IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

ALFREDO R. PRIETO, **Plaintiff,** **v.**	**Civ. Act. No.** 1:15-CV-1258 (AJT/MSN)
HAROLD W. CLARKE, **Director, Virginia Department of Corrections,**	**IMMINENT EXECUTION SCHEDULED FOR OCTOBER 1, 2015 AT 9:00 P.M.**
EDDIE PEARSON, **Warden, Greensville Correctional Center,**	
DAVID ZOOK, **Warden, Sussex I State Prison,**	
OTHER UNKNOWN EXECUTIONERS, EMPLOYEES, AND AGENTS, Virginia Department of Corrections,	
Defendants.	

COMPLAINT AND MEMORANDUM OF LAW

On September 22, 2015, just after close of business, counsel for Petitioner Alfredo R. Prieto received information suggesting for the first time that Defendants, all agents of the Virginia Department of Corrections (referred to collectively as "the VDOC"), had changed the drugs they planned to use to put Mr. Prieto to death on October 1, 2015. In response to an inquiry made pursuant to the Virginia Freedom of Information Act (FOIA) (Va. Code § 2.2-3700, et seq.), the VDOC revealed that it had disposed of its supply of midazolam, a benzodiazepine sedative, that the VDOC had previously said it would use instead of a barbiturate as the first of three drugs in its

lethal injection procedure. The VDOC further revealed that it had obtained from the Texas Department of Criminal Justice ("TDCJ") three 2.5-gram bottles of a substance purported to be pentobarbital, a fast-acting barbiturate, apparently made by a compounding pharmacy. Ex. A at 12, 14. In response to a request for "[a]ny and all documents . . . relating to attempts by the VDOC to acquire compounded execution drugs between January 2015 and the present.[,]" the VDOC reported that "[t]he requested documents do not exist." Ex A at 2.

In its response to the FOIA request, the VDOC admitted that it failed to make reasonable inquiry, or, indeed any inquiry, into the quality and authenticity of the purported pentobarbital, where it was made and by whom, the conditions of its storage and transfer, or any other information necessary to assess the risks involved in using the chemicals in the VDOC's possession. Instead, the VDOC recklessly obtained a drug that it plans to use to execute Mr. Prieto, without any background information, from a source that is not regulated in the way pharmaceutical manufacturers are. The information VDOC failed to obtain is critically important due to the serious risk of harm involved in using purportedly compounded pentobarbital as the first drug in Mr. Prieto's execution by a three-drug protocol.

Mr. Prieto asks the Court to enjoin Defendants from carrying out the execution in the manner currently intended—relying on compounded pentobarbital (a high-risk sterile preparation) from a secret source—until Defendants provide evidence establishing that they exercised due diligence in acquiring and analyzing crucial information needed to assess the risks involved in using the purported compounded pentobarbital transferred from the TDCJ. This information should include:

i.) the identity of the actual supplier of the drugs transferred from the TDCJ, and the character and quality of the supplier's facility and record of safe and stable compounded sterile preparations (CSPs);

ii.) scientific testing confirming current and sufficient sterility and potency of the drug transferred by the TDCJ; and

iii.) documentation and other evidence establishing the condition of the handling of the drugs, including storage and transportation.

Mr. Prieto meets the standard for preliminary injunction, as he shows: (1) that he is likely to succeed on the merits; (2) that he is likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in his favor; and (4) that an injunction is in the public interest. *See Winter v. Natural Res. Def. Counsel,* 555 U.S. 7, 20 (2008).

I. Nature of Action

This action is brought pursuant to 42 U.S.C. § 1983 for violations, threatened violations, or anticipated violations of Plaintiff's right to be free from cruel and unusual punishment guaranteed by the Eighth Amendment and the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

The suit does not challenge the fact of Plaintiff's conviction or death sentence, nor does it challenge the constitutionality of Virginia's statute providing for execution by lethal injection or electrocution. Plaintiff's action, if successful, would not vacate his sentence or prevent the Commonwealth from executing him. Plaintiff seeks only to enjoin the Defendants from executing him in a manner that causes a foreseeable risk of gratuitous and unnecessary pain. Plaintiff concedes that the Defendants could modify their procedures in ways that would make them constitutional. No Virginia statute or regulation requires the Defendants to use the current challenged procedures.

