacy that has a history of significant safety violations, *see* Section I.C, *supra*, the State of Texas has repeatedly sanctioned Greenpark.

Defendants through secrecy and refusing to answer Garcia's (and other condemned prisoners') requests for information (*see* Ex. D) have thereby prohibited Garcia from investigating the pharmacy, steps that TDCJ should have undertaken before hiring a pharmacy to provide a drug that Defendants claimed would not create unconstitutional executions.¹⁷

As also explained in Section I.D., *supra*, the risk of harm from using substandard compounded pentobarbital includes the risk of forming visible, solid precipitate. These precipitates can travel rapidly through the heart and into the

¹⁷ Defendants work closely with their chosen pharmacists, to the point of promising them that TDCJ will keep information of the pharmacies' participation "on the down low." (*See* Aff. of Jasper Lovoi, RPh., *Schad v. Brewer*, No. 2:13-cv-02001-ROS (D. Ariz. Oct. 4, 2013), ECF 21-1 *attached as* Ex. P (explaining that "[b]ased on the phone calls I had with Erica Minor of TDCJ regarding its request for these drugs, including statements that she made to me, it was my belief that this information would be kept on the 'down low' and that it was unlikely that it would be discovered that my pharmacy provided these drugs."))

pulmonary capillary vasculature. Given the size of the particles, they could occlude these capillaries and lead to rupture and hemorrhage of blood into the lungs.

Defendants' failure to guard against these and other harms, the risks of which are caused by Defendants' deliberate indifference to the risks posed by their drug supplier, creates "a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment.'" *Baze v. Rees*, 553 U.S. 35, 50 (2008) (quoting *Farmer v. Brennan*, 511 U.S. 825, 842, 846, and n.9 (1994)).

Accordingly, Garcia can demonstrate a likelihood of success on the merits of his claim that Defendants act in a deliberately indifferent manner to the risk of the use compounded pentobarbital obtained from an unsafe pharmacy, and that consequently, there is a substantial and unnecessary risk of serious harm, in violation of the Eighth Amendment.

2. Claim Two: By deliberately concealing necessary information from Garcia, Defendants have violated Garcia's First Amendment right to be informed about the manner in which the State implements the most serious penalty available in the criminal-justice system.

"The First Amendment serves to ensure that the individual citizen can effectively participate in and contribute to our republican form of self-government." *Globe Newspaper v. Super. Ct.*, 457 U.S. 596, 604-05 (1982).

Garcia is an "individual citizen" with a First Amendment right of access to

governmental proceedings. In order for him to participate effectively, he must be permitted his First Amendment right of access to governmental proceedings. This right of access arises from the “common understanding that ‘a major purpose of [the First] Amendment was to protect the free discussion of governmental affairs.’” *Globe Newspaper*, 457 U.S. at 604 (quoting *Mills v. Alabama*, 384 U.S. 214, 218 (1966)). His rights as an individual citizen are not diminished by the fact that he is a prisoner; prisoners retain their First Amendment rights absent deprivation procedures that meet due-process requirements. *See, e.g., Pell v. Procunier*, 417 U.S. 817, 822 (1974) (recognizing that a prisoner “retains those First Amendment rights that are not inconsistent with his status as a prisoner or with the legitimate penological objectives of the corrections system”); *Pell*, 417 U.S. at 837 (Douglas, Brennan, Marshall, JJ., dissenting) (“[F]oremost among the Bill of Rights of prisoners in this country, whether under state or federal detention, is the First Amendment. Prisoners are still ‘persons’ entitled to all constitutional rights unless their liberty has been constitutionally curtailed by procedures that satisfy all the requirements of due process.”) (citing *Procunier v. Martinez*, 416 U.S. 396, 428-429 (Douglas, J., concurring) (*overruled by Thornburgh v. Abbott*, 490 U.S. 401 (1989))). No such procedures have occurred in this case; accordingly, Garcia retains his First Amendment rights.

