IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

RICHARD JORDAN and RICKY CHASE,	)	
Plaintiffs,	)	
THOMAS EDWIN LODEN, Jr.,	)	
Putative Intervenor,	)	
v.	)	**Civil Action No. 3:15-cv-00295**
MARSHALL L. FISHER, Commissioner, Mississippi Department of Corrections, in his Official Capacity, et al.,	)	
Defendants.	)	

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

The Motion for Preliminary Injunction (Doc. 21) currently before the Court, like the Complaint filed by Plaintiffs Richard Jordan and Ricky Chase (Doc. 1), is narrowly focused on the substantial risks posed by the Defendants' plan to have active pharmaceutical ingredients (APIs) compounded into pentobarbital for use as the first drug in Mississippi's three-drug lethal injection series. Defendants admit that Mississippi has never before used compounded pentobarbital as the anesthetic designed to prevent the condemned prisoner from experiencing the extreme, torturous pain caused by the second and third drugs in the series.[1] Thus if Plaintiffs are executed using pentobarbital compounded from APIs, they will be the first death row prisoners in Mississippi to be subject to this experiment.

[1] Defendants' Answer (Doc. 19) at ¶¶ 97, 98, 100.

This lawsuit does not challenge the entirety of the lethal injection protocol promulgated by MDOC. The Complaint instead targets specific decisions of the Defendants which present substantial risks that Plaintiffs Jordan and Chase will be tortured to death by chemical entombment, conscious suffocation, and intense internal burning. These include:

- MDOC's decision to continue its three-drug lethal injection procedure, after a majority of currently executing states have implemented a single-drug, barbiturate-only execution protocol to eliminate the substantial risk of torture threatened by the use of a paralytic agent and potassium chloride in a three-drug series.

- MDOC's decision to use a drug compounded from pentobarbital sodium API as the first drug in a three-drug series, despite the risk that this substance will not sufficiently anesthetize the condemned prisoner prior to the administration of drugs which indisputably cause severe and torturous pain prior to death.

- MDOC's lack of any plan for compounding the raw ingredients for pentobarbital into an injectable solution.

- MDOC's choice of pentobarbital, which is not an "ultra short-acting barbiturate or other similar drug" as required of the anesthetic by Miss. Code Ann. § 99-19-51, the method of execution statute.

- MDOC's refusal to disclose the identity and source of its lethal injection drugs to the condemned prisoners who may be tortured to death by sub-potent, irregular, degraded, or counterfeit drugs.

Plaintiffs' Motion for Preliminary Injunction is even more limited than the Complaint. The order sought would prohibit the Defendants from (1) using any anesthetic that is not in the statutorily-mandated class of "ultra short-acting barbiturates"; (2) using any anesthetic that is not manufactured under the regulation of the FDA; (3) using any drug which has passed its expiration date; and/or (4) using the three-drug series that is only being actively used by a minority of states.[2]

[2] Counts IV and V of the Complaint, which challenge Defendants' wall of secrecy involving lethal injection drugs, are not at issue in the Motion for Preliminary Injunction.

Defendants recently filed their Answer (Doc. 19), which includes several critical admissions. These facts are established against the Defendants in this litigation and, as discussed below, support Plaintiffs' Motion for Preliminary Injunction.

STATEMENT OF FACTS RELEVANT TO THE MOTION FOR PRELIMINARY INJUNCTION

I. MISSISSIPPI'S NEW ERA IN LETHAL INJECTION

A. Baze and Thorson

In Mississippi, the manner of execution for individuals sentenced to death is "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced . . . ." Miss. Code Ann. § 99-19-51. As Dr. Mark Heath, Assistant Professor of Clinical Anesthesiology at Columbia University in New York City, explains, Mississippi uses the three-drug series for lethal injection first proposed by Drs. Chapman and Deutsch in Oklahoma: (1) The administration of general anesthesia. (2) The administration of a neuromuscular blocking agent that has a paralyzing effect to ensure the execution appears serene and peaceful. (3) The administration of potassium chloride, which kills the prisoner by stopping his heart.[3]

Eight years ago, Mississippi was not alone in using this three-drug series. In 2008, when the Supreme Court first considered the constitutionality of lethal injection, 36 states had adopted lethal injection as the exclusive or primary means of implementing the death penalty. *Baze v. Rees*, 553 U.S. 35, 42, 128 S.Ct. 1520, 1527 (2008) (plurality op. of Roberts, C.J.). Of those 36 states (including Kentucky, the respondent in *Baze*), 30 used the same combination of three drugs in their lethal injection protocols:

[3] Declaration of Mark J.S. Heath, M.D., Doc. 21-1 ("Heath Decl."), at ¶¶ 14-15.

