IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

DAVID ZINK, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 2:12-CV-4209-NKL
	)	
GEORGE A. LOMBARDI, et al.,	)	
	)	
Defendants.	)	

ORDER

Plaintiff Joseph Franklin is one of twenty-one Plaintiffs currently challenging the constitutionality of the execution protocol issued by the Missouri Department of Corrections. On August 14, 2013, the Missouri Supreme Court ordered that Franklin be executed on November 20, 2013. Pending before the court is Franklin's Motion for Stay of Execution. [Doc. 157]. For the reasons set forth below, the Motion for Stay of Execution is GRANTED.

I. Background

On May 15, 2012, the Missouri Department of Corrections (Department) announced a new execution protocol using the drug propofol as a lethal agent. On June 26, 2012, Franklin and other prisoners sentenced to death filed a petition in the Circuit Court of Cole County, Missouri, challenging the protocol under the Eighth and Fourteenth Amendments to the United States Constitution as well as their Missouri counterparts, the ex post facto laws of both Constitutions, the Supremacy Clause, and the separation of powers guaranty provided in Mo. Const. art. II § 1. On August 1, 2012,

Defendants removed this case to this Court. In an order issued November 16, 2012, this Court partially granted Defendants' Motion to Dismiss, dismissing the Supremacy Clause and separation of powers claims but declining to dismiss the remaining claims.

On August 1, 2013, and again on September 24, the Department issued changes to the existing protocol. On October 11, Governor Nixon ordered the Department to adopt a different method of lethal injection, and on October 18, the Department issued its current protocol, which includes the use of pentobarbital instead of propofol. The Department announced on October 22 that an unnamed compounding pharmacy was added to the execution team and will provide the pentobarbital necessary for executions under the new protocol.

Based on these protocol changes, on October 16, Defendants moved to dismiss the case as moot because the execution protocol no longer included propofol. On November 8, Franklin and other Plaintiffs moved for leave to file an amended complaint, to raise various federal and state law claims related to the new protocol. Many, if not most, of the allegations in the Plaintiffs' amended complaint mirror their original complaint. Both Defendants' Motion to Dismiss and Plaintiffs' Motion for Leave to File an Amended Complaint remain pending before this Court.

II. Jurisdiction

The first question to be addressed is whether the Court has jurisdiction to determine if a stay of execution is appropriate in this case. After Governor Nixon ordered the Department to abandon its propofol protocol, and after the Department announced a new protocol using pentobarbital, Defendants filed a motion to dismiss.

[Doc. 143]. Defendants argue in their motion that Plaintiffs' claims, which are based on the alleged pain caused by propofol, no longer present a live case and controversy because the Department no longer plans to use propofol. Plaintiffs counter that while the Department's drug of choice has changed, the linchpin of Plaintiffs' arguments was not that the use of propofol was unconstitutional, but that Plaintiffs are entitled to be free of cruel and unusual punishment in the manner of their execution. Plaintiffs continue to allege that the Department's current method of execution is unconstitutional; the fact that the drug has changed does not mean the controversy has; otherwise, every time a state changes some aspect of its protocol, it could deprive the federal court of jurisdiction, even though an execution is imminent.

While the facts have changed – both in minor and significant ways – there is clearly an overarching controversy concerning the Department's method of execution. The Court also finds it telling that at no other time when the facts of the protocol changed did Defendants question the Court's jurisdiction. In fact, when the Department changed the propofol protocol in an effort to address Plaintiffs' original concerns, Defendants chose to continue litigation by filing a motion for summary judgment rather than to challenge the Court's jurisdiction. *See* [Doc. 116].

Further, even if Plaintiffs' original complaint were dismissed, Plaintiffs could and would immediately file a new lawsuit alleging violations involving the latest version of the protocol. The only difference in the subsequent lawsuit would be a new case number and filing fee. The same controversy would remain: whether the Department's current execution protocol is in violation of the Eighth Amendment. The triviality of the

difference between this case and a hypothetical new case is further evidence that the Court continues to have jurisdiction.

