IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

FRANK ROBERT CHESTER, et al.,	:	
Plaintiffs	:	
	:	**No. 1:08-cv-1261**
v.	:	
	:	**(Judge Kane)**
JOHN E. WETZEL, et al.,	:	
Defendants	:	

MEMORANDUM

Before the Court is Defendants' motion for summary judgment (Doc. No. 205), and Defendants' motion to strike (Doc. No. 240-1.). The motions are fully briefed and ripe for disposition. For the reasons that follow, the Court will grant the motion for summary judgment, and enter summary judgment in favor of Defendants. It will also grant the motion to strike in part and deny it in part.

I. BACKGROUND

A. Procedural Background

The original complaint in the above-captioned class action was filed on November 9, 2007. (Doc. No. 1.) The complaint alleged that Pennsylvania's lethal injection protocol poses an unnecessary risk that Plaintiffs will suffer pain in violation of the proscription against cruel and unusual punishment and the guarantees of due process of law under the Eighth and Fourteenth Amendments of the United States Constitution. (Id. ¶ 40.) The Plaintiff class consists of all persons who are presently under a sentence of death in Pennsylvania or who at some point during the pendency of this action will be under a sentence of death by lethal injection in Pennsylvania. Defendants are John E. Wetzel, Secretary of the Pennsylvania Department of Corrections ("DOC") and Marirosa Lamas, Superintendent of the State

Correctional Institute at Rockview, both of whom were automatically substituted for former Secretary of the DOC Jeffrey A. Beard, and former Superintendent Franklin J. Tennis. (Doc. No. 206 ¶ 2.)

The full procedural history of this case through late 2012 is set forth in the Court's memorandum order, filed November 6, 2012, denying class Plaintiff Hubert Michael's motion for a stay of execution, and the Court will not recount it here. (See Doc. No. 186.) Following discovery, Defendants filed a motion for summary judgment on May 24, 2013. (Doc. No. 205.) Briefing on the summary judgment motion was initially completed on September 5, 2013.

On November 18, 2013, with disposition of the motion pending, Plaintiffs filed a motion to supplement and develop the record on summary judgment. (Doc. No. 226-2). They asked the Court to re-open discovery for the limited purpose of uncovering further information regarding the laboratory that analyzed the drugs to be used in conjunction with the scheduled execution of Mr. Michael. (Id.) The Court granted the motion and gave Plaintiffs a period of time in which to conduct limited discovery, and further granted each party the opportunity to file supplemental briefing. On June 5, 2014, once Plaintiffs filed their supplemental discovery and the parties filed their respective supplemental briefs, Defendants filed a motion to strike three documents the Plaintiffs sought to introduce into the record. That motion is also before the Court.[1]

[1] On September 11, 2014, a motion to intervene was filed by the Guardian News & Media LLC, the Philadelphia Inquirer, the Pittsburgh Post-Gazette, and the Philadelphia City Paper. (Doc. No. 251.) They sought to intervene for the sole purpose of challenging confidentiality orders that had previously been entered in this case. On November 13, the Court granted the motion, and ordered that the Intervenors motion to unseal be added to the docket. (See Doc. Nos. 263, 264.) Full briefing on their motion to unseal is still pending.

B. Material Facts[2]

1. The execution process

At issue are Pennsylvania's procedures for lethal injection, set forth principally in Capital Case Administration Policy Number 6.5.8.[3] (Doc. No. 206 ¶ 3.) The protocol requires that all members of the lethal injection team "must be trained heath care professionals who have completed intravenous therapy training and are experienced in performing venipuncture." (Id. ¶ 16.) There are currently three members of the lethal injection team, all of whom meet these requirements. (Id. ¶ 17.) The lethal injection procedure is rehearsed at least three times per year, with additional rehearsals whenever an execution is imminent. (Id. ¶¶ 18-19.)

The protocol calls for the injection of three drugs in order to effectuate execution of the prisoner. (Doc. No. 206 ¶ 4.) The first drug injected into the prisoner will be either 5,000 mg of pentobarbital or 3 gm sodium thiopental. (Id. ¶ 5.) Half of this first drug will be injected into the left arm, and the other half will be injected into the right arm. (Id.) Once the first drug is administered, the left IV line will be flushed with saline.[4] (Id. ¶ 6.)