> The first drug, sodium thiopental (also known as Pentothal[4]), is a fast-acting barbiturate sedative that induces a deep, comalike unconsciousness when given in the amounts used for lethal injection. The second drug, pancuronium bromide (also known as Pavulon), is a paralytic agent that inhibits all muscular-skeletal movements, and, by paralyzing the diaphragm, stops respiration. Potassium chloride, the third drug, interferes with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest.

Id., 553 U.S. at 44, 128 S.Ct. at 1527-28 (Roberts, C.J.).

If the first drug in the series does not sufficiently anesthetize the prisoner, these second two drugs will cause serious harm and severe pain. Chief Justice Roberts wrote that "[i]t 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." *Id*., 553 U.S. at 53, 128 S.Ct. at 1533 (Roberts, C.J.).

At the same time, the experts for both parties in *Baze* agreed that "a proper dose of thiopental obviates the concern that a prisoner will not be sufficiently sedated." *Id*., 553 U.S. at 59, 128 S.Ct. at 1536 (Roberts, C.J.). The important question in *Baze* was thus whether the procedures used in Kentucky's development and administration of the first drug raised a substantial risk of severe pain and/or serious harm. A majority of the Court held that they did not.

Following *Baze*, the Fifth Circuit in *Thorson v. Epps*, 701 F.3d 444, 448 (5th Cir. 2012), found that Mississippi's protocol, which at that time employed the same three-drug series as was approved in *Baze*, did not violate the Eighth Amendment. Like *Baze*, *Thorson* involved the use of

[4] Significantly, by referring to the trade name for sodium thiopental, the Court made clear that the drug was not compounded from active pharmaceutical ingredients (APIs), but rather was purchased from a manufacturer subject to FDA regulation. The importance of this is discussed below.

sodium thiopental (purchased from an FDA-approved manufacturer), a drug in the class of ultra short-acting barbiturates,[5] as the anesthetic in Mississippi's three-drug protocol.

B. Abandonment of Three-Drug Protocol by Majority of Executing States

There have been two significant changes since *Baze* and *Thorson* were decided. **First, Mississippi now stands nearly alone in continuing to use the three-drug protocol**: "the majority of executing states have abandoned the second and third drugs in the original three-drug protocol, instead executing prisoners by a single overwhelming dose of a barbiturate . . . . [T]he states which have adopted a single-drug anesthetic-only barbiturate technique have done so to reduce the substantial risk of serious harm and severe pain presented by the use of a paralytic agent and potassium chloride in a three-drug series. At least eighty (80) executions nationwide have been accomplished with a single-drug barbiturate-only protocol."[6]

This change is illustrated in the following chart,[7] which tracks executions nationwide since 2010 and illustrates the lethal injection statutes enacted by state legislatures and the lethal injection protocols implemented by state departments of corrections:

[5] Defendants' Answer (Doc. 19) at ¶ 173.

[6] Heath Decl. at ¶ 16. This includes Kentucky, the state which was involved in the *Baze* case. *Id*.

[7] The chart is compiled from data maintained by the Death Penalty Information Center, and *available at*: http://www.deathpenaltyinfo.org/executions-united-states.

	3-drug sodium thiopental	1-drug sodium thiopental	3-drug pentobarbital	1-drug pentobarbital	3-drug midazolam	2-drug midazolam	Other	Total
2010	34 TX, LA, OK, FL, MS, VA, AL, GA, AZ	9 OH, WA	1 OK	0	0	0	2 VA, UT	46
2011	7 AL, GA, MO, TX, AZ	1 OH	31 OK, TX, SC, MS, AL, AZ, GA, DE, VA, FL, ID	4 OH	0	0	0	43
2012	0	0	21 OK, TX, MS, FL, DE	22 AZ, OH, ID, TX, SD	0	0	0	43
2013	0	0	12 OK, FL, AL	24 TX, GA, OH, AZ, MO	2 FL	0	1 VA	39
2014	0	0	2 OK	22 TX, MO, GA	9 FL, OK	2 OH, AZ		35
2015	0	0	0	12 GA, TX, MO	2 FL, OK	0	0	14 (to date)