Defendants, however, violate those rights by failing to provide the

information he has requested. Through this course of action, Defendants prevent Garcia from participating in a robust discussion about the methods by which the State obtains the implements by which it carries out its judicial sentences. *See Press-Enter. Co. v. Super. Ct.*, 478 U.S. 1, 7 (1986) (“People in an open society do not demand infallibility from their institutions, but it is difficult for them to accept what they are prohibited from observing.”) (quoting *Richmond Newspapers Inc. v. Virginia*, 448 U.S. 555, 575 (1980)).

Defendants’ secrecy also deprives Garcia of his First Amendment right to petition the government for redress of grievances. “The First Amendment is thus broad enough to encompass those rights that, while not unambiguously enumerated in the very terms of the Amendment, are nonetheless necessary to the enjoyment of other First Amendment rights.” *Globe Newspaper*, 457 U.S. at 604; *cf. Pell*, 417 U.S. at 829 n.6 (holding that prison restrictions did not unconstitutionally burden prisoners’ First Amendment rights to petition the government for redress of grievances because prison accorded “alternative means of communication with the press”). Here, Defendants’ intentional concealment of the information he requests deprives him of the means necessary to petition the government for redress.

For these reasons, Garcia has shown a likelihood of success on, the merits of Claim Two.

3. Claim Three: Defendants' deliberate actions in hiding information regarding the source of the pentobarbital that they intend to use to execute Garcia denies him of his federal rights to due process and meaningful access to the court, in violation of the Fourteenth Amendment.

The Fourteenth Amendment prohibits a state from depriving “any person of life, liberty, or property, without due process of law.” U.S. Const. amend XIV. 214. “The fundamental requisite of due process of law is the opportunity to be heard.” *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950) (citations omitted). Consistent with the opportunity to be heard is the “constitutional right of access to the courts.” *See Bounds v. Smith*, 430 U.S. 817, 821 (1977). The “right of access to the courts . . . is founded in the Due Process Clause.” *Wolff v. McDonnell*, 418 U.S. 539, 579 (1974).

Garcia has a liberty interest in assuring that his execution is carried out in a manner consistent with the Eighth Amendment. Defendants cannot hide information that Garcia has a constitutional right to obtain. *See Claim Two, supra*. By denying his legitimate and reasonable request for information regarding the drug to be used in his execution, Defendants have actively prevented Garcia from being able to determine the ways in which Defendants will violate his Eighth Amendment right to be free from cruel and unusual punishment during his execution.

Under *Baze v. Rees*, an execution will violate the constitution where a prisoner can show that there is “a ‘substantial risk of serious harm,’ an ‘objectively intolerable

risk of harm’ that prevents prison officials from pleading that they were ‘subjectively blameless for purposes of the Eighth Amendment.’” 553 U.S. 35, 50 (2008) (quoting *Farmer v. Brennan*, 511 U.S. 825, 842, 846, and n.9 (1994)). “[S]ubjecting individuals to a risk of future harm—not simply actually inflicting pain—can qualify as cruel and unusual punishment.” *Baze*, 553 U.S. at 49. Garcia recognizes that his burden under the *Baze* standard is high.

But Defendants’ failure to provide Garcia with the requested information regarding the drug TDCJ intends to use in his scheduled execution has created an insurmountable barrier to filing and successfully prosecuting an Eighth Amendment claim. “[W]here governmental action seriously injures an individual, and the reasonableness of the action depends on fact findings, the evidence used to prove the Government’s case must be disclosed to the individual so that he has an opportunity to show that it is untrue.” *Greene v. McElroy*, 360 U.S. 474, 496 (1959).

The information that Defendants have refused to disclose is critical to an assessment of the ways in which Garcia’s execution will violate his constitutional rights. That refusal is at odds with the “the concepts of dignity, civilized standards, humanity, and decency that animate the Eighth Amendment.” *Hudson v. McMillian*, 503 U.S. 1, 11 (1992) (quoting *Estelle v. Gamble*, 429 U.S. 97, 102 (1976)) (internal quotation marks omitted). By deliberately concealing such information from Garcia, Defendants have actively prevented him from successfully vindicating his Eighth

Amendment rights. Therefore, Defendants' actions have violated Garcia's rights to due process and access to the courts.