Once the first drug is administered, regardless of whether an electroencephalograph (EEG) is used to monitor consciousness, steps are taken in order to confirm that the prisoner is unconscious. (Doc. No. 206 ¶¶ 7-8.) The prisoner's name is called in a loud voice and the prisoner is observed for any reaction. (Id. ¶ 9.) Moreover, the procedure calls for tactile

---

[2] These facts are undisputed, unless noted otherwise.

[3] These current procedures were issued on August 27, 2012 and became effective the following day.

[4] Plaintiffs note a discrepancy in the procedure regarding this saline flush: the protocol itself expressly calls for only a flush of the left IV, while an accompanying checklist calls for a flush of the IV in both arms. (Doc. No. 219 ¶ 17.)

stimulation, such as brushing the prisoner's eyelashes and shaking his shoulders to test his or her responsiveness. (Id.) Both a lethal injection team member and a Department of Corrections supervisory employee must monitor the prisoner's consciousness, and both must agree that the prisoner is unconscious before the second drug can be administered. (Id. ¶¶ 10-11.) If they do not agree that the inmate is unconscious, an equal amount of the first drug is re-administered. (Id. ¶ 12.)

Next, the second drug, pancuronium bromide, is injected by IV into the left arm in two 50 mg doses, and the IV is flushed with saline. (Doc. No. 206 ¶ 13.) Finally, the third drug, potassium chloride, is injected into the prisoner's left arm in two 50 meq doses, at which time the lethal injection team will monitor for asystole, the absence of any electrical activity in the prisoner's heart. (Id. ¶ 14.) If asystole is not found within two minutes of injection of the second dose, two addition 50 meq doses will be injected into the prisoner's left arm. (Id. ¶ 15.)

2. Source of the drugs

The protocol provides that when the DOC is unable to obtain the drugs necessary to carry out an execution from pharmaceutical factories, it will arrange to get them from compounding pharmacies. (Doc. No. 206 ¶ 20.) According to the DOC, it requires that the source of the compounded drugs possess all necessary licenses and meet any other criteria required in the jurisdiction where it is located. (Id. ¶ 22.) The DOC also maintains that it requires the source to provide copies to the DOC of all current, relevant licensing documents. (Id. ¶ 22.) Plaintiffs insist that whether this licensing requirement exists at all is a dispute of material fact, inasmuch as the requirement is not present anywhere in the written protocol. (Doc. No. 219 ¶ 22.)

Moreover, the DOC states that it requires that drugs obtained from any compounding

vendor to be independently analyzed for composition, strength, and sterility prior to use. (Doc. No. 206 ¶ 23.) Plaintiffs insist that whether such testing is in fact required is also a disputed fact, as it, too, is not part of the DOC's written protocol. (Doc. No. 219 ¶ 22.)

II. LEGAL STANDARD

Rule 56(a) of the Federal Rules of Civil Procedure provides that summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A factual dispute is material if it might affect the outcome of the suit under the applicable law, and it is genuine only if there is a sufficient evidentiary basis that would allow a reasonable fact finder to return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-49 (1986). At summary judgment, the inquiry is whether the evidence presents a sufficient disagreement to require submission to the jury or whether it is so one-sided that one party must prevail as a matter of law. Id. at 251-52. In making this determination, the Court must "consider all evidence in the light most favorable to the party opposing the motion." A.W. v. Jersey City Pub. Schs., 486 F.3d 791, 794 (3d Cir. 2007).