Thus, from 2010 to 2012, of the 132 executions conducted nationwide, over 70 percent (94 executions) were conducted using a three-drug protocol. Yet since 2013, just three (3) states have conducted executions using a three-drug protocol, a total of 27 executions (31 percent) of the 88 conducted nationwide. Only 14 of these 88 executions used pentobarbital in a three-drug series (16 percent of executions nationwide).[8]

C. The Transition to Use of Compounded Drugs in Lethal Injection

The second significant change in lethal injection practice post-*Baze/Thorson* is that, in June 2012, Mississippi obtained the active pharmaceutical ingredients (APIs) used for compounding pentobarbital. Before then, Mississippi used Pentothal, the brand-name for sodium thiopental, an FDA-approved ultra short-acting barbiturate, and then Nembutal, an FDA-

[8] The data is maintained by the Death Penalty Information Center, and *available at*: http://www.deathpenaltyinfo.org/executions-united-states.

approved preparation of pentobarbital,[9] as the first drug in its three-drug lethal injection series. These two drugs are produced by pharmaceutical companies subject to FDA regulation to ensure conformity with Current Good Manufacturing Practice (GMP) requirements, as well as periodic testing to ensure that the batches of drugs manufactured by these companies meet FDA standards.

Sodium thiopental has not been used in executions in Mississippi since 2010,[10] and can no longer be purchased from its manufacturer for use in executions.[11] Also, any unused drugs from MDOC's purchase of Nembutal have expired,[12] and MDOC can no longer purchase Nembutal from its manufacturer.[13] Thus, Mississippi purchased 70 grams of API for the compounding of pentobarbital from H&W Compounding, Inc. ("Brister Brothers").[14] Brister Brothers had purchased this API from Professional Compounding Centers of America, Inc. ("PCCA") in Houston, Texas.[15] Significantly, Defendants do not know the original source of the API purchased from PCCA through Brister Brothers.[16]

Understanding the important differences between FDA-approved drugs[17] and those non-FDA-approved drugs produced by "non-traditional pharmacy compounding" is necessary to a full appreciation of the risks raised by this transition.

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[9] Heath Decl. at ¶ 44; Defendants' Answer (Doc. 19) at ¶¶ 59, 65, 66, 68, 88, 173, 186, 197, 208.

[10] Defendants' Answer (Doc. 19) at ¶ 59.

[11] Defendants' Answer (Doc. 19) at ¶¶ 52, 197, 208.

[12] Defendants' Answer (Doc. 19) at ¶ 66.

[13] Defendants' Answer (Doc. 19) at ¶¶ 61, 62, 88, 145, 186, 209.

[14] Defendants' Answer (Doc. 19) at ¶¶ 88, 89, 90, 92, 93.

[15] Defendants' Answer (Doc. 19) at ¶ 89.

[16] Defendants' Answer (Doc. 19) at ¶¶ 109, 111.

[17] The term "FDA-approved" will be used to refer to a drug manufactured under FDA-controlled and regulated conditions. A drug which is compounded is not considered an "FDA-approved" medication. FDA, The Special Risks of Pharmacy Compounding (2012), Doc. 21-2 ("2012 FDA Special Risks"), *available at*

1. Traditional versus Non-Traditional Pharmacy Compounding

The process of creating drugs by pharmacy compounding is not the same as that involved in the manufacture of drugs (either "name-brand" or "generic") by a pharmaceutical company. Pharmacy compounding originated to meet a very specific need in the health care system. What the FDA now defines as "traditional pharmacy compounding" is:

> [T]he extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized medical needs of an individual patient. Traditional compounding typically occurs when an FDA-approved drug is unavailable or a licensed health−care provider decides that an FDA-approved drug is not appropriate for his or her patient's medical needs.[18]

Dr. Larry Sasich,[19] an expert on pharmacy compounding, explains why and how traditional pharmacy compounding is used in the medical context:

> Traditional compounding does not involve the creation of drugs from scratch. Rather, it uses active and inactive ingredients to meet the specific, individual needs of a patient whose needs cannot be met with an FDA-approved product for medical reasons.
>
> Traditional compounding requires a legal prescription for an individual patient. For example, a two year-old transplant patient may require a medication that is only available in an FDA-approved tablet form. In such a case, a tablet's ingredients may be reformulated into an oral liquid for administration.[20]

Importantly, the FDA does not consider a compounded drug to be the same substance as the manufactured drug to which it may relate:

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http://www.fda.gov/forconsumers/consumerupdates/ucm107836.htm.