This case is distinguishable from the Eighth Circuit's decision in *Ringo v. Lombardi*, 677 F.3d 793 (8th Cir. 2010), cited by Defendants. In *Ringo*, the Eighth Circuit reversed this Court's order granting summary judgment in favor of the Missouri Department of Corrections and against prisoners sentenced to death on the grounds that the case was moot. *Id.* at 796. The Department's protocol at the time included the use of thiopental as part of a three drug cocktail. However, the Department's supplier ceased production of the drug, and the Eighth Circuit documented significant challenges to importing the drug from outside the United States. *Id.* at 796-97. The court remarked that because the Department had not yet announced a new protocol due to difficulties in obtaining replacement drugs, the court could not analyze the relative risks of the drug in an Eighth Amendment claim. *Id.* at 797-98. Because no drug replacement had been announced, the prisoners failed to present a concrete and definite controversy. *Id.* at 797.

In contrast to the events in *Ringo*, the Department in this case has announced a new protocol replacing propofol with pentobarbital. There is no speculation as to what drug the Department may use. Plaintiffs have sought to amend their complaint to address grievances with this new protocol. Unlike in *Ringo*, the facts here are concrete and do not require this Court to speculate as to the immediacy and reality of the injury.

Despite the change in the drugs used to carry out the Department's execution protocol, a case or controversy still remains in this case. Accordingly, this Court retains

jurisdiction under Article III to determine whether a stay of execution is appropriate and for the same reason DENIES Defendants' pending Motion to Dismiss [Doc. 143].

III. Discussion

"[B]efore granting a stay, a district 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." *Hill v. McDonough*, 547 U.S. 573, 584 (2006); *Nelson v. Campbell*, 541 U.S. 637, 649-50 (2004); *Nooner v. Norris*, 491 F.3d 804, 808 (8th Cir. 2007).

A. Likelihood of Success on the Merits

An inmate seeking time to challenge the manner in which the State plans to execute him must show a "significant possibility of success on the merits." *Hill* 547 U.S. at 584; *Nooner*, 491 F.3d at 808. The evidence currently before the Court convinces it that the Department's new protocol and its use of an unnamed compounding pharmacy, shows a significant possibility of success on the merits of Plaintiffs' Eighth Amendment claim.

There are two components to an Eighth Amendment challenge. "First, the punishment must not involve the unnecessary and wanton infliction of pain. Second, the punishment must not be grossly out of proportion to the severity of the crime." *Taylor v. Crawford*, 487 F.3d 1072, 1079 (8th Cir. 2007). As to the first prong, when assessing the constitutionality of a written lethal injection protocol, the court must determine whether the protocol "presents a substantial risk of inflicting unnecessary pain." *Nooner v. Norris*, 594 F.3d 592, 599 (8th Cir. 2010).

On October 22, the Department announced that an unnamed compounding pharmacy will provide the pentobarbital necessary for executions under the new protocol. The Department has not provided any information about the certification, inspection history, infraction history, or other aspects of the compounding pharmacy or of the person compounding the drug. Decl. of Mark J.S. Heath, M.D., [Doc. 157-4], ¶¶ 10-11.

In the little time Plaintiffs have had to research the Department's new protocol, Plaintiffs have managed to document numerous risks associated with the use of compounded pentobarbital in quantities sufficient for execution. For instance, Plaintiffs' experts, Dr. Larry Sasich and Dr. Mark Heath, opine that compounding pharmacies are generally not subject to the drug approval process, and as a result of a lack of oversight, serious complications are foreseeable. *See* Aff. of Larry D. Sasich, [Doc. 157-3], ¶¶ 9-10; Decl. of Mark J.S. Heath, M.D., [Doc. 157-4], ¶ 9. Dr. Sasich contends that compounded drugs do not meet federal requirements of purity, potency, efficacy, and safety, and that compounding pharmacists generally do not have the ability to test these factors. Sasich at ¶¶ 12, 17. If poor quality or adulterated ingredients are used, the drug may be contaminated, super-potent, or sub-potent. *Id.* at ¶25. Dr. Sasich opines that pentobarbital compounded from unverified ingredients poses a substantial risk of harm from the ingredients alone. "These risks of harm include sub- or super- potency, contamination with dangerous allergens or substances that may cause immediate anaphylactic reactions, contamination with bacteria or fungus with immediate excruciating effects before the condemned person is unconscious (assuming it works even to that extent), and even the administration of an entirely incorrect chemical or