For these reasons, Garcia has shown a likelihood of success on the merits of Claim Three.

4. Claim Four: Defendants' actions violate Garcia's right to Equal Protection under the law, pursuant to the Fourteenth Amendment.

Under the Equal Protection Clause, the government cannot make distinctions, which either burden a fundamental right, target a suspect class, or intentionally treat one person differently from others similarly situated without any rational basis for the difference. *See Vacco v. Quill*, 521 U.S. 793, 799 (1997); *Village of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000) (per curiam).

The fundamental rights are those rights from the Bill of Rights incorporated into the Fourteenth Amendment Due Process Clause, which includes the Eighth Amendment protection against cruel and unusual punishment. *McDonald v. Chicago*, 561 U.S. 742, 764 n.12 (2010). When the disparate treatment burdens a fundamental right, strict scrutiny applies. *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1 (1973).

Here, Defendants' failure to test the pentobarbital compounded for Garcia's execution and provide him with the results, is, given their testing of previous supplies, *Whitaker v. Livingston*, No. H-13-2901, 2016 WL 3199532, at *3 (S.D.

Tex. June 6, 2016), disparate treatment that burdens Garcia’s fundamental Eighth and Fourteenth Amendment rights, putting him at substantial risk for serious harm. The failure to test also has no rational basis, since Defendants have shown such testing can readily and easily be performed. *Id.*

Here, Defendants have no rational basis for using pentobarbital compounded by Greenpark—as opposed other pharmacies—in Garcia’s execution. Defendants’ use of pentobarbital compounded by Greenpark to execute Garcia constitutes disparate treatment and subjects Garcia to substantial risk of serious harm.

Similarly, Defendants’ deviation from the dose of pentobarbital required by Defendants’ execution procedure, *see* Section I.E, *supra*, violates the Due Process and Equal Protection Clauses of the Fourteenth Amendment. Those clauses protect a prisoner’s right to a state’s consistent and non-arbitrary application of and adherence to its own announced procedures where those procedures concern a fundamental interest. *See, e.g., Dist. Attorney’s Office v. Osborne*, 557 U.S. 52, 68 (2009); *Bush v. Gore*, 531 U.S. 98, 103 (2000); *Ohio Adult Parole Auth. v. Woodard*, 523 U.S. 272 (1998).

For these reasons, Garcia has shown a likelihood of success on the merits of Claim Four.

B. Without a preliminary injunction, Garcia will suffer concrete, irreparable harm. The harm is not “mere speculation.”

If the Court denies Garcia’s request for a preliminary injunction, he will be

executed without having the opportunity to vindicate his constitutional rights. First, in violation of his First Amendment rights, he will be unable to exercise his right-of-access to the courts to vindicate his Eighth Amendment right to be executed in a manner free from cruel and unusual punishment, and he will be executed without having had the opportunity to participate in the robust discussion about the death penalty. Second, he will be executed in a manner that arbitrarily treats him differently than similarly situated prisoners, in violation of his Fourteenth Amendment rights. That harm is irreparable—there is not only “no adequate remedy at law, such as monetary damages[,]” *Alguire*, 647 F.3d at 600, but there is no remedy at all for a person whose life has been extinguished. This harm is a harm in fact; it is more than a “speculative injury.” *Alguire*, 647 F.3d at 600 (noting that “a showing of ‘[s]peculative injury is not sufficient; there must be more than an unfounded fear on the part of the applicant.’”) (quoting *Productos Carnic, S.A. v. Cent. Amer. Beef & Seafood Trading Co.*, 6221 F.2d 683-686-87 (5th Cir. 1980) (internal quotation marks and citations omitted) (alteration in original)); *id.* at 601 (“The party seeking a preliminary injunction must also show that the threatened harm is more than mere speculation.”).

C. The grant of preliminary injunction will not disserve the public interest—indeed, the public has an interest in an execution that comports with the Constitution.