[18] 2006 Limited FDA Survey of Compounded Drug Products, Doc. 21-3 ("2006 FDA Survey"), *available at* http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm204237.htm.

[19] Dr. Sasich is Chair of the Department of Pharmacy Practice at the LECOM School of Pharmacy in Erie, Pennsylvania.

[20] Declaration of Larry D. Sasich, PharmD., MPH, FASHP, Doc. 21-4 ("Sasich Decl."), at ¶¶ 15-16.

> By definition, **pharmacy compounding involves making a new drug** for which safety and efficacy have not been demonstrated with the kind of data that FDA requires to approve a new drug. **In virtually all cases, FDA regards compounded drugs as unapproved new drugs**.[21]

In recent years, however, pharmacy compounding has expanded beyond this limited medical necessity. Compounding pharmacies exploited then-existing loopholes in Federal law to create and market copies of FDA-approved drugs for general distribution. Dr. Sasich explains: "Non-traditional pharmacy compounding involves the use of raw ingredients called Active Pharmaceutical Ingredients (APIs) to manufacture a copy or substitute for an FDA-approved drug. These products are not made for a specific patient with a specific medical need, but for general distribution."[22]

2. Concerns about Non-Traditional Pharmacy Compounding

Describing the growth of non-traditional pharmacy compounding, the FDA stated in 2012 that "[t]he emergence of firms with pharmacy licenses making and distributing drugs in a way that's outside the bounds of traditional pharmacy compounding is of great concern to FDA."[23] The FDA identified concerns related to (a) the under-regulation of non-traditional pharmacy compounding which impacts the quality, safety, and effectiveness of the final products, as well as to (b) the often unknown and unregulated sources of the active pharmaceutical ingredients (APIs) which implicate the identity and integrity of the final compounded products.

[21] 2006 FDA Survey (emphasis added), Doc. 21-3.

[22] Sasich Decl. at ¶ 17.

[23] 2012 FDA Special Risks, Doc. 21-2.

a. Lack of FDA Monitoring and Regulation

Drugs created by non-traditional pharmacy compounding are developed and sold without the testing required by the FDA to ensure that drugs are potent, pure, safe, and effective. The director of the FDA Office of Unapproved Drugs stated in the 2012 FDA Special Risks report that "consumers need to be aware that **compounded medications are not FDA-approved** . . . . This means that **FDA has not verified their quality, safety and effectiveness**."[24]

Because pharmacies are not meant to be large-scale pharmaceutical manufacturers, a far less restrictive regulatory regime controls their operation:

> Drug manufacturing is highly technical, requiring strict adherence to current GMP guidelines and a rigorous and continuous process of FDA inspection, regulation, supervision, and oversight.
>
> The manufacture of sterile drugs intended for intravenous administration, such as pentobarbital sodium, is acknowledged by pharmaceutical manufacturers and the FDA alike to be one of the most difficult of all pharmaceutical processes to execute. The preparation of sterile drugs is unavoidably complex, often involving many steps and manipulations. Each step poses an opportunity for error, including unintended introduction of potentially dangerous cross contaminants, and the possibility of a problematic osmolality or imbalanced pH.
>
> Unlike manufacturers, compounding pharmacies do not have to adhere to the stringent FDA approval procedures for manufacturing sterile drugs. Instead, the less rigorous United States Pharmacopoeia (USP) <797> chapter standards may be applied to compounders. As a result, the potential for product contamination with compounded drugs is far higher than that of manufactured drugs. In some states, state law and Boards of Pharmacy do not even require compliance with this lesser USP standard.
>
> The Mississippi Board of Pharmacy Regulations, effective July 1, 2014, do not specifically require compliance with all of USP Chapter <797> for the compounding of high-risk sterile products and appear to be the Board's own creation. There are some references to select USP standards.

[24] 2012 FDA Special Risks, Doc. 21-2, citing Kathleen Anderson, acting director of the Office of Unapproved Drugs and Labeling Compliance in FDA's Center for Drug Evaluation and Research (CDER) (emphasis added).