The moving party has the initial burden of identifying evidence that it believes shows an absence of a genuine issue of material fact. Conoshenti v. Pub. Serv. Elec. & Gas Co., 364 F.3d 135, 145-46 (3d Cir. 2004). Once the moving party has shown that there is an absence of evidence to support the non-moving party's claims, "the non-moving party must rebut the motion with facts in the record and cannot rest solely on assertions made in the pleadings, legal memoranda, or oral argument." Berckeley Inv. Grp. Ltd. v. Colkitt, 455 F.3d 195, 201 (3d Cir. 2006); accord Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). If the non-moving party "fails

to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden at trial," summary judgment is warranted. Celotex, 477 U.S. at 322. With respect to the sufficiency of the evidence that the non-moving party must provide, a court should grant summary judgment when the non-movant's evidence is merely colorable, conclusory, or speculative. Anderson, 477 U.S. at 249-50. There must be more than a scintilla of evidence supporting the non-moving party and more than some metaphysical doubt as to the material facts. Id. at 252; see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Further, a party may not defeat a motion for summary judgment with evidence that would not be admissible at trial. Pamintuan v. Nanticoke Mem'l Hosp., 192 F.3d 378, 387 (3d Cir. 1999).

III. DISCUSSION

The Court will first address Defendants' motion to strike. The Court will then address Defendants' motion for summary judgment on Plaintiffs' claim that Pennsylvania's execution protocol poses a risk of cruel and unusual punishment.

A. Motion to strike

Defendants move to strike three of the documents Plaintiffs submitted with their supplemental discovery: (1) the May 15, 2014 report of Dr. Andy Papas, (2) the May 15, 2014 Declaration of Dr. David Waisel, and (3) an article from the Washington Post.[5] (Doc. Nos. 240-1, 244.) First, Defendants assert that the reports of Papas and Waisel should be stricken as

[5] Defendants argue that this Washington Post article, dated October 6, 2013, is inadmissible hearsay. Plaintiffs respond that they included the article "only for the purpose of providing background information," and that they therefore do not oppose that aspect of Defendants' motion. (Doc. No. 245 at 2 n.1.) Accordingly, the Court will strike the article.

untimely, as the Court's order gave the parties 45 days to conduct supplemental discovery, meaning that discovery was to be completed by April 24, 2014; both documents are dated May 15, 2014. (Doc. No. 244.) Plaintiffs contend, however, that it understood the Court's order to provide an initial 45 days of discovery, in addition to a limited opportunity to supplement the record with its own expert reports concerning evidence uncovered during the discovery process. (Doc. No. 245.) As stated by Plaintiffs, "Plaintiffs' right to supplement the record after completing the additional limited factual discovery allowed by the Court would be of little benefit to the Court if it did not include the right to provide expert opinion testimony based on such additional facts." (Id. at 8.)

The Court will not strike either document as untimely. The Court's order provided in part that:

> 1. Plaintiffs have 45 days from the date of this order in which to conduct limited supplemental discovery insofar as they seek more information on the FDA investigation referenced in their motion. General discovery regarding the testing laboratory will be denied as beyond the scope of the Court's order;
>
> 2. Plaintiffs may supplement the record with information regarding the FDA report.

(Doc. No. 234.) Both parties have different interpretations of the Court's order re-opening discovery, but the Court finds that Plaintiffs' interpretation of the Court's order was reasonable. As Plaintiffs point out, it follows that the substance of any proposed expert report would necessarily be based on facts uncovered during the 45 days of extended fact discovery. The Court further finds that, given that disposition of this motion has experienced a long delay in order to give the parties an opportunity to procure this exact information, to strike these supplements from the record now is an unduly harsh response to the parties' dispute over the

proper interpretation of the Court's order. Defendants also argue that this Court's prior orders set deadlines for the exchange of expert reports (Doc. Nos. 58, 62), deadlines that have long since passed. (Doc. No. 247 at 3-4.) However, any such deadlines were effectively vacated by the Court's order allowing the parties to conduct additional discovery.