active ingredient." *Id.* at ¶ 28. Other risks associated with compounded pentobarbital may include pulmonary embolism from unanticipated drug incompatibilities and partial or complete lack of effect due to ingredient tampering – circumstances that would be expected to prolong the execution and multiply the pain and suffering beyond the objective of causing death. *Id.* at ¶ 30; Heath at ¶ 9. Highly unpredictable and potentially painful and agonizing reactions may ensue should the administered pentobarbital be contaminated.

Defendants' expert, Dr. Mark Dershwitz, opines that the dosage of pentobarbital required by the Department's protocol "will result in the rapid and painless death of the inmate to whom it is administered." *See* Expert Report of Mark Dershwitz, M.D., Ph.D., [Doc. 157-5], ¶ 9. However, Plaintiffs' expert, Dr. Sasich, correctly points out that Dr. Dershwitz's report only discusses pentobarbital and not compounded pentobarbital, which, as discussed above, is subject to risk of contamination beyond that of pentobarbital supplied by FDA-approved sources. *See* Aff. of Larry D. Sasich, [Doc. 157-3], ¶ 45. Defendants also provided laboratory analysis of the compounded pentobarbital to the Missouri Supreme Court and argued that the drug is 98.8% pure. [Doc. 157-7]. However, this laboratory report indicates that "the methods used for testing are not validated," which raises serious concerns as to the report's reliability. Further, Plaintiffs' expert, Dr. Sasich, notes that while the anonymous laboratory conducting the analysis is accredited by the American Association of Laboratory Accreditation, he is "not aware of any drug regulatory authority (either the Food and Drug Administration or State Boards of Pharmacy) that recognize accreditation" by this

Association. *See* Supp. Decl. of Larry D. Sasich, [Doc. 157-8], ¶ 1. Dr. Sasich notes that the report does not disclose whether the drug was manufactured in an FDA approved facility and questions why the drug was not tested for adulterants, endotoxins, and sterility. *Id.* at ¶ 3. Accordingly, this report is not sufficient to overcome the specific risks documented by Plaintiffs through their experts.

Further, this case is distinguishable from *Brewer v. Landrigan*, 131 S.Ct. 445 (2010). In *Brewer*, a district court ordered a temporary stay of execution after finding that based on the record, issues regarding efficacy and possible side-effects surrounded the drug. *Landrigan v. Brewer*, 2010 WL 4269559 at *10 (D. Ariz. 2010). The court remarked that because the drug was not FDA-approved, the court was "left to speculate whether the . . . drug will perform in the exact same manner as an FDA-approved drugs and whether the non-FDA approved drug will cause pain and suffering." *Id.* On appeal, the Supreme Court of the United States held that speculation as to the risk of harm from an injection protocol "cannot substitute for evidence that the use of the drug is *sure or very likely* to cause serious illness and needless suffering." *Landrigan v. Brewer*, 131 S.Ct. at 445. The Court vacated the temporary restraining order because there was no evidence in the record to suggest the drug was unsafe. *Id.*

Here, Plaintiffs have provided testimony from two experts who have opined that the risk of harm is foreseeable and that substantial risk of harm exists with the use of unregulated, compound pentobarbital. Unlike the court in *Landrigan*, this Court need not speculate as to whether the risk of unnecessary pain is both real and very likely. The record in *Landrigan* contained no evidence to suggest the drug was unsafe. On the

contrary, the current evidence presented before this Court suggests that the drug to be used by Defendants is unsafe. Defendants' expert's report does not address compound pentobarbital, and is therefore insufficient to rebut Plaintiffs' experts' opinions.