II. The Parties

Plaintiff Alfredo Prieto is a death-sentenced inmate in the custody of Defendants and under the control and supervision of the Commonwealth of Virginia Department of Corrections. His Department of Corrections (DOC) Number is 1391143. Plaintiff is presently being held at Greensville Correctional Center. His execution is scheduled for October 1, 2015.

Defendant Harold W. Clarke is the Director of the Commonwealth of Virginia Department of Corrections, 6900 Atmore Drive, Richmond, VA 23225; phone (804) 674-3000. Defendant Eddie Pearson is the Warden at Greensville Correctional Center, 901 Corrections Way, Jarratt, VA 23870-9614; phone (434) 535-7000. Greensville Correctional Center is the facility at which Defendants plan to carry out Plaintiff's execution. Defendant David Zook is the Warden at Sussex I State Prison, 24414 Musselwhite Drive, Waverly, Virginia, 23891-1111, phone (804) 834-4000. Sussex I State Prison is the facility where Plaintiff was held on Death Row prior to being moved to Greensville Correctional Center. Other unknown Defendants are corrections officers, pharmacists, physicians, medical personnel, executioners, and other unknown individuals who are employed by, have a contractual relationship with, or perform appointed or voluntary work for the Commonwealth of Virginia Department of Corrections. They will participate in Plaintiff's execution by virtue of their roles in designing, implementing, and/or carrying out the lethal injection process. Plaintiff does not know, and it is Plaintiff's understanding that the Defendants will not reveal, the identities of these persons.

III. Jurisdiction and Venue

This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 (federal question), 1343 (civil rights violations), 2201 (declaratory relief), and 2202 (further relief). This action arises under the Eighth and Fourteenth Amendments of the United States Constitution and under 42 U.S.C. § 1983. A challenge to the constitutionality of a state's procedures for lethal injection comes within the scope of § 1983. *Hill v. McDonough*, 126 S. Ct. 2096, 2099 (2006).

Venue in this Court is proper under 28 U.S.C. § 1391(b) because all the events giving rise to this claim have occurred and will occur within the Eastern District of Virginia. The Court has personal jurisdiction over the Defendants because they are located within this District.

IV. Factual Allegations

In a response dated September 16, 2015, the VDOC responded to a request for information made pursuant to the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). Ex. A. According to the documents provided by the VDOC, the VDOC filled out an order form on August 26, 2015, requesting 3 packages of 50 ml of pentobarbital sodium from the TDCJ. Ex. A. In response to a request for documents or records containing expiration dates and lot numbers of drugs intended or considered for use in executions by the VDOC, the VDOC produced a photograph of three bottles labeled "Pentobarbital, Lot: 04142015@8." Ex. A at 12. The labels claim a "UseBy" date of April 14, 2016.[1] *Id.*

[1] The VDOC also claimed that no other document existed relating to any attempts by the VDOC to acquire compounded execution drugs between January 2015 and the present. Ex. A at 2.

Upon information and belief, the VDOC will use the purported pentobarbital in the execution of Alfredo Prieto, currently set for October 1, 2015. Other drugs listed in the documents as held by the VDOC for potential use in lethal injection are: midazolam (expiring September 2015); rocuronium bromide; and potassium chloride. Ex. A. It appears that the VDOC plans to use the purported pentobarbital as the first drug of a three-drug protocol, with rocuronium bromide as the second drug and potassium chloride as the third drug. *See* Ex. B at 19-22. *See also* Ex. C.

Upon information and belief, the purported pentobarbital held by Virginia is compounded. *See, e.g.*, Ex. C. No information has been provided about the identity or capacity of the compounding pharmacy that made the purported pentobarbital provided by the TDCJ, the ingredients used to make the preparation, the circumstances under which the preparation was made, or the manner in which the preparation has been stored, handled, and transported since it was compounded for the TDCJ. According to a TDCJ spokesman, Jason Clark, the drugs provided to the VDOC "have been tested for purity and will expire in April 2016. State law [in Texas] prohibits the agency from disclosing the identity of the supplier of lethal injection drugs." Ex. D. It appears that the VDOC did not request, investigate, obtain, or confirm any of the information listed above about the purported pentobarbital, or the results of any alleged testing.[2] The only

