APPENDIX A

Order and Opinion in the United States Court of Appeals for the Fifth Circuit

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 18-70032

United States Court of Appeals
Fifth Circuit
FILED
December 2, 2018
Lyle W. Cayce
Clerk

JOSEPH C. GARCIA,

Plaintiff - Appellant

v.

BRYAN COLLIER; LORIE DAVIS; JAMES L JONES; JOHN OR JANE DOES, 1-50,

Defendants - Appellees

Appeal from the United States District Court
for the Southern District of Texas
USDC No. 4:18-CV-4521

Before DENNIS, ELROD, and HIGGINSON, Circuit Judges.

PER CURIAM:*

Death row inmate Joseph C. Garcia filed this 42 U.S.C. § 1983 action on November 30, 2018, seeking to stay his execution scheduled for December 4, 2018. Garcia alleges that the drug the Texas Department of Criminal Justice (TDCJ) will use in his execution—compounded pentobarbital—was obtained from an unsafe pharmacy, and that executing him using the drug obtained from this pharmacy would violate his Eighth and Fourteenth Amendment

* Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

rights. Garcia's complaint asserts four claims related to the use of compounded pentobarbital allegedly obtained from a pharmacy in Houston that has been cited for violations of state and federal regulations: (1) that the TDCJ's use of pentobarbital from an unsafe pharmacy violates his Eighth Amendment right to be free from cruel and unusual punishment; (2) that TDCJ violated his First Amendment "right to be informed about the manner in which the State implements" executions by concealing necessary information; (3) that this alleged concealment by TDCJ also violates his rights to due process and access to the courts; and (4) that the TDCJ's use of pentobarbital from other pharmacies on other death row inmates violates his right to equal protection.

The district court denied injunctive relief and declined to stay Garcia's execution, finding that none of his claims demonstrated a likelihood of success on the merits. It first concluded that Garcia's Eighth Amendment claim was merely hypothetical because he did not cite to evidence establishing that the pentobarbital "carrie[d] a demonstrated risk of causing severe pain." Regarding Garcia's allegations about TDCJ's concealment of information, the district court held that both his First Amendment access to courts and Fourteenth Amendment due process claims failed because they were "dependent on the existence of a valid underlying Eighth Amendment claim." Finally, the court concluded that Garcia's equal protection claim was unlikely to succeed on the merits because (1) "using pentobarbital obtained from a compounding pharmacy does not implicate the Eighth Amendment"; and (2) Garcia had not established that the drug obtained from the identified pharmacy carried an unconstitutional risk not present in other pharmacies' versions of the drug. Accordingly, he had not demonstrated that he was subject to disparate treatment in violation of the Fourteenth Amendment. For essentially the reasons stated by the district court, with which we agree, we are not persuaded of the likelihood of Garcia's success on the merits. We

therefore AFFIRM the district court's denial of Garcia's motion for a preliminary injunction and DENY his motion for stay of execution.

APPENDIX B

Memorandum and Order in the
United States District Court for the
District of Arizona

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

JOSEPH C. GARCIA,	§	
	§	
Plaintiff,	§	
	§	
V.	§	CIVIL ACTION H-18-4521
	§	
BRYAN COLLIER, *et al*.,	§	
	§	
Defendants.	§	

MEMORANDUM AND ORDER

Plaintiff Joseph C. Garcia is a Texas death row inmate. The defendants are officials, employees, and agents of the Texas Department of Criminal Justice ("TDCJ"). Garcia is scheduled for execution on December 4, 2018.

On Friday night November 30, 2018, Garcia filed a complaint under 42 U.S.C. § 1983 alleging that his upcoming execution violates his rights under the First, Eighth and Fourteenth Amendments. He seeks a preliminary injunction staying his execution to allow him time to fully litigate his claims. For the following reasons, Garcia's motion for a preliminary injunction is denied.

I. Background

Garcia alleges that the State of Texas intends to execute him using the drug pentobarbitol that it obtained from a compounding pharmacy in Houston. He alleges that this pharmacy has been "repeatedly cited for dangerous practices" by regulators. Garcia contends that:

(1) the use of drugs from this pharmacy constitutes deliberate indifference to his right to be free from cruel and unusual punishment;

(2) TDCJ's secrecy regarding the source of its execution drugs violates his First Amendment right to be informed about the manner in which he will be executed;

(3) TDCJ's secrecy violates his rights to due process and meaningful access to the courts; and

(4) the defendants' alleged actions violate his right to equal protection of the law.

He seeks declaratory and injunctive relief, including a preliminary injunction staying his execution.

II. Analysis

A. The Preliminary Injunction Standard

There are four prerequisites for the extraordinary relief of a preliminary injunction. A court may grant a preliminary injunction only when the movant establishes that: (1) there is a substantial likelihood that the movant will prevail on the merits; (2) there is a substantial threat that irreparable harm will result if the injunction is not granted; (3) the threatened injury [to the movant] outweighs the threatened harm to the defendant; and (4) the granting of the preliminary injunction will not disserve the public interest. *Clark v. Prichard,* 812 F.2d 991, 993 (5th Cir.1987) (citing *Canal Auth. of the State of Florida v. Callaway,* 489

F.2d 567, 572 (5th Cir.1974) (en banc)). The party seeking injunctive relief must prove each of the four elements before a preliminary injunction can be granted. *Mississippi Power & Light Co. v. United Gas Pipeline,* 760 F.2d 618, 621 (5th Cir.1985); *Clark,* 812 F.2d at 993.

Because a preliminary injunction is considered an "extraordinary and drastic remedy," it is not granted routinely, "but only when the movant, by a clear showing, carries the burden of persuasion." *Holland Am. Ins. Co. v. Succession of Roy,* 777 F.2d 992, 997 (5th Cir.1985). The decision to grant or deny preliminary injunctive relief is left to the sound discretion of the district court. *Mississippi Power & Light Co.,* 760 F.2d at 621. Even when a movant establishes each of the four *Canal* requirements, the decision whether to grant or deny a preliminary injunction remains discretionary with the court, and the decision to grant a preliminary injunction is treated as the exception rather than the rule. *Mississippi Power & Light,* 760 F.2d at 621. The same standards apply to stay requests. *See*, *e.g.*, *Nken v. Holder*, 556 U.S. 418, 434 (2009).

B. Likelihood of Success on the Merits

1. Deliberate Indifference

Garcia argues that the use of pentobarbitol from this particular compounding pharmacy demonstrates deliberate indifference to a risk that he will suffer serious pain because of the pharmacy's alleged record of safety violations. "Deliberate indifference" is more than mere negligence, *Estelle v. Gamble*, 429 U.S. 97, 104-06 (1976), but "something less than acts or omissions for the very purpose of causing harm or with knowledge that harm

will result." *Farmer v. Brennan*, 511 U.S. 825, 835 (1994). Rather, deliberate indifference requires that the defendants be subjectively aware of a substantial risk of serious harm to the inmate and recklessly disregard that risk. *Id.* at 829, 836.

To prevail, Garcia must demonstrate 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.'" *Baze v. Rees*, 553 U.S. 35, 50 (2008) (quoting *Farmer,* 511 U.S. at 842, 846, and n. 9). "Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of "objectively intolerable risk of harm" that qualifies as cruel and unusual." *Baze*, 553 U.S. at 50.

Garcia acknowledges in his complaint that TDCJ has been purchasing pentobarbitol from this pharmacy for approximately three and a half years. Garcia does not give an exact date when TDCJ began purchasing from this pharmacy, but Texas has executed 32 inmates in the 42 months immediately preceding Garcia's scheduled execution. *See* www.tdcj.state.tx.us/death_row/dr_executed_offenders.html. Garcia's only evidence that the drug might cause pain is an article from Buzzfeed News quoting inmates as stating that they experienced a burning sensation when the pentobarbitol was administered. Motion for Preliminary Injunction (Docket Entry 4), Exh. C.

At most, Garcia points to anecdotal evidence that some inmates experienced some pain during their executions. The Constitution, however, does not require a pain free

execution. *See, e.g.*, *In re Ohio Execution Protocol*, 860 F.3d 881, 890 (6th Cir. 2017); *Bible v. Davis*, No. 4:18-CV-1893, 2018 WL 3068804, at *8 (S.D. Tex. June 21, 2018), *aff'd*, 739 F. App'x 766 (5th Cir. 2018). The absence of evidence that inmates suffered an unconstitutionally excessive level of pain in the nearly three dozen executions carried out by Texas during the time it has allegedly purchased pentobarbitol from this pharmacy establishes that the defendants are not disregarding a serious risk that the drug will cause Garcia undue suffering, but merely a hypothetical risk that it will do so.

The hypothetical nature of Garcia's claims is highlighted by his lack of argument that the burning sensation identified in the Buzzfeed article is unconstitutional. Instead, Garcia speculates that tainted or improperly formulated pentibarbitol could cause the formation of precipitate which could cause blood vessels to rupture and hemorrhage into the lungs. *See* Motion for Preliminary Injunction at 21-22. He cites no evidence that this has happened in any of the 32 executions carried out since TDCJ allegedly began purchasing drugs from this pharmacy.

Moreover, to successfully challenge Texas' method of execution, Garcia must show not only that the use of the compounded pentobarbitol carries a demonstrated risk of causing severe pain, he must also show that the risk is substantial when compared to the known and available alternatives. *Glossip v. Gross*, 135 S.Ct. 2726, 2737 (2015). As noted above, Garcia does not show that the use of the compounded pentobarbitol from this pharmacy carries a demonstrated risk of severe pain. His only attempt to identify an alternative is his

conclusory allegation that Texas can source the drug from another pharmacy. He does not, however, identify any other pharmacy willing and able to provide execution drugs to TDCJ. Thus, while Garcia identifies a known alternative drug, he does not identify an available one. He is unlikely to succeed on the merits of this claim.

2. Secrecy

Garcia next argues that TDCJ's secrecy regarding the source of pentobarbitol violates his First Amendment right to be informed about the manner of his execution, and his right to due process and meaningful access to the courts. Prisoners have a First Amendment right of access to the courts. *Bounds v. Smith*, 430 U.S. 817, 822 (1977). Garcia complains that secrecy regarding the source of the pentobarbitol that will be used to execute him violates this right by making it difficult for him to learn exactly how he will be executed, and to litigate claims relating to his execution.

To prevail on his access to the courts claim, Garcia must "show a potential Eighth Amendment violation. One is not entitled to access to the courts merely to argue that there might be some remote possibility of some constitutional violation." *Whitaker v. Livingston*, 732 F.3d 465, 467 (5th Cir. 2013). As noted above, Garcia has failed to demonstrate anything more than a hypothetical possibility of an Eighth Amendment violation. He therefore fails to satisfy a necessary precondition of his access to the courts claim, and is unlikely to succeed on the merits of that claim.

Garcia's claim that he has either a due process or First Amendment right to highly specific information about the drug's manufacturing process is also dependent on the existence of a valid underlying Eighth Amendment claim.

> Even if the Fourteenth Amendment sometimes protects liberty interests not explicitly enumerated in the Constitution, we know of no case, in the context of executions, in which the Supreme Court has found a liberty interest to exist, based on the contours of the Eighth Amendment, that goes beyond what that Amendment itself protects.

Id. Therefore, Garcia is unlikely to prevail on his claims related to TDCJ's alleged secrecy regarding the source of the execution drug.

3. Equal Protection

Finally, Garcia argues that the use of pentobarbitol from this particular compounding pharmacy violates his right to equal protection because other condemned inmates were executed with drugs obtained from pharmacies that did not have the record of regulatory violations alleged here. He contends that this constitutes disparate treatment in violation of the Fourteenth Amendment.

It is beyond dispute that pentobarbitol is routinely used in executions, and that such use is constitutional. *See*, *e.g.*, *Whitaker v. Collier*, 862 F.3d 490, 499 (5th Cir. 2017); *Raby v. Livingston*, 600 F.3d 552, 555-56 (5th Cir. 2010). Moreover, using pentobarbitol obtained from a compounding pharmacy does not implicate the Eighth Amendment. *Whitaker*, 862 F.3d at 498-99. Garcia's disparate treatment claim thus rests on his contention that the drug

obtained from *this* pharmacy carries an unconstitutional risk of causing undue pain that would not be present if TDCJ used pentobarbitol obtained from another pharmacy. However, as discussed above, that claim is entirely speculative. Garcia thus fails to demonstrate that he is subject to disparate treatment, and is unlikely to succeed on the merits of this claim.

III. Conclusion

Because Garcia is unlikely to succeed on the merits of any of his claims, he is not entitled to a preliminary injunction or a stay of execution.

IV. Order

Garcia's motion for a preliminary injunction (Docket Entry 4) is **Denied**.

Signed at Houston, Texas on December 1, 2018.

Gray H. Miller
United States District Judge

APPENDIX C

Plaintiff's Motion for
Preliminary Injunction

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

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

PLANTIFF'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* TDCJ[1] 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/chrismcdaniel/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/ORA/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

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[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 adultered 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 spokeperson 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 undertook 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 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
Lorie Davis, Director
James L. Jones, Senior Warden

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EXHIBIT A

TEXAS DEPARTMENT OF CRIMINAL JUSTICE

CORRECTIONAL INSTITUTIONS DIVISION

EXECUTION PROCEDURE

July 2012

ADOPTION OF EXECUTION PROCEDURE

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

R C Thaler

Rick Thaler
Director, Correctional Institutions Division

7-09-2012

Date

EXECUTION PROCEDURES

PROCEDURES

I. Procedures Upon Notification of Execution Date

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

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

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

II. Stays of Execution

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

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

III. Preparation of the Execution Summary and Packet

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

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

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

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

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

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

6. The Death Row Unit is responsible for completion of the Execution Packet, which shall include:

   a. Execution Summary;

   b. Religious Orientation Statement;

   c. Copy of the Offender Travel Card;

   d. Current Visitation List;

   e. Execution Watch Notification;

   f. Execution Watch Logs;

   g. I-25 Offender's Request for Trust Fund Withdrawal;

   h. Offender Property Documentation (PROP-05 and PROP-08); and

   i. Other documents as necessary.

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

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

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

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

B. The Day of Execution

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. Drug Team Qualifications and Training

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

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

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

V. Pre-execution Procedures

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

B. Inventory and Equipment Check

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

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

3. An inventory and equipment check shall be conducted.

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

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

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

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

F. The CID Director or designee, the Huntsville Unit Warden or designee and the Huntsville Unit Chaplain or a designated approved TDCJ Chaplain shall accompany the offender while in the Execution Chamber.

VI. Set up Preparations for the Lethal Injection

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

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

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

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

VII. Execution Procedures

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

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

C. A medically trained individual shall insert intravenous (IV) catheters into a suitable vein of the condemned person. If a suitable vein cannot be discovered in an arm, the medically trained individual shall substitute a suitable vein in another part of the body, but shall not use a "cut-down" procedure to access a suitable vein. The medically trained individual shall take as much time as is needed to properly insert the IV lines. The medically trained individual shall connect an IV administration set, and start a normal saline solution to flow at a slow rate through one of the lines. The second line is started as a precaution and is used only if a potential problem is identified with the primary line. The CID Director or designee, the Huntsville Unit Warden or designee, and the medically trained individual shall observe the IV to ensure that the rate of flow is uninterrupted.

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

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

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

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

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

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

J. The CID Director or designee and the Huntsville Unit Warden or designee shall observe the appearance of the condemned individual during application of the Pentobarbital. If, after a sufficient time for death to have occurred, the condemned individual exhibits visible signs of life, the CID Director or designee

shall instruct the drug team to administer an additional 5 grams of Pentobarbital followed with a saline flush.

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

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

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

EXHIBIT B

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

JASON MCGEHEE, *et al.*,	§	
Plaintiffs,	§	
	§	**Case No. 4:18-mc-01546**
v.	§	
	§	**Related to E.D. Ark. Case**
TEXAS DEPARTMENT OF	§	**No. 4:17-CV-00179-KGB**
CRIMINAL JUSTICE,	§	
Defendant.	§	

TEXAS DEPARTMENT OF CRIMINAL JUSTICE'S DISPOSITIVE MOTION TO DISMISS PLAINTIFFS' MOTION TO COMPEL COMPLIANCE WITH SUBPOENA

EXHIBIT 4

Declaration of Pharmacy X

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

Jason McGehee, Stacey Johnson, Bruce Ward, Terrick Nooner, and Don Davis, Plaintiffs,	§	Cause No. 04:18mc01546
v.	§	
Texas Department of Criminal Justice, Defendant.	§	

DECLARATION OF PHARMACY X

I, Pharmacy X, declare as follows:

1. I, Pharmacy X, am over the age of 21 and competent to testify in this matter. I have personal knowledge of the facts contained in this declaration.