Whitaker v. Livingston, 732 F.3d 465 (5th Cir. 2013), is also distinguishable. In *Whitaker*, the Fifth Circuit affirmed the district court's denial of a preliminary injunction restraining the state from conducting executions with pentobarbital procured from compounding pharmacies. *Id.* at 465. The court dismissed Plaintiffs' argument that pentobarbital obtained from a compound pharmacy presents the possibility of contamination, increased pain at the injection site, or pulmonary embolism. The court remarked that Plaintiffs failed to "offer some proof that the state's own process – that its choice of pharmacy, that its lab results, that the training of its executions, and so forth, are suspect. *Id.* at 468. Plaintiffs only presented hypothetical possibilities of risk, and even if those hypotheticals were true, Plaintiffs failed to show the risk was substantial when compared to known and available alternatives. *Id.* In particular, the court remarked that Plaintiffs failed to show the risk of contamination is substantially greater than obtaining the drugs from a customary pharmacy. *Id.* at 469.

In contrast, Plaintiffs in this case have provided proof of more than hypothetical risk. Plaintiffs' expert, Dr. Sisach, points to the suspect nature of the laboratory reports provided by Defendants. These laboratory reports are provided by a laboratory accredited by an association not recognized by the FDA, and even more concerning, the reports specifically state that "[t]he method(s) used for testing are not validated." [Doc. 157-7, at 3]. Plaintiffs also argue that the report provided by the Defendants' expert is

inadequate because it only discusses the risks associated with pentobarbital in general and not compounded pentobarbital specifically. It also fails to disclose whether the drug contains contaminants. Plaintiffs also argue that the anonymous nature of the compounding pharmacy raises serious concerns as to the quality of the drug produced. Further, unlike the parties in *Whitaker*, the Plaintiffs here have provided reports from two experts opining that the risk of contamination in compound pentobarbital is not only foreseeable, but substantially greater than the risk of obtaining the drug from a customary pharmacy. For instance, Dr. Sasich notes that unlike customary pharmacies who receive their supply from FDA-approved sources, compounding pharmacists may not be able to define risks associated with compounding drugs and may not know that the drug is made from adulterated or counterfeit chemicals. *See* Aff. of Larry D. Sasich, [Doc. 157-3], ¶¶ 10-11. Dr. Sasich also points to the American Veterinary Medical Association's recent policy of discouraging the use of compounded drugs such as pentobarbital due to the high risk of contamination. *Id.* at ¶ 26. In sum, Plaintiffs have provided sufficient evidence to support a finding of significant risk of harm that is greater than if the pentobarbital were supplied by a customary, FDA-approved pharmacy.

Defendants have instituted a protocol implementing pentobarbital produced from a bulk drug substance from an unknown source and of unknown composition prepared under unregulated conditions. *See* Aff. of Larry D. Sasich, [Doc. 157-3], ¶ 44. Plaintiffs were afforded no opportunity to inspect the qualifications of this compound pharmacy. Defendants cannot repeatedly change the execution protocol, including within five days of a scheduled execution, and rely on Plaintiffs' lack of time to research the protocol's

effects when arguing that Plaintiffs have not presented a substantial likelihood of success on the merits. What research Plaintiffs have produced in the little time afforded to them suggests a high risk of contamination and prolonged, unnecessary pain beyond that which is required to achieve death. Plaintiffs have proven that the Department's protocol "presents a substantial risk of inflicting unnecessary pain," and therefore, Plaintiffs have shown a significant possibility of success on the merits of their Eighth Amendment claim.

Defendants also suggest that because the Supreme Court has never found that any execution protocol violates the U.S. Constitution, this Court should not grant a stay here. But absent some directive from a higher court that these execution protocol claims are frivolous and need not be decided on their merits, the Court will continue to follow procedures in place for handling all litigation in the federal courts, which cannot be done efficiently if the Department keeps changing how they plan to execute the Plaintiffs.