[2] The submitted FOIA request asked for:

> Documents or records in any form (including but not limited to packaging, labels on drug vials and package inserts) containing the expiration date(s) and /or lot numbers of any and all drugs intended or considered for use in executions currently in the possession of the VDOC, including but not limited to the following drugs: sodium thiopental, pancuronium bromide, rocuronium bromide, vecuronium bromide, propofol, potassium chloride, pentobarbital, phenobarbital, brevital, midazolam and hydromorphone.

potential identifying information regarding the labeler/manufacturer is the National Drug Code (NDC) number, "51927 361300," a unique identifier code. The first five numbers are supposed to identify the manufacturer of the drug. Because the VDOC was able to fill out the DEA 222 form with the NDC, they would have had information about the source and therefore would have been able to appropriately investigate matters such as the source and quality of the drug if they chose to do so—apparently, they did not.

"Compounding" is a practice used by pharmacists to combine, mix, or alter ingredients to create "pharmaceutical preparations." There are two types of compounding: Traditional (503 A) and Non-traditional (503 B). Traditional compounding typically is used to prepare drugs prescribed to an individual who, for medical reasons, cannot have his or her needs met with an FDA-approved product. Non-traditional compounding more closely resembles drug manufacturing than it does the practice of pharmacy. Unlike pharmaceutical manufacturers, compounding pharmacies are generally not subject to the rigorous drug approval process and the certain checks and regulatory procedures required under FDA standards. The FDA does not verify the safety or effectiveness of drugs prepared in these pharmacies or the quality of their

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Ex. A at 1. In response, the VDOC provided photographs of packaging, stating, "[s]ee Attachment II for copies of documents maintained by the Department that are responsive to your request." Ex. A at 1, 12. *Compare* Ex. E (asking for "Lot #" of sample).

The request also asked for:

> Any and all documents or correspondence (including but not limited to emails, faxes, letters, memos of telephone calls) relating to attempts by the VDOC to acquire compounded execution drugs between January 2015 and the present.

Ex. A at 2. In response, the VDOC reported, remarkably, that no such documents exist. Ex. A at 2.

manufacture. Compounded preparations made at these facilities, thus, remain outside the FDA regulatory framework that ensures the quality of pharmaceuticals.

However, since a serious fungal meningitis outbreak in 2012, the FDA has begun to inspect some compounding pharmacies. When problems were identified, the FDA issued a Form FDA-483; according to the FDA website, federal inspectors:

> have issued a Form FDA-483 at the majority of the inspections we have conducted since the fall of 2012. As these Form FDA-483s reflect, we observed serious quality problems, including contaminated products and sterile practices that create a risk of contamination. Numerous recalls of sterile products have been conducted, and numerous pharmacies chose to stop sterile compounding after we identified problems with their sterile compounding processes. New problems continue to be identified at compounding pharmacies across the country . . .

FDA, *FDA Implementation of the Compounding Quality Act*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm (last visited Sept. 29, 2015).

Compounding involves the use of raw ingredients, called Active Pharmaceutical Ingredients (APIs). There are significant questions about the quality of APIs used in compounding. Compounding pharmacies have been identified as "a primary route of entry for counterfeit bulk drugs." Ex. F at 4 (citing Prepared Statement of Honorable Fred Upton before the Subcommittee on Oversight and Investigations Counterfeit Bulk Drugs, June 8, 2000, available here: http://www.gpo.gov/fdsys/pkg/CHRG-106hhrg65846/html/CHRG-106hhrg65846.htm). It is difficult to trace the raw chemicals back to the original manufacturer for quality information. So, a chemical labeled as a certain active ingredient may actually be a different ingredient, and there is no way to have confidence that the APIs are not contaminated. Ex. F at 5. If poor ingredients are

used, "[t]he compounded drug may be contaminated, super-potent or sub-potent, non-sterile, or at risk of an unusually short shelf life." Ex. F at 5.

Compounded pentobarbital is classified as a high-risk sterile injectable. *See* United States Pharmacopeia ("USP") General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations.[3] The compounding of pentobarbital must be a sterile process and must be carried out under specific environmental conditions, using precise equipment and performed by highly trained personnel. There is very little tolerance for error. Ex. G-A at 4-5.