2. Pharmacy X is a licensed pharmacy located in Texas.

3. Pharmacy X has supplied lethal injection chemicals to the Texas Department of Criminal Justice for use in executions of death row inmates.

4. Pharmacy X's decision to supply the Texas Department of Criminal Justice with lethal injection chemicals was and is contingent on Pharmacy X's identity remaining secret. If Pharmacy X's identity is disclosed or revealed, Pharmacy X will no longer conduct business with the Texas Department of Criminal Justice.

5. Pharmacy X did not and will not supply lethal injection chemicals to any state other than Texas under any circumstances.

6. Pharmacy X reasonably fears that if its identity is disclosed or revealed, anti-death penalty advocates will harass and retaliate against Pharmacy X, resulting in physical and financial harm to Pharmacy X, its owner(s), and its employees.

7. Pharmacy X's fears are based, in part, on documentary evidence of threats, harassment, and boycotts to which other suppliers of lethal injection drugs have been subjected as a result of their lawful decision to supply state correctional departments with drugs needed to carry out executions.

8. I declare under penalty of perjury that the foregoing is true and correct. Executed on June 22, 2018.

Pharmacy X

Pharmacy X

EXHIBIT C

BuzzFeed News

Inmates Said The Drug Burned As They Died. This Is How Texas Gets Its Execution Drugs.

Greenpark Compounding Pharmacy gave kids the wrong medicine. It forged documents. Its employees didn't wash their hands adequately. So why did the state with the most executions hire it to make lethal injection drugs?

By Chris McDaniel
Posted on November 28, 2018, at 5:09 p.m. ET

Greenpark Compounding Pharmacy & Gifts in Houston.

Google

The Texas Department of Criminal Justice, which has carried out more executions than any other state, has for the last three and a half years bought drugs for lethal injections from a pharmacy that regulators have repeatedly cited for dangerous practices.

The source of the state's execution drugs has until now been a closely guarded secret. Texas, like other death penalty states, has a law that prevents the disclosure of that information, making it impossible for the public to learn about the manufacturer's safety record. But documents obtained by BuzzFeed News indicate that one source is Greenpark Compounding Pharmacy in Houston, which has been cited for scores of safety violations in recent years. Its license has been on probation since November 2016, when the Texas State Board of Pharmacy found that it had compounded the wrong drug for three children, sending one to the emergency room, and forged quality control documents.

Questions about the source and quality of Texas's execution drugs have been particularly acute in the past year, since in their final moments of life, five of the 11 inmates who Texas put to death in 2018 said the drug they were injected with, which is supposed to be painless, felt like it was burning as it coursed through their bodies.

"I can feel that it does burn. Burning!" Anthony Shore said, his voice rising, as he died in January. Four months later, Juan Castillo swore and said the drug burned and that he could taste it in his throat. In the next few months, inmates Troy Clark, Christopher Young, and Danny Bible all made similar statements as they were dying. A sixth inmate, William Rayford, writhed and shook on the gurney after the drug began to flow into him.

Two more inmates are scheduled to be executed in coming days: Joseph Garcia on Dec. 4 and Alvin Braziel on Dec. 11.

Texas has faced growing difficulties in securing supplies of lethal drugs in recent years, as manufacturers have become increasingly unwilling to be associated with capital punishment, and the Food and Drug Administration has

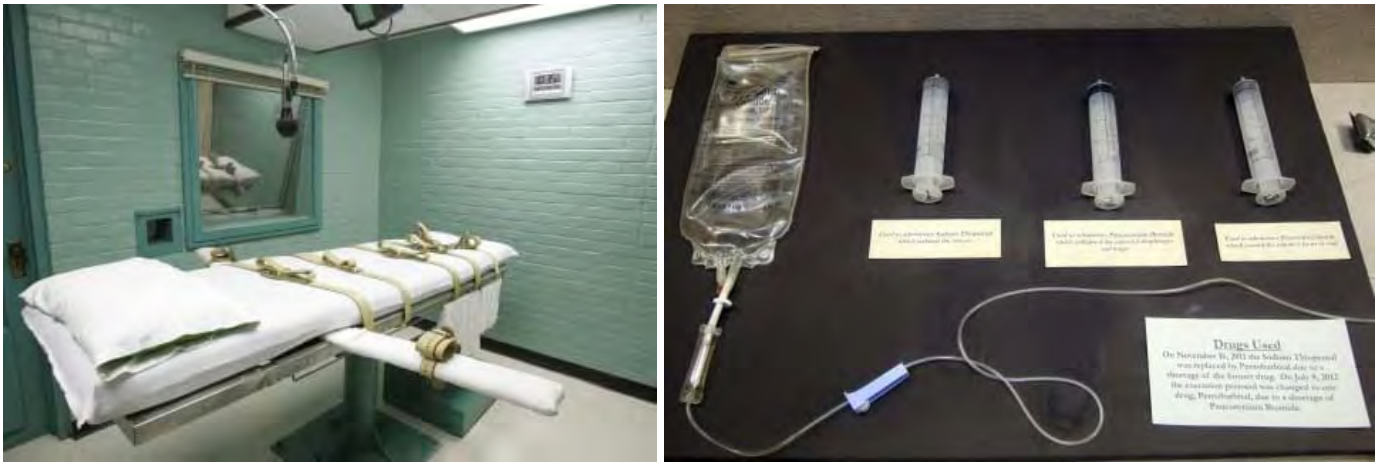
manufacturer of pentobarbital, the substance Texas uses in executions, requires its distributors to sign agreements that they will not sell their drugs to death penalty states. So Texas sought out a compounding pharmacy, which can combine the basic ingredients of known drugs according to a prescription for a specific patient — for example, a child who needs a medicine in a liquid rather than pill form. (The state has also tried importing drugs from a supplier in India, but the FDA seized the shipment.)

Compounding pharmacies are not subject to the same stringent federal standards as large manufacturers, and the products they make have a significantly higher failure rate and shorter shelf life, one measured in days, than conventionally manufactured drugs.

Attorneys for death row inmates have long warned that compounded pentobarbital could expire or degrade over time, putting their clients at risk of a painful death that would amount to torture.

“Improper compounding and testing procedures may leave fine particles undetectable by the naked eye in the solution, or larger particles that would not be detected by an untrained eye,” Dr. David Waisel wrote in a 2016 affidavit. “These particles can cause great irritation to the vein, resulting in extraordinary pain.”

The Texas Department of Criminal Justice has repeatedly dismissed the attorneys’ concerns, calling them “speculation upon speculation.”



Left: The gurney in Huntsville, Texas, where death row inmates are strapped down for lethal injection. Right: An exhibit at the Texas Prison Museum shows the three-chemical mixture used from 1982 until 2012, when it was replaced by a single drug.

Pat Sullivan / AP, Michael Graczyk / AP

In inspections by state regulators, Greenpark has been cited for 48 violations over the past eight years, according to documents obtained by BuzzFeed News. The violations included keeping out-of-date drugs in stock, using improper procedures to prepare IV solutions, and inadequate cleaning of hands and gloves.

Federal documents show that in November 2014, the Texas Department of Criminal Justice obtained, from an unnamed source, enough of the raw ingredient in pentobarbital to be used in hundreds of doses. The documents indicate that over the years, the state has transferred fractions of the ingredient to two compounding pharmacies, which use it to produce pentobarbital. The department first transferred 50 grams of the raw ingredient to Greenpark in April 2015, then again in February 2016. The documents indicate the state has not sent any of the ingredient to any other compounding pharmacy since then.

In a declaration it submitted under a pseudonym in June, Greenpark said it had supplied lethal injection drugs to Texas, and that the relationship "was and is contingent on" the pharmacy's "identity remaining a secret." If its identity became public, Greenpark wrote, it "will no longer conduct business with the Texas Department of Criminal Justice."

ingredient (80 grams of it in August 2015) remains unidentified. It's unclear which pharmacy supplied the compounded drugs for each execution, but over the last three years Texas appears not to have acquired the drugs from any other sources.

BuzzFeed News shared the documents with two pharmaceutical experts who are familiar with such records. The experts confirmed the methodology behind the reporting.

Speaking by phone to BuzzFeed News, Ken Hughes, Greenpark's head pharmacist, said that his pharmacy had performed drug testing for the criminal justice department, but added, "It's none of your business what I do." Asked about the compounding of execution drugs, Hughes repeatedly said, "I don't do it."

When asked if that meant that the pharmacy, which also operates as a gift shop, does not do it currently or if it has never done so, Hughes said that he had two other calls on hold and ended the conversation. He did not respond to repeated follow-up emails or phone calls.

The Texas Department of Criminal Justice declined to comment.

It's unclear how the state selected Greenpark. Of the state's nearly 200 pharmacies that perform this sort of high-risk compounding, Greenpark is one of only eight that currently have their licenses on probation or revoked.

That probation, which is scheduled to expire at the end of this month, was put in place after a pharmacy technician made a mistake in compounding a batch of lansoprazole, a drug that can be used to treat high levels of stomach acid. Instead, the pharmacy gave three children lorazepam, a benzodiazepine similar to Xanax.

The state board found that one of the children had to receive "emergency treatment in a hospital after experiencing adverse effects," and that the pharmacy technician forged quality-control documentation. Without admitting

dispensing errors.

The parents of the child who went to the hospital after taking Greenpark's drugs sued the pharmacy in September 2017. Without admitting liability, the pharmacy settled, agreeing to pay $55,000 toward the child's college saving fund.

The FDA also inspected Greenpark in October 2017, and cited the pharmacy for several potential sterility violations. Greenpark said that it adhered to state pharmaceutical guidelines. Hughes added that the inspection has "given us an opportunity to review our procedures and look for improvements."

The FDA told BuzzFeed News it could not release its full report on Greenpark because doing so "could reasonably be expected to interfere with enforcement proceedings."

Chris McDaniel is an investigative reporter for BuzzFeed News and is based in New York. His secure PGP fingerprint is C90B B2EF E872 EF22 4EDA DABB 50E6 F2BE 1164 FCAF

Contact Chris McDaniel at chris.mcdaniel@buzzfeed.com.

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EXHIBIT D

Kim Stout

From: Dale Baich
Sent: Wednesday, November 28, 2018 7:13 PM
To: Sharon.Howell@tdcj.texas.gov
Cc: jason.clark@tdcj.texas.gov
Subject: Joseph Garcia, No. 999441 (execution date Dec 4, 2018)
Attachments: 2018.11.28 Baich-LDavis - flattened.pdf

Dear Ms. Howell,
Attached is a letter directed to Director Davis regarding Joseph Garcia, No. 999441. Mr. Garcia is scheduled to be executed on Tuesday, December 4. Please bring this matter to the Director's attention as expeditiously as possible.
Thank you for your assistance and courtesy.
Best regards,

Dale A. Baich
Office of the Federal Public Defender for the
District of Arizona, Capital Habeas Unit
602-382-2816 office
602-625-2111 mobile

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit

Jon M. Sands
Federal Public Defender

direct line: 602-382-2816
email: dale_baich@fd.org

November 28, 2018

Lorie Davis
Director, Correctional Institutions Division
Texas Department of Criminal Justice
Huntsville, Texas 77342

Via email transmission to:
TDCJ General Counsel Sharon Howell: Sharon.Howell@tdcj.texas.gov

Dear Director Davis:

I represent Joseph Garcia, No. 999441, and in my capacity as his counsel, I write to ask that the Texas Department of Corrections and Justice provide me with notice of the source from which TDCJ has acquired or intends to acquire the pentobarbital[1] or any related chemical[2] (hereinafter "lethal drugs") that it intends to use in Mr. Garcia's execution, which is scheduled for Tuesday, December 4, 2018. I am making this request because a news story was published today that indicates that TDCJ obtains its pentobarbital from a compounding pharmacy that has been cited by the FDA for multiple safety violations in its compounded products.[3]

Specifically, I request the following information for the pentobarbital that TDCJ has in its possession or will order for use in Mr. Garcia's execution, whether or not those drugs were originally ordered for use in his execution.

---

[1] If TDCJ intends to use a drug other than, or in addition to, pentobarbital, please make the same disclosures for that drug(s) that I request for pentobarbital.
[2] *E.g.*, any API (Active Pharmaceutical Ingredient) or other substance necessary to make pentobarbital or any other substances TDCJ will use or intends to use in the execution of Joseph Garcia.
[3] Chris McDaniel, "Inmates Said The Drug Burned As They Died. This Is How Texas Gets Its Execution Drugs." Buzzfeed, Nov. 28. 2018, https://www.buzzfeednews.com/article/chrismcdaniel/inmates-said-the-drug-burned-as-they-died-this-is-how-texas?utm_term=.pkxy4410jP#.pkxy4410jP

1. If TDCJ ordered or will order the drug or chemicals from a supplier, please provide a copy of the order forms used. The physician's name and DEA registration number may be redacted. All other information must be legible, including-but not limited to-the date that the order was placed, the quantity ordered, the name of the supplier, the address to which the order was shipped, and the date that TDCJ received the order.

2. If TDCJ obtained or will obtain the drugs or chemicals via a prescription, please provide a copy of each prescription for each drug or chemical. The physician's name and DEA registration number may be redacted. All other information must be legible, including-but not limited to-the superscription (including the date that the prescription was issued), the inscription, the subscription, the signatura, and any refill information. If the prescriptions were filled from presigned order sheets, please provide a copy of those documents as well.

3. If TDCJ obtained or will obtain the drugs or chemicals by some means other than ordering through a supplier or through a prescription, please provide all documentation pertaining to that manner of acquisition. The physician's name and DEA registration number may be redacted. All other information must be legible, including-but not limited to-the date the drugs or chemicals were ordered and acquired, the source that provided the drugs or chemicals, and the legal authorization by which the source was permitted to transfer the drugs or chemicals to you. This request encompasses, but is not limited to, letters requesting or authorizing transfer of the drugs or chemicals; and all logs pertaining to the issue, including drug logs, property logs, and chain-of-custody logs.

4. A copy of the prescription label from each drug or chemical obtained or already possessed by TDCJ. The physician's name and DEA registration number may be redacted. All other information must be legible, including-but not limited to-the date the prescription was originally filled, the original number of refills, the date the prescription was last refilled, the number of refills remaining, and the prescription number.

5. A copy of all drug logs pertaining to each drug or chemical. Physicians' names and DEA numbers may be redacted. Additionally, the names of persons for whom the drugs or chemicals were used may also be redacted. However, all other information must be legible, including-but not limited to-the dates on which any of the drugs or chemicals were used; the amount remaining of the

drug or chemical after each use; and the purpose for which the drug or chemical was used.

6. A copy of the package label, including the lot number and expiration date, for each drug or chemical obtained or already possessed by TDCJ. If the lot number or expiration date does not appear on the package label, please also provide a copy of that information from the appropriate location on the package. All information must be legible.

7. All chain-of-custody information for each drug or chemical obtained or already possessed by TDCJ, from the time the drug or chemical was dispensed, to the current time. This information should include all details pertaining to person-to-person transfer of the drugs (the names of involved individuals may be redacted); the date and time any transfers were made; the time in possession by each individual who handled the drug or chemical; the manner in which the individual(s) transported the drug or chemical (e.g., via automobile, airplane, etc.); and the amount of time each drug or chemical spent in transport.

8. All information about the storage of each drug or chemical obtained or already possessed by TDCJ, *from the time of dispensing to the current time.* This information must include the storage location; the storage temperature; and the means by which the storage temperature was ensured, maintained, determined, and recorded. All information must be legible.

9. If any of the drugs or chemicals have already been mixed or otherwise prepared, provide the date and means of preparation, and provide the same storage information for the prepared dose(s) as listed above, #8.

10. All information relating to testing by any facility of the API and finished drug products.

This request is ongoing. As you receive information relevant to this request, please provide it to me immediately via email at dale_baich@fd.org.

Given the documentation in the media relating to the problems with the pharmacy identified as the business that supplies TDCJ with execution drugs, I am requesting this information so I can advise Mr. Garcia of the status of relevant facts pertaining to the manner and means by which his execution will take place.

Mr. Garcia has a due-process right to be informed about the manner and means by which his execution will take place. *See Oken v. Sizer,* 321 F. Supp. 2d 658, 665 & n.5 (D. Md. 2004) (requiring production of execution protocol and stating. "[d]ue process requires . . . an opportunity to receive notice of how one's rights will be affected and opportunity to respond and be heard."), *stay vacated,* 542 U.S. 916 (2004).

Mr. Garcia has the right to know whether and how TDCJ has obtained the proper chemicals so that he may determine how his rights will be affected, and may seek the appropriate opportunity to respond and be heard. Due to the immediacy of Mr. Garcia's execution, I ask that you respond as quickly as possible.

