No. _____

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

Alfredo R. Prieto,
Plaintiff-Appellant,

v.

Harold W. Clarke, Director,
Virginia Department of Corrections,

Eddie Pearson, Warden,
Greensville Correctional Center

Keith W. Davis,
Warden, Sussex I State Prison,

Other Unknown Executioners, Employees, and Agents,
Virginia Department of Corrections,

Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of Virginia, Richmond Division

MOTION FOR STAY OF EXECUTION

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COMES NOW, Plaintiff-Appellant, Alfredo R. Prieto, by and through undersigned counsel, and requests this Court grant this motion to stay his execution, currently scheduled for today, October 1, 2015 at 9:00 P.M.

STATEMENT OF FACTS

On September 22, 2015, Prieto learned, for the first time, that he was to be executed by the Defendants and the Virginia Department of Corrections (VDOC) using compounded pentobarbital it had received from the Texas Department of Criminal Justice (TDCJ). At a brief hearing this afternoon, October 1, 2015, Prieto learned for the first time that the compounded pentobarbital supplied by the Texas Department Criminal Justice (TDCJ) has never been tested for sterility and has been stored at room temperature since its preparation for a compounding pharmacy in April, 2015.

Compounded pentobarbital is classified as a high-risk sterile injectable. *See* United States Pharmacopeia ("USP") General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations.[1] 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. A at 4-5 (Ruble).

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

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.[2] 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. A at 2 (Ruble).

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;
>
> 72 hours, if kept refrigerated, or
>
> 45 days, if kept in a solid, frozen state.[3]

The United States Pharmacopeia Convention, <797> Pharmaceutical Compounding-Sterile Preparations at 574.

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[2] "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.

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

Thus, the evidence was indisputable that the compounded pentobarbital set by TDCJ was months beyond the "beyond use date" (BUD) established by pharmaceutical industry standards. The industry is bunt and clear about the significance of a BUD. A "beyond use date" is "[t]he date after which th compounded preparation shall not be used." The United States Pharmacopeia Convention, <797> Pharmaceutical Compounding-Sterile Preparations at 574. After this date, it cannot be ensured that the preparation will have its accepted potency, purity, quality, and characteristics. *Id.*

Evidence at the hearing also showed that the compounded pentobarbital the Defendants seek to use was made in Texas on April 14, 2015, and was tested for potency on April 27, 2015. E.D. Va. ECF 12, Exh. 1. The potency was found to be 94.6% of what was anticipated. *Id.* By industry standards, pentobarbital is not to be used if its potency is 92% or below. No testing ever was done to establish the degradation rate of the drugs' potency, and no stability testing has been performed. No sterility tests have been done. *Id.*

There are many potential problems with compounded pentobarbital, identified in the record below. Compounding is a highly technical procedure that is mostly licensed by individual states, rather than the FDA. As such, compounding is both very individualized and not heavily regulated, meaning compounded drugs do not have the same safeguards as manufactured drugs. The potency, stability, and

sterility of the compounded drugs are based on the expertise, proficiency, and specifications of the individual compounder and the compounding pharmacy.

Finally, the evidence at the hearing showed that VDOC decided to switch to compounded pentobarbital based entirely on a single telephone call between administrators and the provision a the lab report showing the April potency level. The VDOC made no independent research, investigation, or consultation, and no expert in pharmaceuticals ever was involved. VDOC assessed potential effectiveness of compounded pentobarbital as the sedative in its three-drug protocol solely based on reports of its use in the one-drug protocol used in Texas.

PROCEDURAL HISTORY

Just eight days after learning on September 22, 2015, that the VDOC had changed it execution and no longer would use FDA-approved druag but not would rely on unknown pharmacies to supply compounded durgs for use in executions, Mr. Prieto filed suit under 42 U.S.C. § 1983, claiming there was a "substantial risk of serious harm" to him in violation of his Eighth Amendment right to be free from cruel and unusual punishment if the execution was allowed to proceed as planned, and sought an emergency motion for temporary restraining order ("TRO") in the Alexandria division of the Eastern District of Virginia yesterday, September 30, 2015. E.D. Va. ECF 1, 3. The District Court granted the TRO, pending a hearing to be held today, October 1, 2015. E.D. Va. ECF 5, 6. The Defendants, through

counsel, filed a motion to change venue and a motion to dismiss, also on September 30, 2015. E.D. Va. ECF 8, 11. The case was transferred to the Richmond division of the Eastern District of Virginia late on September 30. E.D. Va. ECF 14. A hearing was held there at 1:00 P.M. on October 1, 2015. ECF 18. The District Court denied Plaintiff's motion for a preliminary injunction, also on October 1, 2015. E.D. Va. ECF 19, 20. The same day, a Notice of Appeal was filed. E.D. Va. ECF 21.