Because compounding pharmacies do not typically have the type of sophisticated equipment used by FDA-approved manufacturers—equipment that is necessary to produce high quality and large quantities of pharmaceuticals—compounding pharmacies keep batch sizes small, and set relatively short "beyond use dates" (BUDs) for compounded drugs.[4] Compounded drugs have short BUDs because they degrade and become ineffective more quickly than manufactured drugs, which must meet stringent requirements regarding contamination, dilution, and degradation. *See* Ex. G at 2.

According to USP <797>, storage periods for high-risk compounded sterile preparations (CSPs) cannot exceed the following time periods before administration (in the absence of passing a sterility test):

24 hours, if stored at room temperature;

[3] The USP is the seminal scientific advisory publication concerning the compounding of sterile injectables.

[4] "Beyond use dates" often are confused with "expiration dates." Expiration dates are assigned to manufactured product based on rigorous analytical and performance testing. The expiration date of FDA regulated pharmaceuticals is a qualified assurance that they retain their integrity over specified periods of time. The lack of standards makes it difficult to determine an expiration date for a compounded drug.

72 hours, if kept refrigerated, or

45 days, if kept in a solid, frozen state.[5]

The United States Pharmacopeial Convention, <797> Pharmaceutical Compounding-Sterile Preparations at 574 (included as Ex. H). To set a BUD beyond these periods, extensive and documented sterility testing is necessary. Ex.G at 3. Even then, dates are usually set within 90 days or a bit longer in optimal conditions. Ex. G at 3. Estimated BUDs depend on the nature and quality of raw ingredients used, the quality of the process applied by the compounding pharmacy, and the precision and professionalism of the testers of the drug in question. Whether the pharmacy employs the more stringent conditions to increase the BUD beyond 3 days "can be determined by inspecting documentation relevant to the pharmacy and the testing." Ex. G at 3. The bottles holding the purported pentobarbital supplied by the TDCJ have labels suggesting that the BUD for the CSP contained therein is one year. Ex. A at 12.

Because any BUD can be dramatically affected by subsequent storage conditions, CSPs must be kept in very carefully prescribed conditions relating to the stability and properties of the specific medicine in question. Stability "depends on the purity and concentration of specific ingredients, packaging and environmental exposure and storage (humidity, illumination and temperature), especially for solutions. Small changes in any one of those variables can cause rapid loss of drug strength or much shorter than expected shelf-life." David Newton & Bernard Dunn, *A Primer on USP Chapter <797> "Pharmaceutical Compounding-Sterile Preparations," and USP Process for Drug and Practice Standards, available at*

[5] A pentobarbital preparation cannot be frozen, because freezing degrades the preparation. Ex. G at 2.

http://www.nhia.org/members/documents/usp_797_primer.pdf. For example, difference by one pH unit in some solutions can decrease stability to less than 50% of the BUD time assigned; "[t]here can be danger in either assuming correct compounding or expecting a seemingly small formulation change to produce an insignificantly small stability change." *Id.* This confirms the importance of testing—relating to both stability and sterility—multiple times over a drug's shelf life, not just shortly after it is compounded.

The fragility of CSPs justifies chemical testing to assess whether the preparation has retained its integrity. Independent laboratories can be enlisted to test compounded drugs for a wide variety of characteristics, including identity, strength, and contaminants. Pharmacist Larry Sasich has noted that, "[a]dding to the problems of the known risks of pharmacy compounded injectable drugs made from non-sterile bulk API is the testing of these drugs by contract testing laboratories . . . Too often, however, these labs are themselves substandard . . . Five laboratories that test compounded drugs have had enforcement actions taken against them by the FDA." Ex. F at 9. Although "[a] product that passes testing is assumed to have met minimum standards for quality," "the results obtained from contract testing laboratories used by compounding pharmacies are not reliable and should not be used to make reliable decisions about the safety, efficacy, and quality of pharmacy-compounded drugs."[6] Ex. F at 9. *See also* Kimberly Kindy, *Labs that test safety of custom-made drugs fall under scrutiny*, Washington Post (Oct. 5,

[6] In at least one Texas case, the TDCJ provided the results of testing conducted by Eagle Laboratories. Eagle Laboratories is one of the labs under FDA scrutiny, including problems with potency tests. *See* Kimberly Kindy, *Labs that test safety of custom-made drugs fall under scrutiny*, Washington Post (Oct. 5, 2013), http://www.washingtonpost.com/politics/labs-that-test-safety-of-custom-made-drugs-fall-under-scrutiny/2013/10/05/18170a9e-255f-11e3-b3e9-d97fb087acd6_story.html; Ex. L.