Sincerely,

Dale A. Baich
Attorney Supervisor
Capital Habeas Unit

DAB/kls

cc: Jason Clark, Chief of Staff, Jason.Clark@tdcj.texas.gov

EXHIBIT E

AGREED BOARD ORDER #H-16-006-B

RE: IN THE MATTER OF GREENPARK COMPOUNDING PHARMACY (PHARMACY LICENSE #14713)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 14713 issued to Greenpark Compounding Pharmacy (Respondent), 4061 F Bellaire Boulevard, Houston, Texas 77025.

By letter dated August 17, 2016, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Sections 565.001(a)(1), (2), (12) and (13); 565.002(a)(3) and (6); and 568.003(a)(1), (7) and (10) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015);
>
> Sections 281.7(a)(12), (13) and (29)(A); 281.8(b)(4)(A); 281.9(b)(3); 291.31(1), (15), (16) and (17); 291.32(c)(1)(E) and (F); 291.32(c)(2)(D); 291.131(b)(3); 291.131(c)(2)(B) and (C); 291.131(c)(3)(C); 291.131(d)(8)(E); 291.131(d)(9)(B); 291.131(e)(2)(B)(ii)(VIII); and 295.3(b) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015); and
>
> Sections 431.021(a), (b) and (r); and 431.112(a)(1) of the Texas Food, Drug, and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. (2015), in that allegedly:

COUNTS

On or about September 4, 2015, a pharmacist of Greenpark Compounding Pharmacy, 4061 F Bellaire Boulevard, Houston, Texas 77025, failed to verify or incorrectly verified the correct identity of an ingredient used in compounding a batch preparation, in that lorazepam was used in the preparation of a compounded batch preparation calling for lansoprazole. The compounded batch preparation was assigned lot number 09042015@20, and was labeled 480 ml lansoprazole 3mg/ml suspension. Subsequently, three pediatric patients were dispensed prescriptions from the batch preparation, as follows:

(1) On or about September 8, 2015, the pharmacy dispensed 40 ml of the preparation to patient J.N. The prescription bottle was labeled lansoprazole 3mg/ml suspension with directions to "take 1ml (3mg) by mouth every day." The prescription was assigned prescription number 249233.

(2) On or about September 8, 2015, the pharmacy dispensed 140 ml of the preparation to patient S.B. The prescription bottle was labeled lansoprazole 3mg/ml suspension with directions to "take 2.5 ml (7.5 mg) by mouth every day for 8 weeks." The prescription was assigned prescription number 249234.

(3) On or about September 10, 2015, the pharmacy dispensed 300 ml of the preparation to patient S.P. The prescription bottle was labeled 300 ml lansoprazole 3mg/ml suspension with directions to "give 2.5 ml (7.5 mg) by mouth every day." Patient S.P. was given the medication and received emergency treatment in a hospital after experiencing adverse effects, including drowsiness, lack of coordination and irritability. The prescription was assigned prescription number 246935.

On or about September 16, 2015, two samples of the compounded preparation were analyzed, and the results indicated that the samples contained lorazepam (measured at 2.38 mg/ml and 1.28 mg/ml) and did not contain lansoprazole.

(4) On or about September 4, 2015, Cindy Lee Rodriguez, while acting as an employee (pharmacy technician) of Greenpark Compounding Pharmacy, 4061 F Bellaire Boulevard, Houston, Texas 77025, failed to keep and maintain complete and accurate compounding records for lot number 09042015@20 previously described. Specifically, Ms. Rodriguez forged the initials "R.P.," indicating Ranjeet Patel, a pharmacy technician, on the compounding preparation worksheet as having performed in process checks, when Mr. Patel did not do so.

An informal conference was held in the Board's office on October 4, 2016, with Kenneth Lee Hughes, R.Ph., Pharmacist-in-Charge and President of Prescription Labs, Inc., on behalf of Respondent; and Michele Quattlebaum, Legal Counsel for Respondent, in attendance. The informal conference was heard by a Board panel comprised of: Jenny Downing Yoakum, R.Ph., Board Member; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin Arnold, General Counsel. Megan Holloway, Staff Attorney, was also in attendance.

By appearing at the informal conference and by signing this Order, Kenneth Lee Hughes, and Respondent's counsel neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent's license shall be placed on probation for a period of two (2) years, with such period to commence thirty (30) days after the entry of this Order. During the period of probation, Respondent shall abide by the terms of this Order, and shall not violate any pharmacy or drug statute or rule of this state, another state, or the United States with respect to pharmacy, controlled substances, and dangerous drugs.

(2) Respondent shall pay a probation fee of one thousand two hundred dollars ($1,200) due one hundred twenty (120) days after the entry of this Order.

(3) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(4) Respondent shall develop and implement policies and procedures for a Continuous Quality Improvement Program for purposes of preventing and handling dispensing errors. The Continuous Quality Improvement Program shall include pharmacist peer review in compliance with guidelines approved by Board staff. In addition, the policies and procedures for pharmacist peer review shall state that:

(a) The peer review committee will:

- review incident reports;
- determine what caused errors;
- make recommendations to correct the problem that caused the errors; and
- monitor the changes to determine if the changes have improved the operation of Respondent and reduced errors.

(b) The peer review committee must be comprised of at least two employees of Respondent, including the pharmacist-in-charge and other pharmacist(s) or personnel who are employees of Respondent. The committee shall not be solely comprised of a district or regional manager/supervisor and the pharmacist-in-charge and shall not be used for personnel evaluation purposes.

(c) The peer review committee will meet regularly, and no less than quarterly.

(d) The peer review committee will make a record indicating:

- date of meeting
- location of meeting;
- names of persons attending the meeting;
- description of activities;
- discussion of problems in Respondent's operation (e.g., work flow, dispensing process);
- findings;

- description of recommendations; and
- review of actions or changes relating to individuals, systems, or processes made as a result of previous recommendations.

(5) Respondent shall submit a report and/or documentation of such policies and procedures to Board staff within one hundred twenty (120) days after the entry of this Order. Copies of forms used by Respondent to collect the data on errors committed at the pharmacy (i.e., incident report forms) must be submitted to Board staff, as well as any other peer review forms that have been developed by Respondent. Additionally, records of the peer review committee, as described in subparagraph (d) above, shall be maintained for two (2) years at the location of Respondent and made available for inspection by Board employees.

(6) Respondent shall be responsible for all costs relating to compliance with the requirements of this Order.

(7) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(8) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2015), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2016).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 1st day of November, 2016.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Kenneth Lee Hughes, R.Ph., President of Prescription Labs, Inc.
For and on behalf of Greenpark Compounding Pharmacy

Michele Quattlebaum, Legal Counsel for Greenpark Compounding Pharmacy
Spratt Newsom Law Firm
2211 Norfolk, Suite 1150
Houston, Texas 77098

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

EXHIBIT F

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3943
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14713
Name of Facility Greenpark Compounding Pharmacy
Address 4061 F. Bellaire Blvd City Houston Zip 77025
Pharmacist License # 22586
NAME OF PERSON RESPONSIBLE Kenneth Lee Hughes

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.133(d)(14)(A)(iii)(III)
Explanation of violation Conduct and document filter integrity tests on all filters used to sterilize high risk or batch preparations. (de 87)

2. Law/Rule 291.133(d)(6)(B)(ii)
Explanation of violation Re-sterilization procedures for high risk sterile compounding must be completed in no worse than an ISO 8 environment. Hood last certified in June 2015. (de 239)

3. Law/Rule 291.133(d)(7)(D)(B)
Explanation of violation If the pharmacy prepares a low volume of hazardous preparations & is not located in a negative pressure room - it must employ two tiers of containment (i.e. closed ~~vial system~~ vial transfer system) (de 249)

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before April 27, 2017, disciplinary action may be instituted against your license.

by Kathy A. Salinas
Agent, Texas State Board of Pharmacy
Date 3-27-17

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed [signature]

11/00

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3943
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14713
Name of Facility Greenpark Compounding Pharmacy
Address 4061 F Bellaire Blvd City Houston Zip 77025
Pharmacist License # 22586
NAME OF PERSON RESPONSIBLE Kenneth Lee Hughes

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.133(d)(14)(C)(v)
Explanation of violation Failure to conduct and document results of viable air sampling to be performed at least every 6 months as part of the recertification of facilities and equipment. Conduct and document immediately.

2. Law/Rule
Explanation of violation

3. Law/Rule
Explanation of violation

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before April 27, 2017, disciplinary action may be instituted against your license.

By Kathy A. Salinas
Agent, Texas State Board of Pharmacy
Date 3-27-17

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed

11/00

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3943
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14713
Name of Facility Greenpark Compounding Pharmacy
Address 4061 F Bellaire Blvd City Houston Zip 77025
Pharmacist License # 22586
NAME OF PERSON RESPONSIBLE Kenneth Lee Hughes

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.3(g)(1)(A)(ii)
Explanation of violation Include notification on how to file a complaint with all delivered or mailed prescriptions.

2. Law/Rule 297.6
Explanation of violation Complete and maintain documentation of initial tech. training for all pharm. techs and tech. trainees. (missing Devon M Deese and Caitlin Dooley).

3. Law/Rule 291.34(e)(2)(F)
Explanation of violation The PIC failed to sign the daily log printout for 3 months. PIC must consistently sign on each workday.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before April 27, 2017, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By Kathy A. Salinas
Agent, Texas State Board of Pharmacy
Date 3-27-17

Signed Kenneth Hughes

11/00

EXHIBIT G

Phcy. Lic. # 14713

Expiration Date: 12/31/17

NOTICE OF INSPECTION
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-3942
(512) 305-8000

✓ **Compliance**

___ **Investigation**

Name of Individual	Title	R.Ph. Lic. #	Expires
Sejal Dhaval Parekh	Staff RPh	39095	12-31-17

Name of Facility	Class of Pharmacy License
Greenpark Compounding Pharmacy	A-S

Address		
4061 F Bellaire Blvd		
City/State: Houston, TX	Zip: 77025	Phone #: (713) 432-9855
DEA Registration #: BG3031476	Expiration Date: 9-30-18	Expiration Date
Date: 3-27-17	Time of Entry: 9:15 am	

PURPOSE OF INSPECTION

✓ Routine	___ Pre-Inspection	___ Rank Change
___ New Pharmacy	___ Change of Ownership	___ Reverse Rank Change
___ Complaint	___ Follow-up to Complaint	___ Licensee Request
___ Follow-up to Warning Notice	___ Follow-up to Theft/Loss Report	✓ Sterile Compounding (High Risk)
___ Follow-up to Disciplinary Order	___ Other _____	

ACKNOWLEDGEMENT

This is to acknowledge that Texas State Board of Pharmacy Agent Kathy A. Salinas has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I am the Staff RPh for the above-described facility;
2. I have read this Notice of Inspection and understand its contents and purpose;
3. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
4. I have had the purpose of the entry into the above-described facility by the Board's agent stated to me; and
5. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Sejal Parekh
Signature

Witnesses:

Kathy A. Salinas
Signature

_____
Signature

ENTERED

09/16

TEXAS PHARMACY ACT
(Occupations Code, Subtitle J)

CHAPTER 554. BOARD POWERS AND DUTIES; RULEMAKING AUTHORITY
SUBCHAPTER A. POWERS AND DUTIES

Sec. 554.001. General Powers and Duties of Board.

XXX

(c) The board may:

XXX

(2) inspect a facility licensed under this subtitle for compliance with this subtitle.

XXX

CHAPTER 556. ADMINISTRATIVE INSPECTIONS AND WARRANTS
SUBCHAPTER A. GENERAL PROVISIONS

Sec. 556.001. Definition. In this chapter, "facility" means a place:
(1) for which an application has been made for a pharmacy license under this subtitle;
(2) at which a pharmacy licensed under this subtitle is located;
(3) at which a pharmacy is being operated in violation of this subtitle; or
(4) where the practice of pharmacy occurs.

SUBCHAPTER B. INSPECTIONS

Sec. 556.051. Authorization To Enter and Inspect. The board or a representative of the board may enter and inspect a facility relative to the following:
(1) drug storage and security;
(2) equipment;
(3) components used in compounding, finished and unfinished products, containers, and labeling of any item;
(4) sanitary conditions; or
(5) records, reports, or other documents required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws.

Sec. 556.052. Requirements Before Entry and Inspection.
(a) Before an entry and inspection of the facility, the person authorized to represent the board must:
(1) state the purpose for the inspection; and
(2) present to the owner, pharmacist, or agent in charge of the facility:
(A) appropriate credentials; and
(B) written notice of the authority for the inspection.
(b) If an inspection is required by or is supported by an administrative inspection warrant, the warrant is the notice for purposes of Subsection (a)(2)(B).

Sec. 556.053. Extent of Inspection. Except as otherwise provided in an inspection warrant, the person authorized to represent the board may:
(1) inspect and copy documents, including records or reports, required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws;
(2) inspect, within reasonable limits and in a reasonable manner, a facility's storage, equipment, security, prescription drugs or devices, components used in compounding, finished and unfinished products, or records; or
(3) perform an inventory of any stock of prescription drugs or devices, components used in compounding, or finished and unfinished products in a facility and obtain samples of those substances.

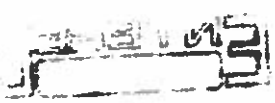
Sec. 556.054. Limitation on Inspection. Unless the owner, pharmacist, or agent in charge of a facility consents in writing, an inspection of the facility authorized by this chapter may not extend to:
(1) financial data;
(2) sales data, other than shipment data; or
(3) pricing data.

XXX

SUBCHAPTER C. WARRANTS

Sec. 556.101. Warrant Not Required. A warrant is not required under this chapter to:
(1) inspect books or records under an administrative subpoena issued under this subtitle; or
(2) enter a facility or conduct an administrative inspection of a facility if:
(A) the owner, pharmacist, or agent in charge of the facility consents to the inspection;
(B) the situation presents imminent danger to the public health and safety;
(C) the situation involves inspection of a conveyance, if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant; or
(D) any other exceptional situation or emergency exists involving an act of God or natural disaster in which time or opportunity to apply for a warrant is lacking.

XXX



TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

CLASS: A (A-S) B C C-S (BEDS____) D Other_____

Name of Pharmacy Greenpark Compounding Pharmacy — **TSBP License #** 14713

Pharmacist in Charge Kenneth Lee Hughes — Lic 22586 Exp 2-28-19

Personnel Kathleen Rigsby Behrman — Lic 22218 Exp 2-28-19

Angela Bailey Olmstead — Lic 44342 Exp 11-30-18

Sejal Dhaval Parekh — Lic 39095 Exp 12-31-17

Jennifer Trang Pham — Lic 53284 Exp 9-30-17

KEY: Circled items need improvement, √ items in Column One Refer to Legal Division (R/L) for review and possible discipline. √ items in Column Two receive a Warning Notice (W/N).

For an explanation of specific violations noted, refer to remarks section of inspection report.

R/L		W/N		R/L		W/N		R/L		W/N	
	1		Licenses not posted				Date of last inventory 12-30-16 close		10		Rxs not separated
	2		Insufficient Equipment		15		No PIC inventory		35		Invoices not separated
	3		Orderly/Clean		69		No annual inventory		67		No written information
	4		Balance ~~Failed~~ 5		68		No change of ownership inventory		21	✓	Computer records incomplete
	5		Equipment Inspection		31		Closed Phcy/Change of owner improper		22		Computer system noncompliance
	6		Inadequate Library		17		Incomplete inventory		82		PMR Incomplete
	7		Improper security		18		Records not available		83		PMR Absent
	8		Environment		46		Improper distribution		84		No drug regimen review
	9		Delinquent licenses/certifications		54		Improper prepackaging procedures		16		No perpetual inventory
	36		No notification of substitution		24		Theft/Loss not reported None		27		Improper inpatient records
	90	✓	No complaint notification		30		Invoices not dated/initialed		51		Improper ER dispensing
	38		Area for non sterile compounding		86		Absence of RPh pick up records		75		Improper absence of RPh procedures
	43		Records for non sterile compounding		19		Rx lacks proper information		70		No P&P manual
	47		Out of date/mislabeled drug stock		25		No documentation of refill authorization		71		Incomplete P&P manual
	48		Improper drug storage		32		Rx label is incorrect		72		Improper procedures for IV preparation
	53		Illegal possession of C/S		40		Non emergency C-II Rx		81		Area for preparation of sterile products
	57		Corresponding Responsibility		26		C II Rx noncompliance		85		Patient Care Guidelines incomplete
	59		Improper drug destruction		37		Illegal dispensing		87		Quality Control/Assurance
	61		Improper supervision of supportive personnel		45		Improper dispensing/ labeling		88		Cytotoxic/Biohazardous Procedures
	62		Aiding and abetting		44		Refill CIII-V over 5x/6mo		89		Refrigerator Temperature Log
	65		Improper registration procedures		55		Refill prn past one year		28		No provision log
	66		Grey Market diversion/ Samples		78		Counseling area		29		Incomplete provision log
	76		No PIC		80		No counseling by RPh		52		Improper provision/ dispensing in Class D
	(34)		Notification Violation		56		Improper transfer of Rx		63		Prohibited drugs in Class D pharmacy
	79		Nametags		50		Out of state verbal Rx for C/S		64		Violation of limited formulary
	60	✓	Improper doc-umentation of training		49		Substitution noncompliance		91		RPh visits/contact documentation
	92		Improper automated dispensing procedures		33		Rx records not in numerical order		73		Formulary not complete

Remarks

Advised to:

(116) Ensure the temperature of the cleanroom is consistently 68° F or cooler.