Defendants alternatively posit that the expert report of Dr. Papas should be stricken on the grounds that Plaintiffs failed to disclose his identity as required by Rule 26 of the Federal Rules of Civil Procedure. (Doc. No. 244 at 4-5.) Whether to exclude evidence in violation of Rule 26 is a matter within the Court's discretion. See Newman v. GHS Osteopathic, Inc., Parkview Hosp. Div., 60 F.3d 153, 156 (3d Cir. 1995). However, the Court will not strike his report on these grounds. Although Plaintiffs give no explanation or justification for their failure to identify Dr. Papas to Defendants, it does not appear to the Court that Plaintiffs are actually in violation of any provision the Federal Rules of Civil Procedure, such as Rule 26(e)(2), setting forth the duty of parties to supplement expert reports "in a timely manner," (i.e., no later than thirty days before trial[6]) or 26(a)(2)(D) which provides that must disclose expert witness "at least 90 days before the date set for trial." Fed. R. Civ. P. 26(e)(2). Here, there is no trial date scheduled. Although the Court is cognizant of the unusual sequence of events, and given that it does not appear that Plaintiffs have violated any applicable rules of civil procedure, the Court finds that the equities do not require that this Court strike Dr Papas' report. Indeed, if Defendants wished to file their own expert reports in response to Dr. Papas', they could have simply petitioned the Court to allow them to do so. However, they did not ask the Court for an

[6] See Fed. R. Civ. P. 26(a)(3)(B), 26(e)(2).

opportunity to respond, they instead asked the Court to strike Plaintiffs' submissions in their entirety. The Court finds this is not justified under the circumstances. Therefore, the Court will deny the motion to strike the reports of Drs. Papas and Waisel.[7]

B. Motion for summary judgment

In moving for summary judgment, Defendants contend that the undisputed record indicates that Pennsylvania's practice of using compounded drugs does not pose an unconstitutional risk of harm. (Doc. No. 209 at 17.) Defendants additionally argue that Pennsylvania's lethal injection protocol is substantially similar to the protocol in Baze v. Rees, 553 U.S. 35 (2008), and, therefore, is constitutional on its face. (Id.) Plaintiffs counter that the protocol in Baze did not use compounded drugs, and therefore Pennsylvania's protocol is not substantially similar. (Doc. No. 218 at 15.) Plaintiffs further assert that there are disputed issues of material fact regarding Pennsylvania's use of compounded drugs and, as such, summary judgment is inappropriate. (Id. at 15; Doc. No. 238-2.)

1. Standard for method-of-execution challenges

As the parties recognize, the United States' Supreme Court's decision in Baze and the United States Court of Appeals for the Third Circuit's opinion in Jackson v. Danberg, 594 F.3d 210 (3d Cir. 2010), are the Court's guideposts for an Eighth Amendment method-of-execution challenge such as this one. In Baze, the United States Supreme Court was confronted with the constitutionality of Kentucky's three-drug lethal injection protocol. Kentucky's protocol called

[7] Most importantly, the Court has thoroughly considered Plaintiffs' supplemental arguments, and concludes, as will be discussed infra, that both expert reports concerning the testing laboratory are immaterial to its resolution of the summary judgment motion. Defendants therefore are not prejudiced by the inclusion of these documents in the record.

for an injection of sodium thiopental, followed by pancuronium bromide, and finally potassium chloride, much like in Pennsylvania. Baze, 553 U.S. at 45. Plaintiffs' argument in Baze rested largely on concerns that, if the first drug was not properly administered the prisoner would remain conscious and, therefore, would be exposed to suffocation and pain during the subsequent injections. Id. at 49-50.

The Baze plurality upheld the constitutionality of Kentucky's protocol. As an initial matter, the plurality noted that it "has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment." Id. at 48. The plurality also made clear that "[t]o establish that such exposure violates the Eighth Amendment, however, the conditions presenting the risk must be 'sure or very likely to cause serious illness and needless suffering,' and give rise to 'sufficiently imminent dangers.'" Id. at 49-50 (citing Helling v. McKinney, 509 U.S. 25, 33, 34–35 (1993)). There also "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.'" Id. (quoting Farmer v. Brennan, 511 U.S. 825, 842, 846, and n. 9 (1994)). Along those lines, "[s]imply 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." Id. The Baze Court also rejected the plaintiffs' argument that the existence of safer alternative methods would lessen the risk of harm, noting that courts are not "boards of inquiry charged with determining 'best practices' for executions," and that a plaintiff "cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative." Id. at 51.