2013), http://www.washingtonpost.com/politics/labs-that-test-safety-of-custom-made-drugs-fall-under-scrutiny/2013/10/05/18170a9e-255f-11e3-b3e9-d97fb087acd6_story.html ("[t]housands of contaminated or potentially tainted medications have made it to market over the past year after laboratories responsible for testing custom-made pharmaceutical products failed to follow proper procedures, FDA records show.").

There have been demonstrated risks as a result of using drugs from compounding pharmacies, including compounded pentobarbital. Execution drugs purporting to be compounded pentobarbital have a very poor performance history. When Oklahoma executed Michael Lee Wilson in January 2014, it used compounded pentobarbital as the first of three drugs. Upon administration of the purported pentobarbital, Mr. Wilson cried out, "I feel my whole body burning!" Charlotte Alter, *Oklahoma Convict Who Felt "Body Burning" Executed With Controversial Drug*, Time Magazine, Jan. 10, 2014. Mr. Wilson's reaction is consistent with exposure to contaminants introduced by the unsafe compounding of pentobarbital. Ex. I at 3 ("the injection used in Mr. Wilson's execution likely contained cross-contaminates that he was allergic to, bacteria and endotoxins . . . . [and] could have had an altered pH due to contaminates or inadequate procedures used in the preparation of the drug."). Jose Luis Villegas similarly complained of a burning sensation when Texas executed him with compounded pentobarbital in April of 2014. *See* Vivian Kuo & Ralph Ellis, *U.S. Supreme Court grants stay of 'excruciating execution,'* CNN, May 21, 2014.

When Eric Robert was executed with compounded pentobarbital in South Dakota in October 2012, he gasped heavily and snored. His skin turned a blue-purplish hue. His

eyes remained open throughout the execution. He took more than twenty minutes to die. Dave Kolpack & Kristi Eaton, *Eric Robert Execution*, Associated Press, http://www.huffingtonpost.com/2012/10/16/eric-robert-execution_n_196940.html. Mr. Robert's heart continued to beat ten minutes after he stopped breathing. Steve Young, Argus Leader, *Execution: South Dakota delivers Eric Robert his death wish*, http://archive.argusleader.com/article/20121016/NEWS/310160016/Execution-South-Dakota-delivers-Eric-Robert-his-death-wish. These events were "consistent with the administration of a compounded drug that was contaminated or sub-potent." Ex. I at 3.

The manner in which the VDOC came into possession of drugs from the TDCJ supports concerns that VDOC is willing to take extraordinary risks in order to carry out Mr. Prieto's execution. Not only has the VDOC recklessly failed to inquire into the preparation's manufacturer, circumstances of preparation, and conditions of storage and transport, it appears that the VDOC has violated both state[7] and federal[8] laws in order to obtain the drugs. This raises further questions about the VDOC's good faith.

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[7] "It is unlawful for any person or entity which is not registered under this article to conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia." Va. Code § 54.1-3434.4. Pentobarbital is a Schedule II substance. Va. Code § 54.1-3448. The Virginia Board of Pharmacy has provided that "only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia." *See* Va. Bd. of Pharmacy Guidance 110-36, at 10, *available at* https://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm. The TDCJ is not included as a registered nonresident pharmacy. In past legal proceedings, the VDOC has maintained it operates free of any restrictions on pharmacies because it is not engaged in the practices of medicine, anesthesiology, or pharmacy when it acts with regard to lethal injections. Brief in Opposition at 21, *Shapiro v. Va. Dep't of Corrections*, No. 122176. But the VDOC has no authority outside its operation as a pharmacy to possess, transport, or administer Schedule II substances. In order to be exempted from the applicable criminal statute prohibiting possession of controlled substances, Va. Code § 18.2-248, the VDOC must be authorized by the Drug Control Act, Va. Code § 54.1-3400, *et seq.* The Act, however, generally authorizes the dispensation of these controlled substances by health care professionals. Nothing in the statute authorizes the VDOC to possess, dispense, sell, or transfer these controlled substances in the ways it appears to have acted. For instance, Mr. Prieto will not be given these chemicals by a "pharmacist . . . pursuant to a prescription of a prescriber." Va. Code § 54.1-3410. Nor will the chemicals be given by a medical practitioner "in good faith for medicinal or therapeutic purposes." Va. Code § 54.1-3408. The VDOC has communicated about the challenges of conforming its proposed use of