(204) Ensure antiseptic hand cleansing is performed using waterless alcohol-based surgical scrub once inside the buffer area prior to donning sterile gloves.

(229) Include time and name on all cleaning records.

(87) Update recall procedure to include notification of TSBP (See TSBP Rules 291.131(g) and 291.133(g)).

(34) Notify TSBP of current employee information.

Action Taken

(1) ✓ Inspection
(2) ___ Pre-Inspection
(3) ___ Partial Inspection
(4) ___ Visit
(5) ___ Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Kathy A. Salinas
Agent of the Texas State Board of Pharmacy

Authorized Individual for the Pharmacy

3-27-17
Date

4:00 pm
Time of Exit

Printed Name and Title of Authorized Individual

Texas State Board of Pharmacy

Inspection Report for Pharmacies Compounding Sterile Preparations

Circle One: (Class A-S) Class B Class C-S

Name of Pharmacy Greenpark Compounding Pharmacy TSBP License # 14713

Deficiency key: Circled items need improvement (N/I); Refer to Legal Division (R/L) for review and possible discipline; and Warning Notices (W/N) which require a written response with an explanation of correction(s). For an explanation of specific violations noted, refer to remarks section of inspection report. Note: "M" = Multiple Codes

R/L	Code	W/N	
			Environment
	M		Is cleanroom clean/free of objects that shed particles? (109) Contains only appropriate supplies? (119) Used only for sterile preps? (110)
	M		Does ante-area provide at least ISO Class 8 under dynamic conditions? (101) Contain a hands-free sink with hot/cold running water? (115)
	M		Does buffer area provide at least ISO Class 7 under dynamic conditions? (102) Area free from sources of water (e.g., sink/floor drains)? (106)
	108		Is there hands-free access to the buffer area?
	113		Are floors, walls, ceilings & fixtures smooth/impervious and free from cracks & crevices? Does floor covering enable regular disinfection (112)?
	118		Are supplies stored above the floor to permit adequate floor cleaning?
	127		Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area/room and ante-area/room and between the ante-area/room and the general environment? Pressure between ISO 7 & general environment shall not be less than 0.02" water column.
	(M)		Is temperature in cleanroom comfortable and monitored? (116) Thermometer available for cleanroom and refrigerator? (167)
			Primary Engineering Control (PEC) Device - i.e., Laminar Air Flow Hood, BSC, CAI, or CACI
	126		Is the Laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02-0.05" water?
	121		Is the PEC able to maintain at least ISO Class 5 conditions, while compounding sterile preparations?
	M		Are hazardous drugs prepared in a Class II or III vertical flow **BSC** or **CACI** located in an ISO 7 area physically separated from other areas? (246) Does the BSC or CACI have not less than 0.01" negative pressure adjacent to the positive pressure ISO 7 environment? (247)
	102		Does the **CAI** provide unidirectional flow? Is CAI required to be located in an ISO 7 buffer area? If CAI is used for high risk compounded sterile preparations, then is the CAI placed in an ISO 8 environment?
	81		Does the pharmacy maintain documentation from mfg that **CAI** or **CACI** meets standards when located outside of an ISO 7 environment?
	81		If CACI is used for high risk compounded sterile preparations, then is the CACI placed in an ISO 8 environment?
	M		PEC certified by independent contractor every 6 months & when relocated? (124) Prefilters inspected periodically & replaced as needed? (125)
	128		Are differential pressures monitored and documented at least every work shift (minimum daily) or by a continuous recording device?
			Equipment and Supplies
	M		Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? (174) Does the pharmacy have lint-free towel or wipes? (177) Does the pharmacy have masks, caps, gowns with tight cuffs, shoe covers, and beard covers? (180)
	M		Does pharmacy have handwashing agents w/ bactericidal action? (176) Disinfectant cleaning solutions and dedicated cleaning supplies? (175)
	M		Does the pharmacy have hazardous spill kits, if applicable (179)? Appropriate disposal containers for needles and syringes? (171)
	174		Does the pharmacy have sterile IPA, sterile gloves, and waterless alcohol-based surgical hand scrub?
	178		Does the pharmacy have appropriate filters and filtration equipment?
	181		If an automated compounding device is used, does the pharmacy calibrate and verify the device for accuracy on a daily basis (is it documented)?
	172		Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?
			High-Risk Sterile Preparations (CSPs)
	103		If high-risk CSPs are compounded, does buffer area provide physical separation from other compounding areas?
	M		Is sterility testing performed under the following conditions: CSPs prepared in groups > 25? (231); MDV prepared for multiple pts or when exposed > 12 hrs at 2-8 degrees Celsius before sterilized? (232); Exposed > 6 hrs at warmer than 8 degrees C before sterilized? (233)
	237		Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with sterile, pyrogen free water, and then thoroughly drained or dried immediately before use for high-risk compounding?
	238		Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2 micron filter to remove particulate matter? Sterilization by filtration shall be performed with a sterile 0.2 micrometer or 0.22 micrometer pore size filter within an ISO Class 5 environment or better.
	87	✓	Are filter integrity tests being performed and documented (e.g., bubble point)?
	239	✓	Are pre-sterilization procedures (weighing & mixing) completed in an ISO Class 8 environment or better?
			Library
	M		Does the pharmacy have: Reference on injectable drugs (154), Specialty Reference (155), Applicable USP Chapters (156)?

R/L	Code	W/N	
			Hazardous Sterile Preparations
	M		Do personnel wear protective apparel (242); use safety/containment techniques (243); dispose of waste appropriately(244); affix proper label (245)?
	248		If using a BSC or CACI, does pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?
	249	✓	Does pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment?
	250		Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?
			Personnel Cleansing, Garbing and Hand Hygiene
	108		Does hand sanitizing and gowning occur in the ante-area (outside the buffer area)?
	M		Do personnel remove: cosmetics (194); hand, wrist, and body jewelry or piercings (195); or artificial nails (196)? Are natural nail kept neat and trim? (196) Do personnel remove debris underneath fingernails using nail cleaner under warm water? (200)
	192		Are personnel with apparent illness or open lesions compounding sterile preparations?
	197		Do compounding personnel garb appropriately? When temporarily exiting ISO 7 environment, are re-donning procedures properly followed?
	M		Do personnel engage in proper hand hygiene? (201) Do personnel don clean non-shedding gowns with sleeves that fit snugly around wrist and enclosed at the neck? (202) Do personnel dry hands and forearms using lint-free disposable towels or hand-dryer? (203)
	204		Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside buffer area & prior to donning sterile gloves?
	206		Is sterile IPA applied to gloves throughout the day & when non-sterile surfaces are touched?
			Cleaning and Disinfection Procedures
	221		Does pharmacy have written procedures regarding cleaning & disinfecting (e.g., beginning of shift; every 30 minutes; before each batch; & spills)?
	230		Is cleaning performed by trained personnel using approved agents (described in written SOPs)?
	228		Are supplies and equipment that are removed from shipping cartons wiped with a disinfecting agent - such as sterile 70% IPA?
	M		Are floors mopped at least once daily? (226) Are walls, ceilings, and shelving cleaned monthly? (227) Does pharmacy maintain documentation of cleaning procedures [i.e., date/time of cleaning, type of cleaning, and name(s) of person(s) carrying out the cleaning]? (229)
			Environmental Sampling
	87		Is surface sampling conducted in all ISO classified areas on a periodic basis?
	M	✓	Is air sampling performed by properly trained individuals for all risk levels? (272) Is air sampling performed at least every six months? (273)
			Records of Compounded Sterile Preparations
	252		Does the pharmacy maintain records relating to CSPs for a minimum of 2 years?
	M		Do records include: date (253); formula (254); who prepared (255); who checked (256); quantity (257); container used and number of units prepared (258); criteria for BUD (259); and documention of performance of quality control procedures? (260)
	M		Are master worksheets for batch compounding complete? (261) Are master worksheets developed and approved by RPh (262)?
			General Operational Requirements
	166		Is RPh available at all times (24/7)?
	87		Are written SOPs followed to ensure accountability, accuracy, quality, safety, and uniformity? Does pharmacy have all required written procedures (e.g., pharmaceutical care services, viable air sampling plan, and recalls)? Does pharmacy follow recall procedures?
	158		If pharmacy compounds commercially available products, does pharmacy meet requirements for such compounding?
	275		Does pharmacy dispense prescriptions to patients in other states without proper licensure in those states?
			Office Use Compounding
	163		Does pharmacy have written agreement with prescriber? Does written agreement meet all requirements?
	162		If pharmacy is distributing compounded sterile preparations to another pharmacy, does pharmacy meet requirements for such distribution?
			Quality Control and Verification of Compounding Accuracy
	207		Does a RPh review all compounding records for accuracy and perform final check? Are periodic in-process checks defined in written procedures?
	191		Are all drug components manufactured in an FDA-registered facility? Are Certificates of Analysis available, if applicable?
			Label
	M		Is CSP properly labeled to include: generic name (209); compounded by pharmacy (210); BUD (211)? If prepared in batch, do labels contain: unique lot# (213); quantity (214); cautionary statements (215); and device-specific instructions, if applicable (216)?
	220		Are CSPs assigned a beyond-use-date that is based upon the specified labeling for the drug, appropriate literature sources, and/or direct testing?
			Training and Competency Testing
	129		Has each pharmacist completed the required education and training prior to engaging in sterile compounding?
	130		Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?
	142		Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation and testing (e.g., media fill testing, gloved fingertip/thumb testing)? Does pharmacy have an on-the-job training program?
	144		Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel?

EXHIBIT H

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3943
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14713
Name of Facility Green park Pharmacy
Address 4061 F Belhire Blvd City Houston Zip 77025
Pharmacist License # 22586
NAME OF PERSON RESPONSIBLE Kenneth Hughes

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.131(e)(2)(A) — code 43
Explanation of violation Failure to have RPh document in process and final checks for non-sterile compounding.

2. Law/Rule 291.33(f)(2) — code 47
Explanation of violation Failure to remove and quarantine out of date drugs from dispensing stock until drugs can be destroyed properly.

3. Law/Rule 291.33(c)(2)(F)(iii) & 291.3(g)(1)(A)(ii) — code 75
Explanation of violation Failure to have in English & Spanish "Written information about this prescription has been provided for you.." and "Complaints concerning the practice of pharmacy..." with delivered medication orders.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 07.23.15, disciplinary action may be instituted against your license.

by Jennifer Dodson
Agent, Texas State Board of Pharmacy
Date 06-23-15

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed [signature]

11/00

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3943
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14713
Name of Facility Greenpark Pharmacy
Address 4061-F Bellaire Blvd City Houston Zip 77025
Pharmacist License # 225816
NAME OF PERSON RESPONSIBLE Kenneth Hughes

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.133(4)(E)
Explanation of violation failure to have all supervising personnel involved in compounding sterile preparations do a gloved fingertip and media-fill challenge tests (#44342; 53234)

ode 160

2. Law/Rule 291.133(2)(A)(v)
Explanation of violation failure to have a RPh accessible at all times, 24 hrs. a day to respond to patients' and other health professionals' questions & needs

ode 12

3. Law/Rule
Explanation of violation

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 01-23-15, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By Jennifer Cook
Agent, Texas State Board of Pharmacy
Date 01-23-15

Signed [signature]

11/00

EXHIBIT I

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3942
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14713

Name of Facility Greenpark Pharmacy

Address 4061-F BelLaire City Houston Zip 77025

Pharmacist License # 22586

NAME OF PERSON RESPONSIBLE Kenneth Lee Hughes

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. TSBP Law/Rule 291.133 (d)(6)(B)(ii)

Explanation of violation Failure to weigh/mix Chemicals in at least ISO Class 8 air quality. Cease this practice, now & Comply.

2. TSBP Law/Rule 291.33 (c)(B)(iv)

Explanation of violation Failure to document initials of counseling pharmacist. Comply now.

3. TSBP Law/Rule 291.33 (c)(7)(A)(xiv)

Explanation of violation Failure to indicate beyond-use date on prescription label. Comply now.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before June 1, 2014, disciplinary action may be instituted against your license.

By Kathy A. Salinas
Agent, Texas State Board of Pharmacy
Date 5-1-14

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed [signature]

11/00

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3942
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14713
Name of Facility Greenpark Pharmacy KMS
Address 4061 F Bellaire Blvd City Houston Zip 77025
Pharmacist License # 22586
NAME OF PERSON RESPONSIBLE Kenneth Lee Hughes

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule TSBP 291.33 (i)(1)(A)
Explanation of violation Failure to calibrate and verify accuracy of automated compounding device. Either remove, replace, or have repaired by an authorized repair person, immediately.

2. Law/Rule TSBP 291.33(e) & 291.33(d)(5) & 291.31(d)(2)
Explanation of violation Failure to include most current references including Law book, patient prescription information, drug interactions, Facts + Comparison etc. Comply now. USP 795 & 797

3. Law/Rule 291.34(7)(B) & 291.34(e)(2)(C)(8)
Explanation of violation Failure to include initials of data-entry pharmacy technician on prescription records (daily printout log); and on hard copy prescriptions. Comply now.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 6-1-14, disciplinary action may be instituted against your license.

By Kathy A. Salinas
Agent, Texas State Board of Pharmacy
Date 5-1-14

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed

11/00

EXHIBIT J

Phcy. Lic. # 14713

Expiration Date: 12/31/15

NOTICE OF INSPECTION
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-3942
(512) 305-8000

✓ **Compliance**

___ **Investigation**

Name of Individual	Title	R.Ph. Lic. # Expires
Kenneth Lee Hughes	PIC	22586 2/28/15

Name of Facility
Greenpark Pharmacy

Address
4061-F Bellaire Blvd

City/State	Zip	Phone #
Houston, TX	77025	(713)432-9855

DEA Registration #	Expiration Date	DPS Registration #	Expiration Date
BG 3031476	9-30-15	J0080453	3-31-15

Date	Time of Entry
5-1-14	9:10 A

PURPOSE OF INSPECTION

___ Routine
___ Pre-Inspection
___ New Pharmacy
___ Change of Ownership
___ Complaint
___ Follow-up to Complaint
___ Follow-up to Warning Notice
___ Follow-up to Theft/Loss Report
✓ Other Rank Change

ACKNOWLEDGEMENT

This is to acknowledge that Texas State Board of Pharmacy Agent Kathy A. Salinas has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I am the Angela Olmstead for the above-described facility;
2. I have read this Notice of Inspection and understand its contents and purpose;
3. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
4. I have had the purpose of the entry into the above-described facility by the Board's agent stated to me; and
5. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Angela Olmstead
Signature

Witnesses:
Kathy A. Salinas
Signature

_____
Signature

ENTERED

09/1

TEXAS PHARMACY ACT
(Occupations Code, Subtitle J)

CHAPTER 554. BOARD POWERS AND DUTIES; RULEMAKING AUTHORITY
SUBCHAPTER A. POWERS AND DUTIES

Sec. 554.001. General Powers and Duties of Board.

XXX

(c) The board may:

XXX

(2) inspect a facility licensed under this subtitle for compliance with this subtitle.

XXX

CHAPTER 556. ADMINISTRATIVE INSPECTIONS AND WARRANTS
SUBCHAPTER A. GENERAL PROVISIONS

Sec. 556.001. Definition. In this chapter, "facility" means a place:
(1) for which an application has been made for a pharmacy license under this subtitle;
(2) at which a pharmacy licensed under this subtitle is located;
(3) at which a pharmacy is being operated in violation of this subtitle; or
(4) where the practice of pharmacy occurs.

SUBCHAPTER B. INSPECTIONS

Sec. 556.051. Authorization To Enter and Inspect. The board or a representative of the board may enter and inspect a facility relative to the following:
(1) drug storage and security;
(2) equipment;
(3) components used in compounding, finished and unfinished products, containers, and labeling of any item;
(4) sanitary conditions; or
(5) records, reports, or other documents required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws.