In Jackson, the United States Court of Appeals for the Third Circuit addressed Delaware's lethal injection protocol, which included the three-drug protocol and was "in all material respects identical to the protocol the Supreme Court found constitutional in Baze."[8] Jackson, 594 F.3d at 223-224. In Jackson, the Third Circuit adopted the standard applied by the Baze plurality and affirmed the district court's grant of summary judgment to defendants. Id. The Third Circuit also emphasized that "the proper administration of [the first drug] is an indispensable link in the lethal injection chain for Eighth Amendment purposes, as it ensures that an inmate will not suffer under the effects of the second two drugs." Id. at 226. Jackson clearly set forth that "[t]o survive summary judgment under Baze, the Plaintiffs must point to record evidence from which a reasonable fact finder could infer that Delaware's protocol does not meet the standards governing the constitutionality of an execution protocol as articulated by Chief Justice Roberts in the plurality opinion." Id. at 223.

2. Pennsylvania's use of compounded drugs

Plaintiffs assert that Pennsylvania's protocol is distinct from those found constitutional in Baze and Jackson on one crucial point: those cases involved the use of regulated, FDA approved drugs manufactured by pharmaceutical companies. (Doc. No. 218 at 20.) Pennsylvania's protocol, on the other hand, allows for the use of non-FDA approved compounded drugs. (Id. at 20.) Drug compounding is a process by which a pharmacy manufactures drug products pursuant to an individual prescription from raw ingredients.

[8] Following Jackson, Delaware revised its procedure to allow the use of pentobarbital as the first drug rather than sodium thiopental. The plaintiffs challenged this revision, but the Third Circuit affirmed the district court's denial of plaintiffs' motion to stay, holding that the district court did not abuse its discretion in finding that pentobarbital is an effective anesthetic for use in the three-drug protocol. Jackson v. Danberg, 656 F.3d 157, 166 (3d Cir. 2011).

The Court finds that, as an initial matter, Plaintiffs' proffered evidence and argument that there are dangers associated with drug compounding is not itself sufficient to defeat summary judgment.[9] While Plaintiffs present evidence in the form of its expert testimony that there is some increased risk involved with the use of compounded drugs, in part because the industry is lightly regulated, the mere possibility that something may go wrong is insufficient to carry Plaintiffs' burden, and the Court finds insufficient evidence in the record from which a reasonable fact-finder could conclude that the risk is "objectively intolerable" and that the practice is "sure or very likely to cause serious illness and needless suffering." See Baze, 553 U.S. at 50 ("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."); Valle v. Singer, 655 F.3d 1223, 1233 (11th Cir. 2011) ("[M]ere speculation cannot substitute for evidence that the use of pentobarbital will or very likely will cause serious illness and needless suffering."). As Baze and Jackson make clear, the standard to succeed on a method-of-execution challenge is imposing. See Baze, 553 U.S. at 53 (noting that Eighth Amendment challenges to a state's execution protocol face a "heavy burden.").

Plaintiffs and their experts propose that, in utilizing compounding drugs, there is a risk the drugs are flawed and will cause pain upon injection, or will otherwise fail to render the prisoner unconscious before the additional drugs are implemented. The Court agrees with

[9] Although these cases do not specifically address drug compounding, "courts have rejected claims that the absence of FDA approval of a drug for use in lethal injections means that the drug is unsafe or suggests that it is sure or very likely to cause serious illness or needless suffering." Valle v. Singer, 655 F.3d 1223, 1234 (11th Cir. 2011) (collecting cases).

Defendants that this argument is nearly identical to the one, rejected in Baze, that the risk of maladministration of the execution protocol violates the Eighth Amendment. See Baze, 553 U.S. at 62 ("The risks of maladministration [the plaintiffs] suggested – such as improper mixing of chemicals and improper setting of IVs by trained and experienced personnel – cannot remotely be characterized as 'objectively intolerable.'"); see also Emmett v. Johnson, 511 F.Supp.2d 634, 644 (E.D. Va. 2007) aff'd, 532 F.3d 291 (4th Cir. 2008) ("To support an Eighth Amendment claim, Plaintiff must go further than merely demonstrating risks. He must show a substantial risk that is reasonably foreseeable.") (emphasis added). Moreover, as the Court will address later in this memorandum, there are a number of safeguards in place under the DOC's procedure that serve to mitigate the compounding risks identified by Plaintiffs.