V. The Manner In Which Defendants Intend to Put Mr. Prieto to Death Involves Substantial Risk of Serious Harm In Violation of the Eighth Amendment.

Mr. Prieto alleges, based on the information available to him and this Court about the intended manner in which the VDOC is prepared to kill him, that there is a substantial, unacceptable and unnecessary risk that his execution will amount to cruel and unusual punishment in violation of the Eighth Amendment. To prevail on such a claim, "there must be a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment.'" *Baze v. Rees*, 553 U.S. 35, 50 (2008) (quoting *Farmer v. Brennan,* 511 U.S. 825, 846, and n. 9 (1994)). The controlling opinion also states that prisoners "cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative." 553 U.S. at 51.

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compounded drugs in executions to state and federal law. *See* Ex. J (noting that there would be no "prescriber," and that a proposed exception might be against federal law).

[8] Because pentobarbital is a Schedule II controlled substance, in order for the drug to be delivered or transferred, a valid prescription written by a licensed practitioner is necessary. CFR Title 21, §1306.11. To be effective, the prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of her professional practice. CFR Title 21, §1306.04. A person who issues a prescription and the person who knowingly fills a prescription that is not in the usual course of business are subject to penalties under the Controlled Substances Act. *Id.* It is unlawful for any person, including a registrant, to distribute a Schedule II controlled substance without a prescription. U.S.C. §842 (Prohibited acts B); U.S.C. §843 (Prohibited acts C). Whether the drugs provided to VDOC were made by a traditional compounding pharmacy, or a non-traditional outsourcing facility, it is clear that the absence of a prescription would be in violation of the Federal Food, Drug and Cosmetic Act (FFDCA) and the Drug Quality and Security Act (DQSA). If the drugs were supplied by a "traditional" compounding pharmacy Section 503A of the FFDCA states that pharmacies must compound only for "an identified individual patient" on receipt of a "valid prescription order" that a compounded product is "necessary for the identified patient" (section 503A(a) of the FD&C Act). Here there is no valid prescription order and there is no identified individual patient for whom the compounded product is necessary. If the drugs were supplied by an "outsourcing facility," Section 503B of the FFDCA provides that the outsourcing facility may only compound with a bulk drug substance which appears on an FDA list of drugs for which there is a clinical need, or which are on the FDA's drug shortage list. Pentobarbital is not on the drug shortage list. The drugs being compounded are effectively copies of existing drugs and there is no demonstrable clinical need for the drugs in these circumstances. Under the FFDCA, it is unlawful to compound drugs that are "essentially copies of existing drugs," unless those drugs are in shortage (which pentobarbital is not).

Instead, prisoners must identify an alternative that is "feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain."[9] *Id.* at 52.

The record of occurrences of abhorrent and cruel executions, and the substantial and foreseeable risks associated with the use of compounded pentobarbital, establish that the VDOC's use of compounded pentobarbital provided by the TDCJ presents an unnecessary and unreasonable risk of pain and suffering.[10] This is especially so in light of the ease with which the VDOC could incorporate safeguards to ensure that any compounded pentobarbital that is used is what it purports to be and meets the necessary quality standards to bring about an effective, constitutional execution.

Risks attendant to the use of a sub-standard compounded drug include "that the compounded drug will be sub-potent, expired, contaminated, contain unintended additives, or will contain a substantial level of particulates." Ex. I at 1. Deficiencies in storing and handling the drugs in compliance with very specific guidelines create the risk that the compounded drugs will expire before they are used.