Sec. 556.052. Requirements Before Entry and Inspection.
(a) Before an entry and inspection of the facility, the person authorized to represent the board must:
(1) state the purpose for the inspection; and
(2) present to the owner, pharmacist, or agent in charge of the facility:
(A) appropriate credentials; and
(B) written notice of the authority for the inspection.
(b) If an inspection is required by or is supported by an administrative inspection warrant, the warrant is the notice for purposes of Subsection (a)(2)(B).

Sec. 556.053. Extent of Inspection. Except as otherwise provided in an inspection warrant, the person authorized to represent the board may:
(1) inspect and copy documents, including records or reports, required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws;
(2) inspect, within reasonable limits and in a reasonable manner, a facility's storage, equipment, security, prescription drugs or devices, components used in compounding, finished and unfinished products, or records; or
(3) perform an inventory of any stock of prescription drugs or devices, components used in compounding, or finished and unfinished products in a facility and obtain samples of those substances.

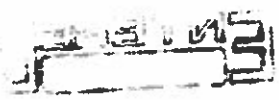
Sec. 556.054. Limitation on Inspection. Unless the owner, pharmacist, or agent in charge of a facility consents in writing, an inspection of the facility authorized by this chapter may not extend to:
(1) financial data;
(2) sales data, other than shipment data; or
(3) pricing data.

XXX

SUBCHAPTER C. WARRANTS

Sec. 556.101. Warrant Not Required. A warrant is not required under this chapter to:
(1) inspect books or records under an administrative subpoena issued under this subtitle; or
(2) enter a facility or conduct an administrative inspection of a facility if:
(A) the owner, pharmacist, or agent in charge of the facility consents to the inspection;
(B) the situation presents imminent danger to the public health and safety;
(C) the situation involves inspection of a conveyance, if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant; or
(D) any other exceptional situation or emergency exists involving an act of God or natural disaster in which time or opportunity to apply for a warrant is lacking.

XXX



TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

CLASS: (A) B C (BEDS____) D Other_____

Name of Pharmacy Greenpark Pharmacy
Pharmacist in Charge Kenneth Lee Hughes
Personnel

TSBP License # 14713
Lic 225586 Exp 2-28-15
Lic_____ Exp_____
Lic_____ Exp_____
Lic_____ Exp_____
Lic_____ Exp_____

KEY: Circled items need improvement, √ items in Column One Refer to Legal Division (R/L) for review and possible discipline.
√ items in Column Two receive a Warning Notice (W/N).
For an explanation of specific violations noted, refer to remarks section of inspection report.

R/L		W/N	
	1		Licenses not posted
	2		Insufficient Equipment
	3		Orderly/Clean
	4	√	Balance Failed (6)
	5		Equipment Inspection
	6	√	Inadequate Library
	7		Improper security
	8		Environment
	9		Delinquent licenses/certifications
	36		No notification of substitution
	90		No complaint notification
	38		Area for non sterile compounding
	43		Records for non sterile compounding
	(47)		Out of date/mislabeled drug stock
	48		Improper drug storage
	53		Illegal possession of C/S
	57		Corresponding Responsibility
	59		Improper drug destruction
	61		Improper supervision of supportive personnel
	62		Aiding and abetting
	65		Improper registration procedures
	66		Grey Market diversion/ Samples
	76		No PIC
	34		Notification Violation
	79		Nametags
	60		Improper documentation of training
	92		Improper automated dispensing procedures

R/L		W/N	
			Date of last inventory 12-31-13
	15		No PIC inventory
	69		No annual inventory
	68		No change of ownership inventory
	31		Closed Phcy/Change of owner improper
	(17)		Incomplete inventory
	(18)		Records not available
	46		Improper distribution
	54		Improper prepackaging procedures
	24		Theft/Loss not reported
	30		Invoices not dated/initialed
	86		Absence of RPh pick up records
	19	√	Rx lacks proper information
	25		No documentation of refill authorization
	32	√	Rx label is incorrect
	40		Non emergency C-II Rx
	26		C II Rx noncompliance
	37		Illegal dispensing
	45		Improper dispensing/ labeling
	44		Refill CIII-V over 5x/6mo
	55		Refill prn past one year
	78		Counseling area
	80	√	No counseling by RPh
	56		Improper transfer of Rx
	50		Out of state verbal Rx for C/S
	49		Substitution noncompliance
	33		Rx records not in numerical order

R/L		W/N	
	10		Rxs not separated
	35		Invoices not separated
	67		No written information
	21	√	Computer records incomplete
	22		Computer system noncompliance
	(82)		PMR Incomplete
	83		PMR Absent
	(84)		No drug regimen review
	16		No perpetual inventory
	27		Improper inpatient records
	51		Improper ER dispensing
	75		Improper absence of RPh procedures
	70		No P&P manual
	71		Incomplete P&P manual
	72	√	Improper procedures for IV preparation
	81		Area for preparation of sterile products
	85		Patient Care Guidelines incomplete
	87		Quality Control/Assurance
	88		Cytotoxic/Biohazardous Procedures
	89		Refrigerator Temperature Log
	28		No provision log
	29		Incomplete provision log
	52		Improper provision/ dispensing in Class D
	63		Prohibited drugs in Class D pharmacy
	64		Violation of limited formulary
	91		RPh visits/contact documentation
	73		Formulary not complete

Remarks

Advise to: (47) Remove all expired/improperly labeled drugs, compounds, chemicals from the dispensing stock. (17) make all quantities clear on controlled substance Inventory (gms.) (82)(84) Complete PMR with all required info including etc health conditions, other meds, etc - To conduct · Complete, DUR (manual)

W/N (4) Balance could not be calibrated to verify accuracy during the inspection (5 passed, 1 failed)

W/N (16) outdated law book, general reference, Handbook of Injectable Drugs, USP 795 & 797 etc.

W/N (19)(21) No data tech initials on daily printout and hard copy Rx's

W/N (80) Counseling RPh initials not documented.

W/N (72) Chemicals for high risk compounding not weighed in at least Iso Class 8 environment.

(18) Read and follow 291.133(d)(1)(D) with regards to compounding commercially available drugs.

Action Taken

(1) ✓ Inspection
(2) ___ Pre-Inspection
(3) ___ Partial Inspection
(4) ___ Visit
(5) ___ Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Kathy A. Salinas
Agent of the Texas State Board of Pharmacy

Authorized Individual for the Pharmacy

5-1-14
Date

2:45P
Time of Exit

Ron Hughes 22586 PIC
Printed Name and Title of Authorized Individual

EXHIBIT K

Greenpark Compounding Pharmacy 10/26/18

U.S. FOOD & DRUG ADMINISTRATION

Office of Pharmaceutical Quality
Operations, Division II
4040 N. Central Expressway,
Suite 300
Dallas, Texas 75204

October 26, 2018

CMS CASE #566233

WARNING LETTER

VIA UPS EXPRESS

Kenneth L. Hughes
Co-Owner and President
Prescription Labs, Inc.
dba Greenpark Compounding Pharmacy
4061-F Bellaire Blvd.
Houston, Texas 77025

Mr. Hughes:

From October 16, 2017, to October 27, 2017, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Prescription Labs, Inc., dba Greenpark Compounding Pharmacy, located at 4061-F Bellaire Blvd., Houston, Texas 77025. The investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on October 27, 2017. FDA acknowledges receipt of your facility's response, dated November 30, 2017. Based on this inspection, it appears that you produced drug products that violate the Federal, Food Drug and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

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 your drug products to be adulterated under section 501(a)(2)(A) of the FDCA [21 U.S.C. § 351(a)(2)(A)]. For example:

1. Personnel were engaged in aseptic processing inside the ISO5 area with partially exposed skin and wearing non-sterile garb.

2. Personnel were observed re-sanitizing gloved hands with non-sterile **(b)(4)** before resuming aseptic processing inside the ISO 5 area.

3. The wipes used for disinfecting the interior of the ISO 5 hood are not sterile.

4. The certification of the ISO 5 classified areas is inadequate because there is no evidence it included non-viable particle counts.

5. Your firm failed to perform smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area. Therefore, your products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination.

6. **(b)(4)** testing of the **(b)(4)** was not routinely performed for products intended to be sterile.

7. The use of **(b)(4)**-minute contact time for the use of **(b)(4)** as a sporicidal agent in the ISO 5 areas is inadequate.

It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

B. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding some of the insanitary condition observations in the Form FDA 483, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. According to your response, you will "conduct a more comprehensive observation of competency assessments: Aseptic Technique." However, you did not provide any details of what the "more comprehensive observation" will entail and who would be conducting these observations. Furthermore, you did not include any timeframe or completion date for these assessments or what actions you intend to take if deviations are identified.

2. According to your response, you will "review with sterile compounding personnel, that sterile **(b)(4)** is the approved sanitizing solution." However, it is unclear how or when you intend to obtain the sterile **(b)(4)** since you did not include a receipt or a Certificate of Analysis (CoA) for the sterile **(b)(4)**. In addition, you did not provide any supporting training documentation for staff pertaining to the use of sterile **(b)(4)** in the aseptic processing areas.

3. According to your response, you will review with compounding personnel "the importance of process documentation for all **(b)(4)** testing." However, you did not provide any supporting training documentation for staff to ensure that they will be documenting and performing the test according to procedure. In addition, you have not provided safeguards to confirm that this process is documented appropriately in the future.

4. According to your response, you will "begin using **(b)(4)** Wipes" with a contact time "determined by the manufacturer." However, you did not provide a receipt, CoA, or the contact time being used for the wipes. Furthermore, you did not provide the expected date the **(b)(4)** wipes would be received or used within the ISO 5 areas or any information regarding the wipes being non-shedding. You also did not provide any personnel training documentation for this changed procedure.

Regarding other observations related to insanitary conditions, some of your corrective actions appear deficient:

1. In your response, you indicated that you comply with the "Texas State Board of Pharmacy and USP <797> requirements, to use lint free wipes in the clean room"; however, the practice of using non-sterile wipes in the ISO 5 hood can increase the potential for contamination to be introduced into the ISO 5 aseptic processing areas.

2. In your response, you indicated that you comply with the "Texas State Board of Pharmacy requirements regarding airflow smoke pattern Test." However, you failed to commit to conducting new certifications or smoke pattern tests under dynamic conditions to show that ISO 5 areas can maintain unidirectional air flow. In response to this letter, please also include the non-viable particle counts as part of the new certifications.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A of the FDCA.

In addition, our review of the information collected during the inspection revealed the following:

1. You did not appear to use biological indicators (BI) during **(b)(4)** sterilization of finished drug products. Consequently, it is unclear if the sterilization conditions are adequate for inactivating all potential microbial contamination.

2. The **(b)(4)** is classified as an ISO 8, even though it is attached to an ISO 7 **(b)(4)** with an ISO 5 **(b)(4)** used for hazardous drug production. When an ISO 7 **(b)(4)** is negative to the **(b)(4)**, the **(b)(4)** should be classified ISO 7 or better to prevent ingress of lesser quality air.

3. Your media fills were not performed under the most challenging or stressful processing conditions. Therefore, there is a lack of assurance that your firm can aseptically produce drug products within your facility.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

C. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the

causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Your written notification should refer to the Warning Letter Number above (**CMS Case #566233**). Please address your reply to John W. Diehl, Director, Compliance Branch, at the FDA address provided on bottom of first page of this letter. Additionally, please submit a signed copy of your response on your firm's letterhead via e-mail to ORAPHARM2_Responses@fda.hhs.gov.

If you have questions regarding the contents of this letter, please contact Rebecca A. Asente, Compliance Officer, via (504) 846-6104 or Rebecca.asente@fda.hhs.gov.

Sincerely,
/S/
Monica R. Maxwell
Program Division Director
Office of Pharmaceutical Quality Operations, Division II

Cc:
Allison Vordenbaumen Benz, Executive Director Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500 333 Guadalupe Street
Austin, Texas 78701

Nancy Hughes, Co-Owner Prescription Labs, Inc.
dba Greenpark Compounding Pharmacy 4061-F Bellaire Blvd.
Houston, TX 77025

More in Warning Letters

Page Last Updated: 11/13/2018
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA

EXHIBIT L

James H. Ruble, R.Ph., Pharm.D., J.D.
SALUS CONSULTING, L.L.C.
3362 South 400 East
Bountiful, Utah 84010

August 26, 2015

Bobbie L. Stratton
Baker Donelson Bearman Caldwell & Berkowitz, P.C.
1301 McKinney St., Suite 3700
Southern District of Texas, Houston Division
Houston, Texas 77010

Re: Case No. 4:13-cv-02901; ***Whitaker, et al. v. Brad Livingston, et al.***; In the United States District Court for the Southern District of Texas, Houston Division

Dear Ms. Stratton:

My name is James H. Ruble. On behalf of Plaintiffs Thomas Whitaker and Perry Williams in the above-referenced case, you have asked me to provide information responsive to Part 2 of the August 19, 2015 Case Management Order of the District Court of the Southern District of Texas, which states that Plaintiffs will file:

A. An incremental time line describing how compounded pentobarbital changes from when it is first tested to when it reaches its beyond use date, and for two-month increments after that date for ten months, including specific qualitative changes and how that alters the efficacy of the drug. The report must evaluate the probable changes to compounded pentobarbital stored under Texas's conditions.

B. A simple, concise explanation of the levels of pain Williams is reasonably likely to experience using the pentobarbital at each time in A.

In preparation of this report, I was provided and reviewed a copy of the August 19, 2015 Case Management Order and a copy of Defendants' answers to Plaintiffs' discovery questions. I also reviewed the guidelines provided in:

1. United States Pharmacopeia ("USP") General Chapter <797> Pharmaceutical Compounding – Sterile Preparations ("USP <797>");
2. USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations ("USP <795>");
3. USP Monograph for Pentobarbital Sodium Injection; and
4. Bing CD, Ross KL. Applying stability data in patient care. In: Bing CD, Nowobilski-Vasilios A, eds. ***Extended Stability for Parenteral Drugs,*** 5th ed. Bethesda, MD: American Society of Health-System Pharmacists, 2013.

These USP sections are from version USP 38/NF 33 and are designated as "official" from August 1, 2015.

The opinions I express in this report assume that Defendants are using compounded pentobarbital to carry out executions by lethal injection and are made to a reasonable degree of scientific certainty. However, as I noted in my previous report, I am a pharmacist by training; I am not a medical doctor or an anesthesiologist. Therefore, my ability to answer the Court's inquiries above is limited to my training and experience as a pharmacist. I can make presumptions of chemical changes and can make statements of physiology, but I cannot make an evaluation of pain levels, as requested by the Court in Part 2.B. Additionally, I am not aware of any stability testing that has been performed on the compounded pentobarbital used by the Texas Department of Criminal Justice (TDCJ), and certainly no testing performed at the time increments requested by the Court in Part 2.A.[1] Therefore, I have answered Part 2.A. to the best of my ability and expertise, given these limitations. Lastly, Defendants did not answer or did not answer in full many of the questions posed in discovery, all of which are relevant to the task before me. As such, I do not have possession of all the information necessary to make as complete a report as possible.

With this in mind, my responses to the Court's Case Management Order are as follows:

A. Response to Part 2.A. of the Case Management Order

The short answer to this inquiry is that scientific data to answer this question is simply not available, as no analysis relevant to a calculation of Beyond Use

[1] Defendants response indicating they are going to conduct additional testing does not change this view.

Dating (BUD) has been done on the particular compounded pentobarbital intended for use by Defendants to carry out executions. Beyond Use Date is an empirical analysis based on general observation and experience; as such, only analytical testing relevant to calculating stability of the compounded pentobarbital in Defendants' possession could yield a reliable answer to the Court's question. That testing has not been conducted, or the results reflecting the existence and validity of such testing have not been provided.[2]

Moreover, the chemical stability of compounded pentobarbital is an area of unknowns, with many moving variables. While there are published studies investigating the chemical stability of pentobarbital, these studies do not use the same ingredients and/or concentrations of ingredients as those used in the compounded pentobarbital in Defendants' possession. As such, it is not possible to state, as a scientific matter, the qualitative or probable changes the compounded pentobarbital in Defendants' possession may undergo over the next ten months.

I am comfortable opining that: (1) the BUD asserted by Defendants with respect to the compounded pentobarbital in their possession is not supported by the relevant provisions of the USP, and in fact, extends far beyond the recommended BUD; (2) without stability and extended stability testing by a qualified laboratory, the default is to resort to the BUD set forth in USP <797>; (3) the goal of a BUD is to preclude degradation, contamination, and/or potency decline of a compound that could be seeded at the moment of compounding, or could be introduced at any later point in the compound's life; the farther from the BUD, the greater the potential for contamination, degradation, and/or sub-potency; and (4) without stability or extended stability testing, it is not scientifically possible to specify qualitative changes over time.