Plaintiff cites a case from the Superior Court of Fulton County, Georgia, Hill v. Owens, No. 2013-CV-233771 (Supr. Ct. Fulton Cty., July 18, 2013) in support of their opposition to summary judgment. (Doc. Nos. 218 at 21-22, 218-1.) Hill, like the present case, contained a challenge related to the use of compounded drugs in lethal injections, and that court granted a stay of execution because "neither the Plaintiff, nor the general public, has sufficient information with which to measure the safety of the drug that would be used to execute Plaintiff." (Doc. No. 218-1.) However, at least one Court of Appeals disagrees with Hill and found that the speculative risks posed by the unknowns related to drug compounding do not pose irreparable harm in violation of the Eighth Amendment. See Whitaker v. Livingston, 732 F.3d 465, 468 (5th Cir. 2013) cert. denied, 134 S. Ct. 417 (U.S. 2013). Ultimately, the Court finds the reasoning in Whitaker more in line with Baze's admonition that the speculative possibility of pain is insufficient to carry an Eighth Amendment claim, and the Court declines to place much weight

upon the opinion in Hill. See Baze, 553 U.S. at 50. As the Court stated in its memorandum and order denying class Plaintiff Hubert Michael's stay of execution, Plaintiffs' "challenge related to the quality of the [compounded] pentobarbital amounts to little more than an argument about the best practices in execution," and while use of an FDA-approved drug may be ideal, "federal courts are not 'boards of inquiry charged with determining best practices for executions.'" (See Doc. No. 186 at 14-15 (citing Baze, 553 U.S. at 51).)

3. Additional safeguards in Pennsylvania's protocol

As stated above, the Court finds that no reasonable fact-finder could conclude that Pennsylvania's practice of drug compounding alone creates an objectively intolerable risk of harm in violation of the Eighth Amendment. However, to the extent that the Plaintiffs have established that risks do exist, these risks are considerably mitigated by the other safeguards in place; specifically, testing requirements, licensing requirements, and a mandated consciousness check after injection of the first drug, all of which support the protocol's constitutionality despite the degree of risk Plaintiffs attribute to the drug compounding process. See Baze, 553 U.S. at 50 ("Kentucky's decision to adhere to its protocol despite [its] risks, while adopting safeguards to protect against them, cannot be viewed as probative of the wanton infliction of pain under the Eighth Amendment.") (emphasis added). Regarding these safeguards, Plaintiffs contend that the Court cannot conclude at the summary judgment stage that any testing and licensing safeguards are in place because there are disputed issues of material fact as to whether Pennsylvania actually has such requirements. (Doc. No. 218 at 19-22.) Specifically, Plaintiffs assert that as the licensing and testing requirements are not included in the written protocol, the existence of these purported requirements are credibility determinations that cannot be resolved at summary

judgment. (Id.)

The Court disagrees with Plaintiffs, and finds that the existence of the testing and licencing safeguards is not genuinely in dispute for purposes of the present summary judgment motion. In response to Plaintiffs' fifth set of interrogatories, Defendants stated (1) "[t]he DOC requires that its vendor have the lethal injection drugs independently analyzed for composition, strength and sterility prior to their use;" and (2) "[t]he DOC requires that the source of compounded pentobarbital currently possess all necessary licenses and meet any other criteria that may be required by the jurisdiction in which it is located in order to provide professional services as a compounding pharmacy. The source is required to furnish copies of current, relevant licensing documents to the DOC." (Doc. No. 218-2 at 94.) Neither of these are listed in the written execution protocol.

Plaintiffs' attempt to paint this as a credibility determination that requires fact-finding at trial is unavailing. First, the Courts have rejected Plaintiffs' argument that execution protocols must always be in writing. See, e.g., Thorson v. Epps, 701 F.3d 444, 448-49 (5th Cir. 2012) cert. denied, 134 S. Ct. 53 (U.S. 2013) (awarding summary judgment to Defendants and rejecting Plaintiffs' speculative argument that Mississippi's "failure to dictate every execution detail in writing could cause a constitutional problem"); Cooey v. Strickland, 610 F. Supp.2d 853, 927 (S.D. Ohio 2009) ("That Ohio significantly supplements its written procedures with the State's unwritten protocol does not offend the Constitution."). Second, Rule 56 of the Federal Rules of Civil Procedure expressly provides that answers to interrogatories may be used as a factual basis in support of a summary judgment motion. Fed. R. Civ. P. 56(c).