ARGUMENT

The district court incorrectly based his assessment of the likelihood of success and showing of irreparable harm failing to engage Prieto's evidence, specifically that the drugs to be used tonight are indisputable far beyond the date established by the pharmaceutical industry beyond which the drugs cannot be used. He also incorrectly claimed the drugs were (and are) maintained "at appropriate temperatures." Again, the scientific weight of the pharmaceutical industry goes against this finding.

Prieto acknowledges that "the mere fact that an inmates states a cognizable § 1983 claim does not warrant the entry of a stay as a matter of right." *Nelson v. Campbell*, 541 U.S. 637, 649 (2004). The Supreme Court has noted that a "stay is an equitable remedy, and '[e]quity must take into consideration the State's strong interest in proceeding with its judgment and . . . attempt[s] at manipulation.'" *Id.*

(quoting *Gomez v. United States Dist. Court for N.D. of Cal.*, 503 U.S. 653, 654 (1992) (per curiam)). "[T]here is a strong equitable presumption against the grant of a stay where a claim could have been brought at such a time as to allow consideration of the merits without requiring entry of a stay." *Id.*

Here, however, there is not such a presumption against the grant of a stay. Prieto only learned of the Defendant-Appellees' intention to use compounded pentobarbital given to it by the Texas Department of Criminal Justice (TCDJ) approximately one week ago, shortly after close of business on September 22, 2015. Indeed, prior information supplied by the Virginia Department of Corrections (VDOC) pursuant to the Virginia Freedom of Information Act as recently as August 2015 did not suggest Virginia intended to execute Prieto with this substance. E.D. Va. ECF 4, Exh. B. Nor does Virginia law require VDOC to disclose to Prieto what "lethal substance" he is to be executed with, though it requires him to choose whether he wishes to be executed by lethal injection or electrocution. *See* Va. Code § 53.1-234; *Orbe v. Johnson*, 601 S.E. 2d 543, 545–46 (Va. 2004). Immediately upon learning of the VDOC's intention to use this drug, Prieto's counsel contacted them seeking further information. E.D. Va. ECF 4, Exh. K. Almost no information was given in reply. Therefore, the "strong equitable presumption" identified in *Nelson* does not apply to Prieto's case. He could not realistically have brought these claims in a manner that would not have

necessitated a stay, because of the late drug switch by Defendants-Appellees, who have failed since this information became known to provide any reasonable information about the drugs they intend to use.

Rather, the equitable assessment of this Court should tip in Prieto's favor. The risk of harm Prieto stands to suffer from the use of an adulterated or ineffective compounded anesthetic is grave: if the pentobarbital does not work, his execution would be undeniably cruel because he would be conscious, albeit paralyzed, while being slowly suffocated and injected with a caustic substance which will ultimately cause cardiac arrest. *Baze v. Rees*, 553 U.S. 35, 53 (2008) (plurality) ("It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride.")

It goes without saying this harm to Prieto, once inflicted, is irreparable. VDOC has not asserted it is able and willing to restore Prieto to life or ease his pain and suffering once the execution has begun, if the anesthetic does not, in fact, anesthetize him and render him insensate to pain. Indeed, VDOC's election to use rocuronium bromide as the second lethal-injection drug means none of the Defendants-Appellees will even know if Prieto is suffering, because he will be paralyzed and unable to register a reaction to any suffering he feels.

By comparison, the harm to Defendants-Appellees is minimal, at best. Though "[e]quity must take into consideration the State's strong interest in proceeding with its judgment," Prieto has not requested an indefinite or interminably long stay of execution. Rather, he merely seeks a stay sufficient that this Court might hear argument on the issues raised in his complaint and order the District Court to allow expedited discovery and a preliminary injunction hearing.