It is important to note at the outset that chemical degradation is not a linear process. Stability requires at least two separate potency measurements on the same specimen of the drug solution, separated by some amount of time (extended stability testing). Depending on the chemical degradation pathway, the Active Pharmaceutical Ingredient (API) may be broken down by one of a few different pharmacokinetic rate equations. In the case of pentobarbital sodium, it likely follows first order chemical kinetics. If two concentrations are known and the time between them is known, then the rate of chemical decay can be estimated using an

[2] In discovery, Defendants indicate that each vial of compounded pentobarbital is labeled with an "expiration date." That term is irrelevant to the compounding setting and is only used when discussing manufactured drugs.

exponential decay equation:

$$[Pentobarbotal]_{time\ t} = [Pentobarbital]_{time\ 0}\ e^{-k\,t}$$

In text form, this equation says that the concentration of pentobarbital at some point in time is equal to the initial concentration of pentobarbital multiplied by an exponential function that includes the rate of degradation and the time between the two measured concentrations. When there are two (or more) concentrations (i.e., potency measurements), the prediction of concentration at other times can be mathematically predicted. In my opinion, the best data on stability would be to utilize direct, sequential analytical testing of potency to determine the actual degradation rate. However, as I noted, we do not have two potency measurements from the same batch of the compounded pentobarbital used by the TDCJ at two points in time. Thus, we cannot perform this analysis.

In the absence of the laboratory data, and the inconsistency of the published studies, compounding pharmacists would be expected to revert to the BUD set forward in USP <797>. This BUD for high-risk compounded sterile preparations is:

- 24 hours, if stored at controlled room temperature,
- 72 hours, if kept at a cold temperature (refrigerated), or
- 45 days, if kept in a solid, frozen state

Therefore, in my opinion, the standard of professional care and practice would be to default to the conservative guidelines in USP and hold to a maximum BUD of 72 hours from the date of compounding, presuming the preparations are continuously kept at an appropriate cold temperature.

Use of compounded pentobarbital beyond its BUD, or based on a faultily calculated BUD, is not an area that has been widely studied, for obvious reasons. A BUD exists for the purpose of preventing degradation of a compound that the USP has calculated is likely to occur after a set time frame (established by the USP as 72 hours on the outside). The BUD (as well as USP 797) is intended to guard against sub-potency, contamination by unknown drugs, micro-organisms or substances, problematic chemical composition (osmolality or acid-base status); and particulates or impurities in the solution.

There are a small number of studies of limited applicability, briefly summarized here:

- Gupta, et al, evaluated the dilution of commercial pentobarbital sodium into glass and polypropylene (i.e. plastic) syringes.[3] That study found that some dilutions are stable up to 31 days; however dilutions placed into syringes had visible crystals in the formulation within 24 hours following dilution; thus, these preparations were deemed to be not fit for use and were discarded from further analysis;
- Hittel and colleagues described the stability of pentobarbital following admixture into large volume containers with Dextrose 5% in Water (D5W) and 0.9% sodium chloride (NS).[4] They described that pentobarbital undergoes first order chemical degradation, and that this is primarily accomplished through water hydrolysis. Unfortunately, they only studied stability out to a maximum of 12 hours. In this interval, there was not evidence of instability;
- Walker and Iazzetta described stability of commercial pentobarbital in polyvinyl chloride (PVC) bags containing either D5W or NS.[5] These admixtures contained pentobarbital diluted to between 4 to 8 mg/mL. Samples from the diluted admixtures were analyzed for pentobarbital potency and found to be within the 4 to 8 mg/mL range. The concentrations remained relatively stable, but were only measured out to 24 hours; and
- Borodkin and colleagues investigated the stability of nonaqueous solutions of sodium pentobarbital for use in laboratory animals.[6] In this study, pentobarbital is mixed into solution with propylene glycol and several other chemical solvents (e.g., alcohol and dimethylacetamide). The authors indicated that the presence of water in the formulation would be expected to cause a first order chemical degradation reaction.

---

[3] Gupta VD. Stability of pentobarbital sodium after reconstitution in 0.9% sodium chloride injection and repackaging in glass and polypropylene syringes. Int J Pharm Comp. 2001;5(6):482-4.

[4] Hittel WP, Infrate RP, Karnes HT, Hendeles L. Am J Hosp Pharm. 1983;40:294-6.

[5] Walker SE, Iazzetta J. Compatibility and stability of pentobarbital infusions. Anesthesiology. 1981;55:487-489.

[6] Borodkin S, Macy L, Thompson G, Schmits R. Stable nonaqueous pentobarbital sodium solutions for use in laboratory animals. J Pharmaceu Sci. 1977;66(5):693-695.

However, none of these studies sheds significant light on the constellation of facts and substances at issue in these proceedings; nor have they propelled a change in the USP's beyond use dating guidelines for compounded high risk sterile injectables.

B. Response to Part 2.B. of the Case Management Order

As previously stated, I am not an expert in the clinical assessment of pain. However, from the standpoint of chemical stability and potential physiologic sequelae, the Gupta scientific data indicates a risk of forming a visible, solid precipitate in pentobarbital formulations. Visible chemical precipitates, upon injection into the vasculature would be expected to rapidly transit through the heart and into the pulmonary capillary vasculature. At this point, the size of the particles, would be expected to occlude those capillaries and lead to rupture and hemorrhage of blood into the lungs. Clinically this condition may be referred to as pulmonary embolus and pulmonary hemorrhage. A patient experiencing this condition is substantially likely to feel exceptional physical pain.

In addition, impurities or particulates in the injectable solution – such as those in the Gupta study - would lead to extreme venous irritation. Chemical imbalances in compounded pentobarbital resulting in osmolality or osmolarity different than that of blood, or acid base status (pH) outside human blood parameters would also cause extreme pain upon injection. Finally, the administration of sub potent drugs (one of the risks of drugs used after their BUD) could also prolong the procedure and lead to suffering at the time of an execution.

I hope you find this information helpful and responsive to the Court's August 19, 2015 Case Management Order. If I can provide further clarification or explanation, please let me know. As always, the application of scientific protocols to a specific set of facts or circumstances could affect my views and opinions because the protocols and/or tests that must be taken into account could compel a different discussion. Please let me know if I can be of further assistance as your litigation proceeds.

Sincerely,

James H. Ruble

EXHIBIT M

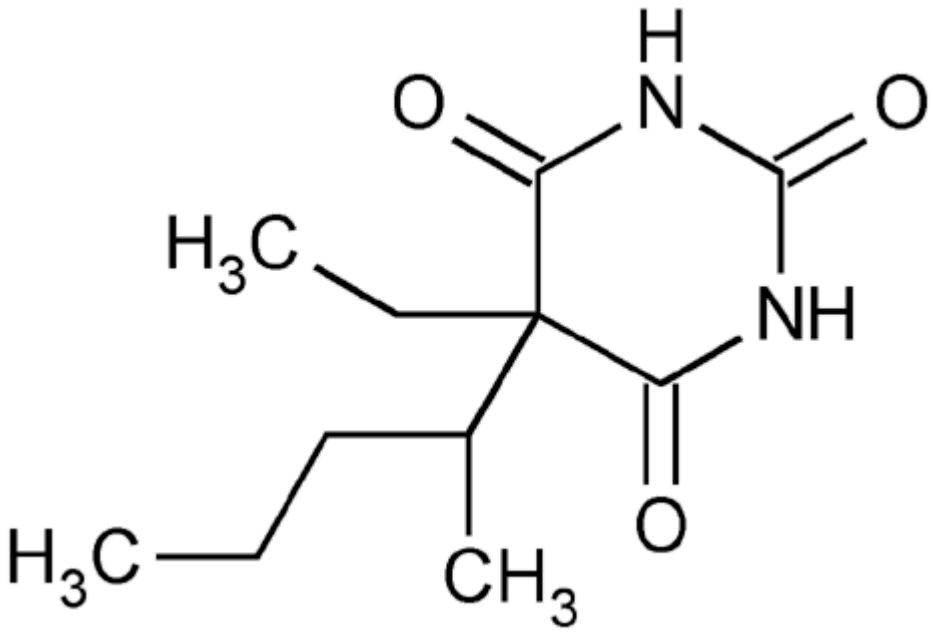
BRIEFING

Pentobarbital , *USP 32* page 3249. On the basis of comments received, the following revisions are proposed:

1. Delete *Identification* test *B* by UV because the remaining two *Identification* tests by IR and HPLC retention time match are sufficient to establish the identity of the drug substance.
2. Delete the *Capacity factor* sytem suitability requirement from both the *Assay* and the test for *Organic Impurities* because it contributes no additional value in establishing the suitability of the HPLC system. The remaining three parameters namely, theoretical plates, tailing factor, and relative standard deviation are adequate to ensure the suitability of the HPLC system.
3. Revise the calculation formula under the *Organic Impurities* test to be consistent with the redesigned format.
4. Delete the test for *Melting Range or Temperature* because it does not contribute any additional value in establishing the quality of the drug substance. This test was included in the original monograph when there was no selective method to quantify the impurities. The currently official monograph contains a selective stability-indicating HPLC method for the *Assay* and the *Organic Impurities* test both of which together provide sufficient information about the purity of the drug substance.

(MD-PP: R. Ravichandran.)
RTS—C64602

Pentobarbital



$C_{11}H_{18}N_2O_3$ 226.27

2,4,6(1*H* ,3*H* ,5*H*)-Pyrimidinetrione, 5-ethyl-5-(1-methylbutyl)-, (±)-;
(±)-5-Ethyl-5-(1-methylbutyl)barbituric acid [76-74-4].

DEFINITION

Pentobarbital contains NLT 98.0% and NMT 102.0% of $C_{11}H_{18}N_2O_3$, calculated on the dried basis. Where the material is labeled as intended solely for veterinary use, Pentobarbital contains NLT 97.0%

and NMT 102.0% of $C_{11}H_{18}N_2O_3$, calculated on the dried basis.

IDENTIFICATION

- **A. Infrared Absorption** ⟨197S⟩

  Sample solution: 7 in 100

  Medium: Chloroform

Delete the following:

- ~~**B. Ul... violet Absorption** ⟨197U⟩~~

  ~~**Sample solution:** 16 µg/mL~~

  ~~**Medium:** 0.1 N sodium hydroxide~~ ■2S (*USP33*)

Change to read:

- ~~**C.**~~

  ■ **B.** ■2S (*USP33*)

  The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

- **Procedure**

  Mobile phase: 0.01 M monobasic potassium phosphate and acetonitrile (65:35). Adjust the pH to 3.5.

  Standard solution: 0.1 mg/mL of USP Pentobarbital RS in *Mobile phase*

  Sample stock solution: 1 mg/mL of Pentobarbital in *Mobile phase* (sonicate until dissolved)

  Sample solution: Transfer 10.0 mL of the *Sample stock solution* to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

  Chromatographic system

  (See *Chromatography* ⟨621⟩ *, System Suitability*.)

  Mode: LC

  Detector: UV 214 nm

  Column: 4.6-mm × 25-cm; 5-µm packing L1

  Flow rate: 1 mL/min

  Injection size: 10 µL

  System suitability

  Sample: *Standard solution*

  Suitability requirements

  Column efficiency: NLT 15000 theoretical plates

  Tailing factor: NMT 1.5

  ~~**Capacity factor, k':** NLT 2.5~~

■ ■2S (*USP33*)

Relative standard deviation: NMT 2.0% for Pentobarbital

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{11}H_{18}N_2O_3$ in the portion of Pentobarbital taken:

$$\text{Result} = (r_U / r_S) \times (C_S / C_U) \times 100$$

r_U = peak area of the *Sample solution*

r_S = peak area of the *Standard solution*

C_S = concentration of USP Pentobarbital RS in the *Standard solution* (mg/mL)

C_U = concentration of Pentobarbital in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis; 97.0%–102.0% on the dried basis, where the material is labeled as intended solely for veterinary use

IMPURITIES

Inorganic Impurities

- **Residue on Ignition** ⟨ 281 ⟩ **:** NMT 0.1%
- **Heavy Metals,** *Method II* ⟨ 231 ⟩ **:** NMT 20 ppm

Change to read:

Organic Impurities

- **Procedure**

Mobile phase: Prepare as directed in the *Assay*.

Standard solution: 0.001 mg/mL of USP Pentobarbital RS in *Mobile phase*

Sample solution: 1 mg/mL of Pentobarbital in *Mobile phase*

Chromatographic system

(See *Chromatography* ⟨ 621 ⟩ *, System Suitability*.)

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 15000 theoretical plates

Tailing factor: NMT 1.5

~~**Capacity factor, k':** NLT 2.5~~

■ ■2S (*USP33*)

Relative standard deviation: NMT 15.0% for Pentobarbital

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any impurity in the portion of Pentobarbital taken:

~~Result = $(r_U / r_S) \times (C_S / W) \times (10{,}000/F)$~~

~~r_U = peak area for any impurity in the *Sample solution*~~

~~r_S = peak area for Pentobarbital in the *Standard solution*~~

~~C_S = concentrationof USP Pentobarbital RS in the *Standard solution* (mg/mL)~~

~~W = weight of Pentobarbital , on the dried basis, in the *Sample solution* (mg)~~

~~F = relative response factor of the impurity according to *Impurity Table 1*~~

■

$$\text{Result} = (r_U / r_S) \times (C_S / C_U) \times (1/F) \times 100$$

r_U = peak area for any impurity in the *Sample solution*

r_S = peak area for Pentobarbital in the *Standard solution*

C_S = concentration of USP Pentobarbital RS in the *Standard solution* (mg/mL)

C_U = concentration of Pentobarbital in the *Sample solution* (mg/mL)

F = relative response factor of the impurity (see *Impurity Table 1*)

Acceptance criteria: See *Impurity Table 1*. ■2S (*USP33*)

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
6-Imino-5-ethyl-5-(1-methyl butyl) barbituric acid	0.39	1.5	0.2
5-Ethyl-5-(1-ethylpropyl) barbituric acid[a]	0.93	1.0	0.1
Pentobarbital	1.0	—	—
5-Ethyl-5-(1,3-dimethylbutyl) barbituric acid	1.5	0.9	0.3
Unknown impurities	—	1.0	0.1
Total	—	—	0.5

[a] Where the material is labeled as intended solely for veterinary use, the limit of 5-ethyl-5-(1-ethylpropyl) barbituric acid is 3.0%.

SPECIFIC TESTS

Delete the following:

■ • ~~**Melting Range or Temperature,** *Class I* ⟨741⟩ : 127° – 133°~~ ■2S (*USP33*)

• **Loss on Drying** ⟨731⟩ **:** Dry a sample at 105° for 2 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** 〈11〉

  USP Pentobarbital RS

Auxiliary Information— Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
Monograph	Ravi Ravichandran, Ph.D. Senior Scientist 1-301-816-8330	(MDPP05) Monograph Development-Psychiatrics and Psychoactives
Reference Standards	Lili Wang, Technical Services Scientist 1-301-816-8129 RSTech@usp.org	

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EXHIBIT N

[redacted]

LABORATORY REPORT

Client #: [redacted]
Sample: Pentobarbital
Lot #:
Sample ID #: [redacted]
Date Rec'd: 1/18/16

	Date	Reported	Measured	Potency
Chemistry Tests:				
Pentobarbital Sodium	01/20/2016	50.00 mg/mL	54.5 mg/mL	109.00 %

	Date	Measured	Result
Microbiology Tests:			
Scan RDI	01/19/2016	1/0 E / M	Pass
Bacterial Endotoxins	01/18/2016	<1.00 units	Pass

Notes:

Bacterial Endotoxins: Endotoxins are measured using USP<85> Turbidimetric procedure, with an inhibition / enhancement test performed on each sample.

Respectfully submitted,

[redacted]

[redacted]

LABORATORY REPORT

Client #: [redacted]
Sample: Pentobarbital Sodium
Conc.: 50 mg/ml
Lot #: [redacted]
Sample ID #:
Date Rec'd: 07/21/2016

Chemistry Tests:	Date	Reported	Measured	Potency
Pentobarbital Sodium	07/22/2016	50.0 mg/mL	51.5 mg/mL	103 %

Microbiology Tests:	Date	Measured	Result
Scan RDI	07/22/2016	28/0 E / M	Pass --
Bacterial Endotoxins	07/26/2016	<1.00 EU/mL	Pass --

Notes:

Bacterial Endotoxins: Endotoxins are measured using USP<85> Turbidimetric procedure, with an inhibition / enhancement test performed on each sample.