The acidity/alkalinity (pH) of any injectable drug must be carefully adjusted. Both compromised ingredients and improper compounding procedures can cause the pH of an injectable drug to be off-balance. If the pH of the preparation is off-balance in a way

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[9] Petitioners' arguments in *Baze* and *Glossip* failed because they did not ultimately prove that any risk posed by the objectionable drug was substantial "when compared to known and available alternative methods of execution," and that the drug would cause severe pain and suffering. *Glossip v. Gross*, 135 S. Ct. 2726, 2737-38 (2015).

[10] Mr. Prieto requests discovery and a fair opportunity to prove his claims. Because of the VDOC's refusal to provide information about many of the questions and issues relating to this purported pentobarbital, and the delay in providing this information, the VDOC has successfully thwarted further investigation into the purported pentobarbital. As described *supra*, the VDOC's change from midazolam to purported compounded pentobarbital obtained from the TDCJ, was revealed just over a week prior to Mr. Prieto's scheduled execution. Counsel promptly requested additional information from the VDOC. As of the time of this filing, no information has been provided.

to make the preparation more caustic than properly manufactured pentobarbital, injection of the purported pentobarbital "would [] cause[]. . . intense, burning pain upon injection." Ex. I at 2. In addition, an out-of-balance pH could cause the ingredients to fall out of the solution in the form of particles, creating risks that the particle contaminates could "become lodged in small blood vessels . . . [or] in a prisoner's lungs," which "would be extremely painful." Ex. I at 2. An out-of-balance pH could also reduce the potency of the drugs. *Id.*

If the preparation is created from non-sterile ingredients, or at a facility or by an individual that lacked the expertise to maintain sterility and quality of the drug, the drug can become "contaminated with fungi, bacteria, and other contaminates." Ex. I at 2. Contaminates include "[e]ndotoxins . . . [which] would elicit an inflammatory reaction and can result in shock." Ex. I at 2. Or, the preparations can become contaminated with a different drug from the same facility. Sterile preparations manufactured from non-sterile ingredients (like the purported pentobarbital in the possession of the VDOC) must be stored and transported within specific temperature requirements. If these are not followed, there is increased risk of "microbial growth, chemical degradation, contamination from physical damage to packaging, and permeability of plastic packaging." Ex. I at 3-4.

The labels on the bottles of the purported pentobarbital supplied by the TDCJ claim that the drug has a BUD of April 14, 2016, a full year after the drugs were compounded. This claim alone requires due diligence to inquire into and obtain the results of sterility testing. *See* Ex. G at 2 ("This is an exceptionally long period of time to claim as a BUD for a high-risk compounded sterile preparation (CSP) like compounded

pentobarbital.") If the maximum established BUD for CSPs without extensive sterility testing is applied to the drugs supplied by the TDCJ, the longest BUD available (3 days, because pentobarbital cannot be frozen) far exceeds the time between the apparent compounding of the drugs (April 2015) and the date they were transferred to VDOC (August or September 2015). If such sterility testing was not performed, there are serious questions about the viability of these drugs. Even if the testing was performed, the time between mixing and Mr. Prieto's execution is well outside the typical 90 days of an extended BUD. *See* Ex. G at 3. Once a drug such as compounded pentobarbital passes its BUD, the potency decreases:

> The rate of degradation is exponential. This is a logarithm—for example, although it may take several months to reach the BUD and a 90% potency, the potency could reach a much lower percentage just several days later. If a drug such as pentobarbital is less potent, this could mean that it would not affect a patient in the same way that a drug at full potency would.

Ex. G at 3.

In addition to the "substantial risk of serious harm" and the "objectively intolerable risk of harm" inherent in the use of sub-standard compounded pentobarbital, use of ineffective pentobarbital as the first drug of a three-drug protocol creates the substantial risk that Mr. Prieto will not be anesthetized for the administration of the second and third drugs. There is a "substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide[11] and pain from the injection of potassium chloride," *Baze*, 553 U.S. at 53, if the purported pentobarbital is ineffective and fails to render Mr. Prieto unconscious and insensate.

[11] Pancuronium bromide has been replaced by rocuronium bromide in Virginia's protocol. *See* Ex. B at 19-22.