Finally, litigation is not a game of chess. *Hill* was intended to be a shield to protect defendants from abusive litigation practices by death row inmates. But it was never intended to be used as a sword permitting defendants to disrupt and delay the litigation process and then complain that time is up. Neither the Plaintiffs nor the Court have been able to address the merits of Plaintiffs' claim that the Defendants have adopted an execution protocol that violates the U.S. Constitution, because the Defendants keep changing the protocol that they intend to use. It would be a substantial departure from the way in which law suits are generally handled by this Court, to allow Defendants to succeed with this strategy. Rather, the pending dispute between the parties should be resolved on the merits after a reasonable opportunity for both sides to be heard, followed

by a prompt, final order resolving the dispute. That is how it is normally done in America and it is a system that has worked quite well.

Because the Court finds that the stay of execution must be granted on the grounds that Plaintiffs have shown a substantial likelihood of success on the merits of their Eighth Amendment claim, the Court declines to discuss Plaintiff's other arguments on the merits at this time.

B. Relative Harm to the Parties

Determining relative harm to the parties necessitates balancing irreparable harm in the absence of the stay with the State's strong interest in enforcing its criminal judgments without undue influence from federal courts. *Nooner v. Norris*, 491 F.3d 804, 808 (8th Cir. 2007). Without a stay, Franklin would suffer irreparable harm. Given the irreversible nature of the death penalty and Plaintiffs' medical evidence and allegations, a stay is necessary to ensure that the Defendants' last act against Franklin is not permanent, irremediable cruel and unusual punishment in violation of the Eighth Amendment.

Further, any harm to Defendants caused by a stay is entirely self-inflicted. Defendants chose an untested, non-litigated method of execution in 2012. After more than a year of litigation and only after the close of discovery did Defendants change the protocol to address specific concerns raised by Plaintiffs. Defendants issued three different protocols in the three months preceding Franklin's execution date, and as recent as five days before the execution, Defendants again changed their method of execution. Defendants' protocol has been a frustratingly moving target. In the face of such a grave

consequence as that of the death penalty, this Court declines to reward Defendants' attempts to prevent Plaintiffs from fully litigating their claims.

C. Unnecessary Delay in Bringing the Claim

Because a stay of execution is an equitable remedy, there is an 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. *Nooner*, 491 F.3d at 808. Once an inmate's sentence of death has become final in the state's courts, there is no impediment to filing an action challenging the constitutionality of a state's lethal protocol as long as lethal injection is the established method of execution, the protocol is known, and no state administrative remedies are available. *Id.*

Here, Franklin has not unnecessarily delayed bringing his claim. The Department first announced a new protocol instituting the use of propofol in May 2012. Franklin subsequently filed a challenge to this protocol in June 2012 in the Circuit Court of Cole County. On August 2, 2013, after more than thirteen months of litigation and shortly after the close of discovery, Defendants notified Franklin and other Plaintiffs that the protocol had been changed to address Plaintiffs' original concerns. On August 19, after Plaintiffs' expert reviewed the amended protocol and determined that serious concerns still existed, Franklin sought a thirty-day extension to the Court's scheduling order so that he could seek leave to amend his complaint. The Department again changed the protocol on September 24 and October 18, a month before Franklin's scheduled execution date. Franklin sought to file an amended complaint on November 8. After each protocol change, Franklin has gathered and presented scientific analysis of the protocol without

delay. Throughout this litigation, the details of the execution protocol have been illusive at best. In fact, the most recent change occurred just four days ago on November 15, when the Department indicated changes to its approach on intravenous access. It is clear from the procedural history of this case that through no fault of his own, Franklin could not resolve his claims without a stay of his scheduled execution date. Franklin has been afforded no time to research the risk of pain associated with the Department's new protocol, the quality of the pentobarbital provided, and the record of the source of the pentobarbital. Both law and equity support a stay under these circumstances.

IV. Conclusion

Plaintiffs have shown a significant likelihood of success on the merits, a showing of irreparable harm in contrast to relatively little harm to Defendants, and no fault in the delay of their current case pending before this Court. Accordingly, Franklin's Motion for Stay of Execution is GRANTED.

s/ Nanette K. Laughrey
NANETTE K. LAUGHREY
United States District Judge

Dated: November 19, 2013
Jefferson City, Missouri