Potency: Potency is determined via USP <621> HPLC, USP<851> Spectrophotometry, and specific monograph testing procedures.

Respectfully submitted,

[redacted]

ACCREDITED

Page 1 of 1

[redacted]

LABORATORY REPORT

4/27/2015

[redacted]

Tel:
Fax:

Client #: [redacted]
Sample: Pentobarbital 50mg/ml
Lot #: [redacted]
Sample ID #:
Date Rec'd: 4/24/2015

LABORATORY TEST RESULTS

Microbiological Tests:	Date	Measured	Result
Bacterial Endotoxin USP <85>	–		
[redacted] Sterility Test	–		
Rapid ScanRDI Microbial Detection	–		

Chemical Tests:	Date	Reported	Measured	Potency
Pentobarbital Sodium	4/27/2015	50 mg/mL	47.3 mg/mL	94.6 %_

Notes:

[redacted]

USP <795> states: "...compound preparations are to be prepared to ensure not less than 90% and not more than 110% of the theoretically calculated and l ingredient...". Potency is determinations follow USP <621> HPLC. USP<851> monograph testing procedures.

Respectfully submitted,

[redacted]

[redacted]

LABORATORY REPORT

Client #: [redacted]
Sample: Pentobarbital 50mg/ml 2ml
Conc.: 50mg/ml
Lot #:
Sample ID #: [redacted]
Date Rec'd: 12/22/2017

Chemistry Tests:	Date	Reported	Measured	Potency
Pentobarbital Sodium	01/09/2018	50.0 mg/mL	48.5 mg/mL	97.0 %

Microbiology Tests:	Date	Measured	Result
Scan RDI	12/26/2017		Pass
Bacterial Endotoxins	12/27/2017	<1.00 EU/mL	Pass -

Notes:

Bacterial Endotoxins: Endotoxins are measured using USP<85> Turbidimetric procedure, with an inhibition / enhancement test performed on each sample.

Potency: Potency is determined via USP <621> HPLC, USP<851> Spectrophotometry, and specific monograph testing procedures.

Respectfully submitted,

[redacted]

[redacted]

EXHIBIT O

Huntsville Unit
Storage Inventory
Pentobarbital 100mg/ml (5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
8-26-15	return from Supplier	—	5		1	6	[redacted]
10-6-15	Garcia, Juan	999360	6	2		4	
10-6-15	Garcia return	999360	4		1	5	
10-14-15	Escamilla, Licio	999432	5	2		3	
10-14-15	Escamilla return	999432	3		1	4	
11-18-15	Holiday, Raphael	999419	4	2		2	
11-18-15	Holiday return	999419	2		1	3	
12-16-15	rec'd from supplier	—	3	—	11	14	
1-7-16	Remove from Stock (Test)	—	14	1	—	13	
1-20-16	masterson, Richard	999414	13	2		11	
1-20-16	masterson return	999414	11		1	12	
1-27-16	Freeman, James	999539	12	2		10	
1-27-16	Freeman return	999539	10		1	11	
2-9-16	Expired	—	11	1	—	10	
7-11-16	Return to Supplier		10	10	—	~~0~~	
2/2/17	Rec. of new Supply		0	0	11	11	
2-7-17	Remove from Stock (Test)		11	1	~~0~~	10	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 100mg/ml (5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
7/27/17	Prieyor Taiclin	999194	10	1		9	[redacted]
10/12/17	Pruett Robert	999411	9	2		7	
10/12/17	Pruett Robert Return	999411	7		1	8	
10/18/17	Shore Anthony	999488	8	2		6	
10/18/17	Shore Anthony Return/Stay	999488	6		2	8	
11/8/17	Cardenas Ruben	999275	8	2		6	
11/8/17	Cardenas Ruben	999275	6		1	7	
1/18/18	Shore Anthony	999488	7	2		5	
1/18/18	Shore Return Anthony	999488	5		1	6	
1/30/18	Bayford William	999371	6	2		4	
1/30/18	Rayford William Return	99931	4		1	5	
2/1/18	Battaglia John	999412	5	2		3	
2/1/18	Battaglia Return John	999412	3		1	4	
2/22/18	Whitaker Thomas	999552	4	2		2	
2/22/18	Whitaker Thomas Return	999552	2		2	4	
3/27/18	Rodriguez Rosendo	999534	4	2		2	
3/27/18	Return	999534	2		1	3	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 100mg/ml (5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
4/25/18	Davila, Erick	999545	3	2		1	[redacted]
4/25/18	Davila Erick Return	999545	1		1	2	
5/16/18	Castillo Juan	999502	2	2		0	
5/16/18	Return	999502	0		1	1	
6/18/18	Stock Received	—	1		15	16	
6/20/18	Removed from Stock (Test)	—	16	1		15	
6/27/18	Bible, Danny	999455	15	1		14	
6/27/18	Return	999455	14		0	14	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 50mg/ml (2.5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
5-13-15	Stock received	—	4	—	17	21	[redacted]
7-14-15	Removed from Stock	—	21	4	—	17	
8-19-15	Stock received	—	17	—	3	20	
8-26-15	Removed from Stock	—	20	3	—	17	
2-3-16	Stock received	—	17	0	1	18	
2-11-16	Removed From Stock	—	18	3	—	15	
2-16-16	Garcia, Gustavo	999018	15	4		11	
2-4-16	return from exec	999018	11		2	13	
3-9-16	Wesbrook, Coy	999281	13	4		9	
3-9-16	return from exec	999281	9		2	11	
3-22-16	Ward, Adam	999525	11	4		7	
3-22-16	return from exec	999525	7		2	9	
3-23-16	Stock received	—	9	—	18	27	
4-6-16	Vasquez, Pablo	999297	27	4		23	
4-6-16	return from exec	999297	23		2	25	
4-28-16	return to supplier		25	6		19	
4-28-16	return from supplier		19		6	25	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 50mg/ml (2.5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
7-11-16	Return to Supplier	—	25	1	—	24	[redacted]
8-1-16	Stock Received	—	24		24	48	
8-3-16	Return to Supplier	—	48	2	—	46	
10-5-16	Fuller, Barney	999481	46	4		42	
10-5-16	Fuller return from exec	999481	42		2	44	
10-31-16	Removed From Stock	—	44	4	—	40	
01/11/17	Wilkins Christopher	999533	40	4		36	
01/11/17	Wilkins Return from exec.	999533	36		2	38	
1/26/17	Edwards Terry	999463	38	4		34	
1/26/17	Edwards Terry Return	999463	34		2	36	
2-21-17	Stock Received (Test)		36	0	1	37	
3/7/17	Ruiz, Rolando	999145	37	4		33	
3/7/17	Ruiz Rolando	999145	33		2	35	
3/14/17	Bigby James	000997	35	4		31	
3/14/17	Bigby James Returned	000997	31		2	33	
3-31-17	Removed from Stock	—	33	16		17	
7-20-17	Return to Supplier ([redacted])		17	16		1	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

Huntsville Unit
Storage Inventory
Pentobarbital 50mg/ml (2.5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
7-20-17	Return from Supplier	——	1		16	17	[redacted]
7/27/17	Preciyor Taichin	999494	17	2		15	
7/27/17	Preciyor Taichin Return	999494	15		2	17	
5/24/18	Return to Supplier		17	1		16	
6/27/18	Bible Danny	999455	16	2		14	
6/27/18	Return	999455	14		2	16	
7/17/18	Young Christopher	999508	16	4		12	
7/17/18	Return	999508	12		2	14	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

EXHIBIT P

The Woodlands Compounding Pharmacy

3200 Research Forest Dr. Ste. A3
The Woodlands, TX 77381
Phone: 281-419-1340
Fax: 281-419-2181

October 4, 2013

Judge Larry Gist
Board Member, Texas Board of Criminal Justice
Fax 512.305.9398

Brad Livingston
Texas Department of Criminal Justice
Fax 936.437.2123

Bryan Collier
Deputy Executive Director, Texas Department of Criminal Justice
Fax 936.437.8925

Jason Clark
Information Director, Texas Department of Criminal Justice
Fax 936.437.6055

Region I Regional Director Richard Alford
Texas Department of Criminal Justice
Fax 936.437.2651

Region I Deputy Director Robert "Jay" Eason
Texas Department of Criminal Justice
Fax 936.437.2651

Katherine D. Hayes
Assistant Attorney General
Fax 512.320.8132

Dear Sirs and Madam:

I am the owner and pharmacist-in-charge of the Woodlands Compounding Pharmacy, the pharmacy that has provided TDCJ with vials of compounded pentobarbital.

Based 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. Based on Ms. Minor's requests, I took steps to ensure it would be private. However, the State of Texas misrepresented this fact because my name and the name of my pharmacy are posted all over the internet. Now that the information has been made public, I find myself in the middle of a firestorm that I was not advised of and did not bargain for. Had I known that this information would be made public, which the State implied it would not, I never would have agreed to provide the drugs to the TDCJ.

I, and my staff, are very busy operating our pharmacy, and do not have the time to deal with the constant inquiries from the press, the hate mail and messages, as well as getting dragged into the state's lawsuit with the prisoners, and possible future lawsuits. For these reasons, I must demand that TDCJ immediately return the vials of compounded pentobarbital in exchange for a refund.

Please contact me immediately to arrange for the return of the drugs. Otherwise I may have to ask the Court in the prisoners' lawsuit to consider my concerns.

Sincerely,

Jasper Lovoi, RPh.

APPENDIX D

Plaintiff's Complaint for Equitable, Injunctive and Declaratory Relief

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

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

PLAINTIFF'S COMPLAINT FOR EQUITABLE, INJUNCTIVE AND DECLARATORY RELIEF [42 U.S.C. § 1983]

NATURE OF ACTION

1. This action is brought pursuant to 42 U.S.C. § 1983 for violations and threatened violations by the Texas Department of Criminal Justice ("TDCJ") of Plaintiff Joseph Garcia's right to be free from cruel and unusual punishments under

the Eighth Amendment to the United States Constitution, his rights to petition the government for redress of grievances and to be informed about the government's conduct under the First Amendment, his right to due process under the Fourteenth Amendment to the United States Constitution, and his right to equal protection of the laws under the Fourteenth Amendment.

2. This Complaint does not challenge Garcia's underlying capital conviction or sentence of death, nor does it allege that lethal injection as a form of execution is per se unconstitutional. Rather, Garcia challenges the manner and means by which TDCJ intends to execute him on December 4, 2018.

3. Garcia has reason to believe that TDCJ obtained pentobarbital—the drug that TDCJ will use in his execution and uses in all executions—from a compounding pharmacy that has been repeatedly cited for safety and sanitation violations by state and federal regulators, and has been on probation with the Texas State Board of Pharmacy since 2016. Because TDCJ obtained the drug from a source that has repeatedly violated federal and state standards and engages in unsanitary practices, Garcia has real, substantial concerns that the pentobarbital will not be what it purports to be, will be contaminated, or will be otherwise substandard.

4. Garcia seeks equitable, injunctive, and declaratory relief to prevent Defendants from carrying out his execution by using pentobarbital that TDCJ obtained from an unsafe source.

THE PARTIES

5. Plaintiff Joseph Garcia is a United States citizen and a resident of the State of Texas. He is presently incarcerated and under a sentence of death at the Allan B. Polunsky Unit of the TDCJ in Livingston, Texas (inmate number 00999441). Garcia is scheduled to be executed at 6:00 p.m. CST on December 4, 2018.

6. Defendant Bryan Collier is the Executive Director of TDCJ.

7. Defendant Lorie Davis is the Director of the Correctional Institutions Division of TDCJ.

8. Defendant James L. Jones is the Senior Warden of the Huntsville Unit, where Garcia is scheduled to be executed.

9. Garcia does not know the true names of Does 1-50, but they have or will participate in his execution, by virtue of their roles in ordering, supplying, distributing, transporting, storing, or mixing lethal injection drugs; or preparing, implementing or carrying out the lethal injection. If Garcia discovers the Doe Defendants' true identities, he will amend his complaint accordingly.

10. Because injunctive relief is sought, Defendants are "persons" for purposes of an action under 42 U.S.C. § 1983. *See Will v. Michigan Dep't of State Police*, 491 U.S. 58, 71 n.10 (1989). Defendants are being sued in their official capacities.

JURISDICTION AND VENUE

11. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1343 (civil rights violations), 28 U.S.C. § 1651 (all writs act), 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C. § 2202 (injunctive relief).

12. Venue in this Court is proper under 28 U.S.C. § 1391, and this Court has personal jurisdiction over Defendants because the events giving rise to this claim—both executions and the procurement and maintenance of drugs used in the lethal injection process—occur in Huntsville, Texas.

13. As this case involves an actual controversy within this Court's jurisdiction, this Court, under 28 U.S.C. § 2201, has the power to declare the rights and legal relations of the parties herein, and, under 28 U.S.C. § 2202, has the power to grant declaratory relief by all necessary and proper means. This Court also has the authority to grant injunctive relief under 42 U.S.C. § 1983, as this action involves the deprivation of Garcia's constitutional rights under the Eighth and Fourteenth Amendments by Defendants acting under the color of State law.

EXHAUSTION OF ADMINISTRATIVE REMEDIES

14. Garcia does not believe that exhaustion is necessary under the Prison Litigation Reform Act ("PLRA"), 42 U.S.C. § 1997e, because this suit does not challenge prison conditions, and because there are no available administrative remedies that could address Garcia's claims.

RELEVANT FACTS

15. Garcia incorporates by reference every statement and allegation set forth throughout this Complaint. Garcia is set to be executed by TDCJ on December 4, 2018 by lethal injection of "100 milliliters of solution containing 5 grams of Pentobarbital." TDCJ Execution Procedure (July 2012) at 8.

I. Texas is procuring compounded pentobarbital to be used in Garcia's execution from a compounding pharmacy that regulators have repeatedly cited for dangerous practices.

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

17. 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 a compounding pharmacy that regulators have repeatedly cited for dangerous practices. *See* Chris McDaniel, *Inmates Said The Drug Burned As They Died. This Is How Texas Gets Its Execution Drugs*, BuzzFeed News, Nov. 28, 2018.[1]

18. Reporter McDaniel identified Greenpark Compounding Pharmacy in Houston ("Greenpark") through investigation, tying the pharmacy to a declaration submitted to the United States District Court for the Southern District of Texas,

[1] Available at https://www.buzzfeednews.com/article/chrismcdaniel/inmates-said-the-drug-burned-as-they-died-this-is-how-texas.

Houston Division under the pseudonym Pharmacy X. 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." 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.

19. Greenpark has been cited for safety violations in recent years, related to its compounding practices, and the Texas State Board of Pharmacy ("TBP") has held its license in a probationary status since November of 2016.

20. TBP also issued several Warning Notices to Greenpark for violations of rules governing practices for producing sterile drug products.

21. As part of its inspection of Greenpark's Houston facilities, TBP noted additional failures on its Inspection Report Checklist, including the temperature of its cleanroom and failure to ensure that antiseptic hand cleansing is performed.

22. TBP issued two Warning Notices to Greenpark on June 23, 2015, for 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.

23. Greenpark also received two Warning Notices from TBP on May 1,

2014, for the failure "to weigh/mix chemicals in at least ISO 8 air quality," for which it was ordered to "[c]ease this practice now and comply," and the failure to indicate beyond use dates ("BUDs") on prescription labels.

24. Greenpark also was in violation for, inter alia, failing to calibrate and verify the accuracy of its automated compounding device and was ordered to have it removed, replaced, or repaired immediately.

25. On October 26, 2018, the U.S. Food and Drug Administration ("FDA") issued a Warning Letter to Greenpark. 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 that put patients at risk.

26. 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.

27. The use of compounded pentobarbital from a suspect source, that is stored in unknown conditions and handled, prepared and administered without adequate safeguards, creates a substantial, demonstrated risk of severe pain at the time of execution.

28. Substandard compounded pentobarbital has a risk of forming visible,

solid precipitate. Visible chemical precipitates, when injected into the vasculature, can travel rapidly through the circulatory system to 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 extraordinary physical pain.

29. 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.

II. TDCJ has gone to great lengths to maintain secrecy around the source of its pentobarbital and prevent Garcia from learning the source of the drug it intends to use to execute him.

30. In the past few years, TDCJ has refused to disclose information about its drug source and has taken steps to prevent condemned prisoners, including Garcia, from learning information about the drugs' provenance, quality, and handling.