There is no evidence in the record that disputes Defendants' interrogatories. For

example, in response to Plaintiffs' discovery requests, Defendants provided Plaintiffs with copies of the licensing documents provided by the compounding pharmacy that produced the drugs for the scheduled execution of Hubert Michael. (See Doc. No. 219 ¶ 22.) Defendants also produced test results indicating that they had sent the drugs to an independent laboratory for testing. (Id.; Doc. No. 218-2 at 92-101.) Moreover, that Defendants replaced the drugs that initially failed the Rapid Scan RDI test (see Doc. No. 218-2 at 93) reinforces their assertion that the testing requirement is in place, and the record does not support a contrary finding.[10] Although Plaintiffs call the existence of the aforementioned safeguards "bald assertions," the Court disagrees; they are sworn interrogatories supported by the factual record before the Court, and, in the absence of record evidence to the contrary, are not facts genuinely in dispute. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-49 (1986). Thus, despite Plaintiffs' argument to the contrary, the Court finds that it has been established for purposes of Defendants' summary judgment motion that Pennsylvania utilizes licensing and testing safeguards, both of which mitigate Plaintiffs' concerns regarding the compounding process.

There is another undisputed safeguard in place in the written protocol to ensure the first

[10] Although Plaintiffs suggest that the DOC failed to address the issue of drugs' sterility (see Doc. No. 218 at 13-15), the record indicates that Defendants in fact received assurances that the drugs passed certain sterility guidelines. (See id.) Specifically, the Defendants revealed during discovery that a Rapid Scan RDI test was performed on the drugs, that this test "is more stringent than the USP 797 sterility testing guidelines," and that the independent laboratory informed the DOC that samples would have passed USP 797 sterility guidelines. (Doc. No. 218-2 at 93-94.) Plaintiffs do not appear to dispute that where compounded drugs meet USP standards, they are safe. (Doc. No. 219 at 5.) Thus, although Plaintiffs now – as the Court will discuss later in this memorandum – dispute the reliability of this testing, crucially, there remains no genuine dispute in the record as to whether DOC utilizes independent testing. As the Court will also discuss later in this memorandum, any possible error attributable to the testing laboratory does not preclude summary judgment for Defendants.

drug has been properly administered before moving on to the second. Jackson noted that "[t]he proper administration of [the first drug] is an indispensable link in the lethal injection chain for Eighth Amendment purposes, as it ensures that an inmate will not suffer under the effects of the second two drugs." Jackson, 594 F.3d at 225. The Court finds that the undisputed written protocol addresses this concern by having a standard "consciousness check" before the delivery of the final two drugs. The District Court in Jackson v. Danberg, whose order denying a stay of execution was affirmed by the Third Circuit in Jackson, noted the importance of a similar step in defraying Eighth Amendment concerns relating to the three-drug protocol. No. 06-300-SLR, 2011 WL 3205453, at *3 (D. Del. July 27, 2011). In light of this additional layer of protection, there is no basis in the undisputed record to support Plaintiffs' assertion – reiterated by Dr. Waisel in his supplemental declaration – that compounding drugs create a substantial risk of harm upon implementation of the second drug, by potentially failing to render the prisoner unconscious. (See Doc. No. 238-2 (quoting supplemental declaration of Dr. Waisel).)

Lastly, the Court must address Plaintiffs' new evidence concerning the laboratory that tested the drugs in conjunction with the scheduled execution of Hubert Michael in 2012. As discussed earlier, on November 6, 2012, the Court denied class Plaintiff Hubert Michael's motion for a stay of execution. (See Doc. No. 186.) In conjunction with that motion, Defendants produced evidence that the pentobarbital prepared for Mr. Michael's execution had a potency of 96.6%, evidence which is part of the record in this case. (Id.) All of the drug testing in conjunction with the 2012 scheduled execution was performed by the same independent laboratory. (See Doc. No. 240 at 5.)