The “balance of harms and service of the public interest[,]” *Alguire*, 647 F.3d at

601, tip sharply in Garcia's favor. Garcia is not seeking an injunction that would forever prevent the State from carrying out his execution. Instead, he seeks only to ensure that his execution comports with the Eighth Amendment, and that it does so without violating his First and Fourteenth Amendment rights as well. *See, e.g., Gomez v. U.S. Dist. Ct. for N. Dist. Cal.*, 966 F.2d 460, 462 (9th Cir. 1992) (Noonan, J., dissenting from grant of writ of mandate) ("The state will get its man in the end. In contrast, if persons are put to death in a manner that is determined to be cruel, they suffer injury that can never be undone, and the Constitution suffers an injury that can never be repaired.").

This Court should not permit Defendants to execute Garcia before he has an opportunity to litigate his constitutional claims. The balance of harms and the service of the public interest favor this Court's grant of a preliminary injunction preventing Defendants from executing Garcia in an unconstitutional manner.

III. This Court has the authority to grant a stay of execution, and should do so. Garcia has not delayed unnecessarily in bringing his claim; accordingly, he is entitled to a stay of his execution.

This Court has the authority to grant a prisoner a stay of execution in order that the Court can hear a prisoner's constitutional claims, provided that the prisoner did not unreasonably delay before asking the Court for a stay. Garcia did not unreasonably delay, and a stay is necessary in order to allow the Court the time to hear his constitutional claims.

But before granting injunctive relief that would prevent an execution, the Court must “consider not only the likelihood of success on the merits and the relative harms to the parties, but also the extent to which the inmate has delayed unnecessarily in bringing the claim.” *Nelson v. Campbell*, 541 U.S. 637, 649 (2004).

Garcia did not delay in filing his Complaint. Until the afternoon of Wednesday, November 28, 2018, he was unaware of the source of Texas’s pentobarbital; he was consequently also unaware of the safety violations for which that source has been repeatedly cited. Within two days of learning this information, he filed this lawsuit.

Accordingly, because this Court has the authority to issue a stay, and because Garcia has met the requirements for obtaining one, this Court should stay his execution and allow him to litigate the claims in his Complaint.

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IV. Conclusion

For the reasons outlined in this Memorandum, this Court should find that Garcia has met the requirements for securing a preliminary injunction, and should grant:

- (1) Temporary, preliminary, and permanent injunctive relief to enjoin the defendants, their officers, agents, servants, employees, and all persons acting in concert with them from executing Garcia with compounded Pentobarbital from Greenpark or any other compounding pharmacy with substandard sanitation practices cited by state or federal regulators;
- (2) A declaratory judgment that TDCJ's current plan to execute Garcia by using compounded pentobarbital from Greenpark violates his rights under the Eighth Amendment of the United States Constitution, that TDCJ's failure to provide Garcia adequate notice regarding the acquisition of the compounded pentobarbital it intends to use in his execution violates his rights under the Due Process clause of the Fourteenth Amendment, the Equal Protection Clause of the Fourteenth Amendment, and the First Amendment, that the State's failure to provide Garcia with the equal treatment under the law violates the Equal Protection Clause of the Fourteenth Amendment, and that TDCJ's administration of compounded pentobarbital from Greenpark demonstrates deliberate indifference to Garcia's right to be free from cruel and unusual punishment;
- (3) Temporary, preliminary, and permanent injunctive relief to enjoin the Defendants, their officers, agents, servants, employees, and all persons acting in concert with them from concealing information that is not related to the identification of persons participating in execution, that is necessary to ensuring Garcia's Eighth Amendment right to be free from cruel and unusual punishment, Fourteenth Amendment right to equal protection of the laws, First Amendment rights to petition the government for redress of grievances and to access government proceedings, and his Fourteenth Amendment right to due process;
- (4) A stay of Garcia's execution;
- (5) Appropriate and necessary discovery and an evidentiary hearing to allow Garcia to prove his constitutional claims;
- (6) Costs of the suit; and

- (7) Any such other relief as the Court deems necessary and proper.

Respectfully submitted this 30th day of November, 2018.

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CERTIFICATE OF SERVICE

I certify that on November 30, 2018 a true and correct copy of the above pleading was served upon Mr. Clendenin as he has agreed to accept electronic service on behalf of all Defendants.

Bryan Collier, Executive Director
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