31. Given the information learned about Greenpark and the substantial concerns that raises, Garcia's counsel sent a letter to Lorie Davis, Director of the

Correctional Institutions Division of TDCJ, on November 28, 2018, the same day the facts discussed above became known to Garcia, requesting a notice of the source from which TDCJ has acquired or intends to acquire the pentobarbital or any related chemical that it intends to use in Garcia's execution. Garcia's counsel has received no response.

32. TDCJ's steadfast secrecy around the source of its pentobarbital has prevented Garcia from determining whether the drug it uses are degraded or contaminated, which would cause intolerable pain.

33. 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 presents a risk that is very likely to cause serious illness and needless suffering.

CLAIMS FOR RELIEF

CLAIM ONE

Defendants' use of compounded pentobarbital from a pharmacy that has a history of compounding unsafe drugs demonstrates deliberate indifference to Garcia's right to be free from cruel and unusual punishment; simultaneously, the use of the compounded pentobarbital creates a substantial risk of serious harm, violating Garcia's right to be free from cruel and unusual punishment.

34. Garcia incorporates by reference every statement and allegation set forth throughout this Complaint.

35. On information and belief, Defendants intend to execute Garcia with pentobarbital compounded by Greenpark, a source that has been repeatedly cited for

safety and sanitation violations by state and federal regulators, and has its license on probationary status. Defendants know or should know the risks involved in procuring and administering a compounded drug from a source with a documented history of producing substandard, faulty products that have harmed people.

36. State actors who knowingly permit the administration of and who administer pentobarbital from a source that has been repeatedly cited for safety and sanitation violations by state and federal regulators and that has its license on probationary status because of bad practices, are acting with deliberate indifference to Garcia's right to be free from cruel and unusual punishment.

37. Defendants' use of pentobarbital from Greenpark also creates a substantial risk of serious harm during Garcia's execution, thereby depriving Garcia of his right under the Eighth Amendment to the United States Constitution to be free from cruel and unusual punishments. This substantial risk of serious harm is unnecessary, given that TDCJ can procure pentobarbital from a different, reputable source.

38. Garcia is not challenging the use of compounded pentobarbital in his execution. Rather he is challenging the use of compounded pentobarbital sourced from Greenpark. For this reason, he need not plead an alternative method of execution.

39. Assuming arguendo that Garcia must plead an alternative, there is a

feasible and readily available alternative: source the execution drug from one of the other hundreds of sterile compounding pharmacies licensed in Texas that is not on probationary status and does not have safety citations.

CLAIM TWO

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.

40. Garcia incorporates by reference every statement and allegation set forth throughout this Complaint.

41. Defendants have failed to provide Garcia with the necessary information to determine how the State intends to carry out his death sentence, including information relating to the safety and provenance of the lethal-injection drugs TDCJ intends to use to execute him, and the safety record and licensure status of the drug's unreliable and potentially dangerous source.

42. Defendants' deliberate concealment of this information demonstrates a lack of transparency and reliability in its intended manner of executing Garcia.

43. Garcia is an "individual citizen" with a First Amendment right of access to governmental proceedings; he is also a prisoner who retains his First Amendment rights absent deprivation procedures that meet due-process requirements. 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.

44. The First Amendment right to petition the government for redress of grievances includes the right of access to the courts and protects the right of the People to know their government acts fairly, lawfully and accurately.

45. The right of access to the courts is especially critical for prisoners because their access to other remedies is limited.

46. State action that denies a plaintiff the opportunity to litigate gives rise to a claim that the State is violating the plaintiff's right of access to the courts.

47. The right of access to the courts is an ancillary claim, which is necessary for the vindication of underlying rights.

48. By deliberately concealing information about the drug that the State intends to use to execute Garcia, Defendants have erected a condition that frustrates Garcia's ability to litigate his claims relating to the constitutionality of his execution. This condition deprives Garcia of his First Amendment rights to petition the government for redress of grievances and of access to governmental proceedings.

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 courts.

49. Garcia incorporates by reference every statement and allegation set forth throughout this Complaint.

50. By failing to provide Garcia with notice and relevant information

regarding the source of the pentobarbital TDCJ intends to use in his execution, Defendants are violating Garcia's right to due process under the Fourteenth Amendment to the U.S. Constitution.

51. Garcia has a liberty interest in assuring that his executions are carried out in a manner consistent with the Eighth Amendment.

52. Defendants' deliberate concealment deprives Garcia of his ability to determine whether the State is capable of carrying out his executions in a lawful, constitutional manner. They have actively prevented him from successfully vindicating his Eighth Amendment rights.

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

CLAIM FOUR

Defendants' actions violate Garcia's right to equal protection under the law pursuant to the Fourteenth Amendment.

54. Garcia incorporates by reference every statement and allegation set forth throughout this Complaint.

55. Under the Equal Protection Clause, the government cannot make distinctions that 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.

56. On information and belief, other similarly situated condemned

prisoners executed by Defendants were injected with pentobarbital compounded by a pharmacy or pharmacies that were not on probationary status or did not have the litany of safety violations of Greenpark.

57. Defendants' use of pentobarbital compounded by Greenpark to execute Garcia constitutes disparate treatment. There is no rational basis to use pentobarbital compounded by Greenpark—as opposed other sterile compounding pharmacies—in Garcia's execution, and this also subjects Garcia to substantial risk of serious harm.

58. In addition, on information and belief, Defendants have not—and will not—test the compounded pentobarbital to be used in Garcia's execution in the days leading up to the December 4, 2018 execution and ensure the drug is safe for use.

59. 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.

60. Whitaker and Williams were condemned prisoners similarly situated to Garcia.

61. The failure of Defendants to test the pentobarbital compounded for Garcia's execution shortly before his execution to ensure the pentobarbital is safe for use is disparate treatment that burdens Garcia's fundamental Eighth Amendment rights, putting him at substantial risk for serious harm. The refusal to perform such testing also has no rational basis, since Defendants have shown the testing can be

readily and easily be performed.

62. Defendants' failure to adhere to critical terms of the execution procedure, like the concentration of the execution drug, creates a substantial risk of serious harm to Garcia as compared to the similarly situated condemned prisoners.

63 TDCJ's execution procedure requires the use of "100 milliliters of solution containing 5 grams of Pentobarbital," which translates to a solution concentration of 50mg/mL.

64. On information and belief, in some of the executions in 2017 and 2018, Defendants used a solution of pentobarbital at a concentration of 100 mg/mL, in violation of the execution procedure.

65. Defendants have consistently, but also arbitrarily, deviated from TDCJ's execution procedure, treating similarly situated condemned prisoners disparately for no rational reason.

66. Defendants' disparate treatment of Garcia from similarly situated condemned prisoners is without rational basis and burdens his fundamental Eighth Amendment right to an execution that is not cruel or unusual.

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PRAYER FOR RELIEF

WHEREFORE, Garcia prays for:

(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 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, and 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.

Jon M. Sands
Federal Public Defender
District of Arizona

Dale A. Baich
Jessica L. Felker

s/ Jessica L. Felker
Attorney-in-charge
IL Bar No. 6296357
Pending Pro Hac Vice Application
850 West Adams St., Suite 201
Phoenix, AZ 85007
(602) 382-2816
Jessica_Felker@fd.org

APPENDIX E

Email to Dale Baich from Amy Lee

From: "**Amy Lee**" <Amy.Lee@tdcj.texas.gov>
Date: Sun, Dec 2, 2018 at 4:03 PM -0700
Subject: RE: Joseph Garcia, No. 999441 (execution date Dec 4, 2018)
To: "Dale Baich" <Dale_Baich@fd.org>

Mr. Baich,

Attached please find the releasable responsive information pertaining to the below request dated November 28, 2018. Redactions made are pursuant to Texas Government Code §§ 552.1081, 552.136, 552.117 and in accordance with Attorney General Letter Rulings OR2018-25093 and OR2018-22458. The beyond use date is June 27, 2019 for the pentobarbital intended to be administered to your client on December 4, 2018.

At this time the TDCJ considers your request closed.

Amy Lee
Project Scheduler
Office of the General Counsel - TDCJ

Welcome To

[redacted]

10	PRESCRIPTION	6277.55 F

SUBTOTAL	6277.55
TOTAL	6277.55
MC	6277.55
FSA Eligible Items - Total	6277.55

MC SALE $6277.55
XXXXXXXXXXXX[redacted] CHIP
APPR: [redacted]
JOURNAL: [redacted]

AID: A0000000041010
Application Label: MASTERCARD
Cryptogram Type: TC
Cryptogram: [redacted]
PIN Statement: PIN Bypassed

ITEMS SOLD: 1

[redacted]

[redacted]
RegID: [redacted] Jun 18 2018 1:07 PM

THANK YOU FOR SHOPPING @ [redacted]
RETURNS WITH RECEIPT ONLY
****
GET $10 OFF OTC ITEMS
WITH PRESCRIPTION TRANSFER
****

[redacted]

Phone Order

xxxxxxxxxxx[redacted]
MASTERCARD Entry Method: Manual

Amount: $ 1,112.80
Tax: $ 0.00
Total: $ 1,112.80

08/22/18 10:23:20
Inv #: [redacted] Appr Code: [redacted]
Apprvd: Online
AVS Code:
CVV2 Code: MATCH M

Customer Copy
THANK YOU!

See Reverse of PURCHASER'S Copy for Instructions

No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).

OMB APPROVAL No. 1117-0010

[redacted]

DATE 13 JUN 18

TO BE FILLED IN BY PURCHASER:

Line No.	No. of Packages	Size of Package	Name of Item	NATIONAL DRUG CODE	TO BE FILLED IN BY [redacted] Packages Received	Date Received
1	15	100 ML	Pentobarbital Sodium 50mg/mL	[redacted]	15	6/18/18
2						
3						
4						
5						
6						
7						
8						
9						
10						

LAST LINE COMPLETED (MUST BE 10 OR LESS)

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT [redacted]

Date Issued: 04/01/2018

DEA Registration No. [redacted]

Name and Address of Registrant [redacted]

Schedules: 2, 2N, 3, 3N, 4, 5

Registered as a: CHAIN HOSP/CLINIC

No. of this Order Form [redacted]

DEA Form - 222 (AUGUST 2011)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
PURCHASER'S Copy 3

[redacted]

See Reverse of PURCHASER'S Copy for Instructions

No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).

OMB APPROVAL No. 1117-0019

[redacted]

DATE 6-20-18

TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No. [redacted]

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	1	100ml	PENTOBARBITAL 50mg/ml			
2						
3						
4						
5						
6						
7						
8						
9						
10						

◁ LAST LINE COMPLETED (MUST BE 10 OR LESS)

SIGNATURE OF PU OR ATTORNEY OR [redacted]

Date Issued

[redacted]

DEA Registration No. [redacted]

Name and Address of Registr [redacted]

Schedules

2, 2N, 3, 3N, 4, 5,

Registered as a

RETAIL PHARMACY

No. of this Order Form [redacted]

[redacted]

DEA Form - 222
(AUGUST 2011)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

SUPPLIER'S Copy 1

Huntsville Unit
Storage Inventory
Pentobarbital 100mg/ml (5 grams)

Date	Name of Offender	TDC#	Inventory Total	Amount Taken	Amount Added	Inventory Total	Ref # (2)
4/25/18	Davila, Erick	999545	3	2		1	[redacted]
4/25/18	Davila Erick (Return)	999545	1		1	2	
5/16/18	Castillo Juan	999502	2	2		0	
5/16/18	Return	999502	0		1	1	
6/18/18	Stock Received	—	1		15	16	
6/20/18	Removed from Stock (Test)	—	16	1		15	
6/27/18	Bible, Danny	999455	15	1		14	
6/27/18	Return	999455	14		0	14	
9/26/18	Clark, Troy	999351	14	2		12	
9/26/18	Return	999351	12		1	13	
9/27/18	Acker, Daniel	999381	13	2		11	
9/27/18	Acker, Daniel (Return)	999381	11		1	12	
11/14/18	Ramos, Robert	999062	12	2		10	
11/14/18	Return	999062	10		1	11	

Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

[redacted]

LABORATORY REPORT

Client #: [redacted]
Sample: Pentobarbital
Conc.: 50mg/mL
Lot #: [redacted]
Sample ID #:
Date Rec'd: 06/22/2018

Chemistry Tests:	*Date*	*Reported*	*Measured*	*Potency*
Pentobarbital	06/27/2018	50.0 mg/mL	49.0 mg/mL	98.0 %

Microbiology Tests:	*Date*	*Measured*	*Result*
Scan RDI	06/25/2018		Pass
Bacterial Endotoxins	06/25/2018	<1.00 EU/mL	Pass -

Notes:

Bacterial Endotoxins: Endotoxins are measured using USP<85> Turbidimetric procedure, with an inhibition / enhancement test performed on each sample.

Potency: Potency is determined via USP <621> HPLC, USP<851> Spectrophotometry, and specific monograph testing procedures.

Respectfully submitted,

[redacted]

[redacted]

TEXAS DEPARTMENT OF CRIMINAL JUSTICE

CORRECTIONAL INSTITUTIONS DIVISION

EXECUTION PROCEDURE

July 2012

ADOPTION OF EXECUTION PROCEDURE

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

R C Thaler

Rick Thaler
Director, Correctional Institutions Division

7-09-2012

Date

EXECUTION PROCEDURES

PROCEDURES

I. Procedures Upon Notification of Execution Date

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

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

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

II. Stays of Execution

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

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

III. Preparation of the Execution Summary and Packet

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

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

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

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

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

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

6. The Death Row Unit is responsible for completion of the Execution Packet, which shall include:

   a. Execution Summary;

   b. Religious Orientation Statement;

   c. Copy of the Offender Travel Card;

   d. Current Visitation List;

   e. Execution Watch Notification;

   f. Execution Watch Logs;

   g. I-25 Offender's Request for Trust Fund Withdrawal;

   h. Offender Property Documentation (PROP-05 and PROP-08); and

   i. Other documents as necessary.

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

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

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

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

B. The Day of Execution

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. Drug Team Qualifications and Training

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

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

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

V. Pre-execution Procedures

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

B. Inventory and Equipment Check

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

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

3. An inventory and equipment check shall be conducted.

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

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

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

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

F. The CID Director or designee, the Huntsville Unit Warden or designee and the Huntsville Unit Chaplain or a designated approved TDCJ Chaplain shall accompany the offender while in the Execution Chamber.

VI. Set up Preparations for the Lethal Injection

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

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

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

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

VII. Execution Procedures

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

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

C. A medically trained individual shall insert intravenous (IV) catheters into a suitable vein of the condemned person. If a suitable vein cannot be discovered in an arm, the medically trained individual shall substitute a suitable vein in another part of the body, but shall not use a "cut-down" procedure to access a suitable vein. The medically trained individual shall take as much time as is needed to properly insert the IV lines. The medically trained individual shall connect an IV administration set, and start a normal saline solution to flow at a slow rate through one of the lines. The second line is started as a precaution and is used only if a potential problem is identified with the primary line. The CID Director or designee, the Huntsville Unit Warden or designee, and the medically trained individual shall observe the IV to ensure that the rate of flow is uninterrupted.

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

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

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

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

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

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

J. The CID Director or designee and the Huntsville Unit Warden or designee shall observe the appearance of the condemned individual during application of the Pentobarbital. If, after a sufficient time for death to have occurred, the condemned individual exhibits visible signs of life, the CID Director or designee

shall instruct the drug team to administer an additional 5 grams of Pentobarbital followed with a saline flush.

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

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

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

APPENDIX F

Email to Dale Baich from
Edward Marshall

From: Marshall, Edward <edward.marshall@oag.texas.gov>

Sent: Monday, December 3, 2018 10:07 AM

To: Dale Baich

Cc: Clendenin, Jay

Subject: Joseph Garcia, No. 999441 (execution date Dec 4, 2018)

Dale, the Texas Public Information Act does not require a governmental body to answer factual questions, conduct legal research, or create new information in responding to a request. See Open Records Decision Nos. 563 at 8 (1990), 555 at 1-2 (1990). My client has provided all the responsive information required or permitted under state law. Please direct any further correspondence regarding this matter to myself or Jay Clendenin, the Assistant Attorney General in charge of Joseph Garcia's case. Thank you!

Edward L. Marshall

Chief, Criminal Appeals Division

Office of the Attorney General

P.O. Box 12548

Austin, Texas 78711-2548

(512) 936-2891

Dear Ms. Lee,

I have reviewed the documents you sent to me on Sunday, December 2, 2018, and the documents and your note are not responsive to my request dated November 28, 2018. In my request, I listed ten specific questions and they were not addressed. You noted in your email to me that "TDCJ considers [my] request closed." However, I am renewing my request and ask TDCJ to respond to my questions.

Best

regards.

Dale A. Baich

FPD AZ CHU

602-382-2816 office

602-625-2111 mobile