The Court allowed for an additional period of discovery after Plaintiffs indicated that

they ucovered information regarding an FDA investigation – which occurred subsequent to the close of discovery in this case – into the entity responsible for testing the drugs at issue, which may have revealed certain deficiencies in the laboratory's procedures. (See Doc. Nos. 233-234.) Having conducted their supplemental discovery, Plaintiffs now also contend that there is "a factual dispute as to the reliability of the [2012] laboratory reports." (Doc. No. 238-2.) Plaintiffs have supplemented the record with an expert report from Dr. Andy Papas, setting forth his belief that the FDA's findings cast doubt on the accuracy and reliability of the 2012 testing results. (See Doc. No 238-2 at 8-10 (citing Dr. Papas' report).) A supplemental declaration from Dr. David Waisel concurs. See id. at 13 (quoting supplemental declaration of Dr. Waisel).)

However, the Court finds the Defendants are entitled to summary judgment regardless of the outcome of any dispute concerning the reliability of the independent laboratory's 2012 drug testing. Even if Plaintiffs have established that the independent laboratory's 2012 testing of the drugs was unreliable, "Baze left no room for doubt that a single instance of mistake does not suffice to demonstrate a substantial risk of serious harm." Cooey v. Strickland, 589 F.3d 210, 224 (6th Cir. 2009) ("Speculations, or even proof, of medical negligence in the past or in the future are not sufficient to render a facially constitutionally sound protocol unconstitutional."). See Jackson v. Danberg, 594 F.3d 210, 226-27 (3d Cir. 2010) (rejecting the plaintiffs' argument that evidence of Delaware's historical noncompliance with its execution protocol – "isolated examples of maladministration" – created a disputed issue of material fact that should preclude summary judgment). The Court has already found that Pennsylvania's protocol and safeguards, such as the requirement that drugs are tested by an independent laboratory and that there be a mandatory consciousness check after injection of the first drug, are constitutional on their face.

Thus, Plaintiffs' proffered evidence – that drugs may have once been improperly tested by an independent laboratory in conjunction with the scheduled execution of Hubert Michael – is an example of a single instance of a mistake does not suffice to demonstrate a substantial risk of harm, and does not defeat Defendants' summary judgment motion. See Baze, 553 U.S. at 62-63.

IV. CONCLUSION

Pennsylvania's execution protocol utilizes compounded drugs, and although Plaintiffs have identified risks associated with that source, the risk identified by Plaintiffs' evidence – as evaluated in the context of the safeguards provided by the Commonwealth's execution protocol – does not establish that Pennsylvania's protocol is sure or very likely to cause serious illness and needless suffering in violation of the Eighth Amendment. As the Court finds that no reasonable fact-finder could conclude that Pennsylvania's three-drug lethal injection protocol is "sure or very likely to cause serious illness and needless suffering," – and no genuine disputes of material fact precluding that determination – it will grant summary judgment for Defendants, and enter judgment for Defendants on the claims brought in Plaintiffs' complaint.[11] An order consistent

[11] Although the Court is granting summary judgment for Defendants on the merits of Plaintiffs' claims, the Court can not yet close the case because the issue of the Intervenors' motion to unseal is still pending, a motion that is yet to be fully briefed by the parties. Nevertheless, the Court will enter final judgment for Defendants and against Plaintiffs on the claims raised in Plaintiffs' complaint. Federal Rule of Civil Procedure 54(b) provides that "when an action presents more than one claim for relief--whether as a claim, counterclaim, crossclaim, or third-party claim--or when multiple parties are involved, the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay. . ." Fed. R. Civ. P. 54(b).

The Intervenors' pending motion – seeking to challenge confidentiality orders entered previously in this action – is entirely collateral to the Court's order on the merits of Plaintiffs' constitutional claims, and the Court finds no just reason to delay entering final judgment in favor of Defendants and against Plaintiffs on the claims raised in the Plaintiffs' complaint. See Elliott

with this memorandum follows.

v. Archdiocese of New York, 682 F.3d 213 (3d Cir. 2012). Accordingly, only the merits of the Intervenors' motion to unseal remains pending before the Court in this action.