The VDOC admitted in its September 16, 2016 response to a FOIA inquiry that there were no "documents or correspondence (including but not limited to emails, faxes, letters, memos of telephone calls) relating to attempts by VDOC to acquire compounded execution drugs between January 2015 and the present." Ex. A at 2. This admission establishes that the VDOC made no documented effort to learn, and received no information, about who made the purported pentobarbital and how, its conditions of storage, the method and conditions of its transport, and the quality of the preparation. The VDOC responded similarly to several requests in August, just shortly before they placed the August 26, 2015 order. *See* Ex. B. For example, the only disclosed correspondence in response to a request for "any records and/or documents in any form from March 2015 to the present reflecting any activity by the VDOC to purchase or acquire any drugs for use in executions, including but not limited to purchase orders, email or fax correspondence, or written notes from phone conversations, about attempts to purchase or acquire such drugs, and internal communications about such attempts, purchase, or acquisitions," was one email from the VDOC pharmacist in March of 2015 discussing midazolam, and saying "I will continue to check on this and explore other options." Ex. B at 13.

In summary, use of the purported pentobarbital obtained from the TDCJ creates a demonstrated risk of serious pain. Compounded preparations are not FDA-approved—the FDA does not verify their identity, quality or effectiveness. Preparation of drugs intended for intravenous administration, such as pentobarbital, is acknowledged to be "one of the most difficult of all pharmaceutical processes to execute," Ex. F at 3, and there are significant issues about obtaining the raw ingredients and about the

mixture, Ex. F at 4. Furthermore, the drugs are subject to contamination, and failure to comply with storage requirements for the delicate preparation introduces further risk of substantial harm and pain due to damage of the preparation. Without proper testing at multiple stages and at a reliable laboratory, use of the compounded pentobarbital creates a substantial risk of serious pain and suffering, including that Mr. Prieto would not be unconscious when the second two drugs are administered to him.

A known and available alternative to Virginia's current execution method exists: use of a fast-acting barbiturate that (1) carries FDA approval for use in humans; or (2) for which the VDOC has taken reasonable and appropriate measures to ensure appropriate safeguards, including transparency as to the execution process, the source of the drugs used, the due diligence supporting the selection of the execution process and the drugs used, and all pertinent information about the selection, purchase, storage and testing of the drug (all of which are relevant to a determination of the drugs' efficacy and purity, i.e. the risk that it will cause substantial pain at the time of the execution).

For the reasons stated above, Mr. Prieto alleges that the manner in which Defendant intends to put him to death involves unnecessary and substantial risk of serious harm in violation of the Eighth Amendment.

CONCLUSION

For the reasons stated above, this Court should enjoin Defendants from executing Mr. Prieto on October 1, 2015, and thereafter until Defendants establish that the manner of execution they intend to impose is without substantial risk of harm in violation of the Eighth Amendment.

PRAYER FOR RELIEF

WHEREFORE, Petitioner Alfredo R. Prieto moves this Court to grant him relief as follows:

1. Grant Prieto a stay of execution until this Court has an opportunity to hear argument on and rule on his complaint.

2. Grant discovery and an evidentiary hearing at which Prieto would have the opportunity to prove his allegations.

3. Grant Prieto such other relief to which he may be entitled.

4. Take such action on the Complaint as the Court deems appropriate.

Respectfully Submitted,

Elizabeth Peiffer

Elizabeth Peiffer (VSB 71353)
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CERTIFICATE OF SERVICE

I hereby certify that on September 30, 2015, a true and correct copy of the foregoing Complaint and Memorandum of Law was served by electronic mail on Richard Vorhis, Section Chief, Correctional Litigation Section, Office of the Attorney General, 900 East Main Street, Richmond, VA 23219, RVorhis@oag.state.va.us.

Elizabeth Peiffer

Elizabeth Peiffer

COMMONWEALTH OF VIRGINIA

COUNTY OF GREENSVILLE

VERIFICATION OF ALFREDO R. PRIETO

I, Alfredo R. Prieto, being first duly sworn, do hereby swear and affirm under penalty of perjury that:

a. I have signed the foregoing petition;

b. The facts stated therein are true and correct to the best of my information and belief.

Alfredo R. Prieto

Subscribed and sworn to before me this 29th day of September, 2015.

Notary Public

My commission expires: April 30, 2018

Commonwealth of Virginia
Lane H. Talbott, Notary Public
Registration Number: 260121
My Commission Expires: 4-30-18