Other cases in which a death-sentenced inmate was denied a stay of execution in a § 1983 suit concerning lethal injection drugs involved at least expedited discovery and an evidentiary hearing. *Reid v. Johnson*, 333 F. Supp. 2d 543, 546 (E.D. Va. 2004) ("Thereafter, the parties conducted expedited discovery and Reid moved for a preliminary injunction. On September 3, 2004, the Court completed the evidentiary hearing on Reid's motion for a preliminary injunction."). Indeed, Prieto's main contention—developed more fully in his brief, submitted this day as well—is that the VDOC and Defendants-Appellees' inquiry (or lack thereof) created a "substantial risk of serious harm." *Glossip v. Gross*, 135 S. Ct. 2726, 2737 (2015). This harm exists despite the fact that an alternative—for instance, conducting a reasonable inquiry into the nature and efficacy of the compounded pentobarbital—is "feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain." *Id.* (quoting *Baze v. Rees*, 553 U.S. 35, 52 (2008)).

The District Court Abused Its Discretion in Determining the Balance of the Equities Favored Defendants.

The District Court also abused its discretion when it held "the balance of equities firmly favors Defendants." E.D. Va. ECF 19 at 11. Describing the harm to Prieto as "a thin shadow," the District court suggested the only harm Prieto faces is "the possibility that he may experience some incremental discomfort and associated pain . . . should the donated pentobarbital fail to perform as expected." E.D. Va. ECF 19 at 10. This significantly underplays the harm Prieto faces. While the Constitution does not guarantee a painless death, it is also clear the efficacy of the pentobarbital is the only thing rendering this execution protocol constitutional. *Baze v. Rees*, 553 U.S. 35, 53 (2008) (plurality) ("It is uncontested that, failing a proper dose of sodium thiopental *that would render the prisoner unconscious*, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride.") (emphasis added). No one has ever suggested—and Supreme Court precedent even dictates—that in three-drug protocol of this nature, the first anesthetic drug *must* work in order for the Eighth Amendment not to be violated. The risk which Prieto has demonstrated is not that he may experience "some incremental discomfort" if the compounded pentobarbital is insufficient. It is that he will be suffocated and have his heart stopped while still conscious.

On the opposite side of the balance, the District Court insists that the "state's interest in finality and in meting out a sentence of death in a timely manner" weigh heavily in favor of balancing the equities on the side of Defendants. Prieto is not contesting the validity of his sentence or conviction. Nor is he suggesting there be a long delay. Prieto simply seeks reasonable assurances that this compounded pentobarbital—which was formulated in secret, transported and stored at room temperature (rather than being refrigerated, as is required if this drug is to be used more than 24 hours after preparation), and only first disclosed to Prieto approximately a week ago—will perform as promised. It would be no more than a matter of days for Defendants to perform current potency, sterility, and stability testing on the drug. If current testing shows this drug will perform as required, the VDOC will rapidly mete out its death sentence.

The District Court Abused Its Discretion in Determining the Public Interest and Equitable Principles Favored Denying the Request for an Injunction

In noting the public interest and equitable principles favored denying the request for an injunction, the District Court focused predominantly on the timing of Prieto's suit. Contrary to the District Court's belief that he could have challenged the method of execution at any point between December 2010 and October 1, 2015, Prieto was entirely unaware that the Defendants would seek to acquire compounded pentobarbital from Texas in the manner they did, without receiving

any reasonable documentation about its potency, stability, or sterility. Indeed, information available to Prieto's counsel over the intervening years suggested the Defendants intended to use an entirely different sedative—midazolam—in his execution. It was only late on September 22, 2015, approximately a week before his execution, that Prieto and counsel learned of this new drug (though the Defendants clearly knew of the intention to use it—and indeed had possession of it—much earlier). The fault for the timing of the lawsuit lies with the Defendants, not Prieto. To find otherwise was an abuse of discretion.

Conclusion and Prayer for Relief

In conclusion, Plaintiff-Appellant respectfully requests this Court grant this motion to stay his execution, currently scheduled for October 1, 2015 at 9:00 P.M., to allow for consideration of his appeal of the District Court's ruling denying him a preliminary injunction and temporary restraining order. His request that the District Court's ruling be overturned accompanies this filing under separate cover.

Respectfully submitted,

/s/

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CERTIFICATE OF SERVICE

I hereby certify that on October 1, 2015, a copy of the foregoing Motion was served electronically via the CM/ECF docketing system on Margaret O'Shea, Office of the Attorney General, 900 East Main Street, Richmond, Virginia 23219, moshea@oag.state.va.us.

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