> Article XXVIII of the Mississippi regulations on the Regulation of Sterile Pharmaceuticals is a lower standard than USP Chapter <797>, and both are significantly lower than federal GMP guidelines.[25]

This is not a case of a *de minimis* failure to follow Federal regulations. Rather, FDA's concerns about non-traditional pharmacy compounding are directly related to the agency's core mission of protecting Americans from unsafe drugs. Thus, FDA warns that "poor compounding practices can result in contamination or in medications that don't possess the strength, quality and purity required."[26] As Dr. Sasich explains:

> Injectable drugs regulated by the FDA must be sterile and meet other stringent requirements for quality, purity, and stability. Compounded injectable drugs made from a non-sterile API outside of an FDA-regulated facility carry a substantial risk of causing immediate harm and pain to the recipients of such drugs. This risk is real, not hypothetical or speculative, and is based on objective evidence from the real world that has been observed over the last century in this country.[27]
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> A recent example of the consequences of injectable drugs not meeting strict FDA standards is the 2012 fungal meningitis epidemic caused by the New England Compounding Center that resulted in more than 700 cases of meningitis and over 60 deaths, all of which were preventable.[28]

b. The Integrity of APIs for Non-Traditional Compounding of Drugs

Defendants admit that they do not know the source of the raw ingredients they obtained in June 2012.[29] This is the rule, rather than the exception, in the "grey market" of non-traditional pharmacy compounding. In this unregulated market, a chemical labeled as a certain active

[25] Sasich Decl. at ¶¶ 22-26 (emphasis added).

[26] 2012 FDA Special Risks, Doc. 21-2, citing Ilisa Burnstein, Pharm.D., acting director of FDA's Center for Drug Evaluation (CDER) Office of Compliance.

[27] Sasich Decl. at ¶ 45.

[28] Sasich Decl. at ¶ 47.

[29] Defendants' Answer (Doc. 19) at ¶¶ 109, 111.

ingredient may actually contain another, quite different ingredient. Practitioners, regulators, and experts have identified this problem as to chemicals distributed in large quantities to pharmacies throughout the nation for use in compounding.[30] As Dr. Sasich explains:

> Much of the bulk API used in non-traditional compounding is not produced in FDA-registered and inspected facilities. This is not an idle concern. Plants in China have been found to manufacture pesticides using the same equipment used to make APIs bound for human ingestion as part of a compounded product . . . . By contrast, APIs used in manufactured (FDA-regulated) pharmaceuticals must come from a manufacturer that holds a Drug Master File for the chemical (a confidential, detailed document submitted by API manufacturers to the FDA containing the chemistry, manufacturing, and controls of a drug component) and must be manufactured in a FDA-registered plant.[31]

A hearing before the U.S. House Energy and Commerce Committee cited **compounding pharmacies as a primary route of entry for counterfeit bulk drugs**: "Lured by high prices and potential profits in the United States, counterfeit bulks [APIs] can get into our prescription drugs in several ways: (1) as imported ingredients to U.S. manufacturers; (2) as **imported ingredients to pharmaceutical compounders**; and (3) as source ingredients for Internet pharmacies marketing to the U.S. The counterfeiters use sophisticated methods such as preparing false labeling, containers, seals and certificates of analysis, or using a manufacturing process that differs from the filed manufacturing process."[32]

At the same hearing, former FDA Associate Commissioner Dennis Baker testified that "[counterfeit bulk drugs] pose a real or potential health hazard because their manufacturer is often

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[30] Sasich Decl. at ¶ 32.

[31] Sasich Decl. at ¶ 30, citing Statement of Dennis Baker, former FDA Associate Commissioner, before the House Commerce Committee Subcommittee on Oversight and Investigations Counterfeit Bulk Drugs, June 8, 2000, *available at* http://www.hhs.gov/asl/testify/t000608a.html.

[32] Sasich Decl. at ¶ 27, quoting Prepared Statement of Honorable Fred Upton before the House Commerce Committee Subcommittee on Oversight and Investigations Counterfeit Bulk Drugs, June 8, 2000, *available at* http://www.fda.gov/ohrms/dockets/dockets/05p0116/05p-0116-cp00001-17-Exhibit-16-vol1.pdf (emphasis added).

unknown . . . . The impurity profile is unknown, and the age, the storage, the manufacturing environment, or the synthesis of the product cannot be determined," creating a situation where "no amount of finished product testing can build quality into the product."[33]

The importance of receiving the API from a reputable, regulated source should be obvious. But to be clear, Dr. Sasich has described this importance in detail:

> There can be no guarantees that APIs purchased from the grey market are safe for use, are not contaminated, or even contain the ingredient listed on the product label. Furthermore, because chemicals may not have been manufactured in an FDA-registered facility under current GMP standards, there can be no assurance as to the quality variation from lot-to-lot or container-to-container.
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> If poor quality ingredients are used, even the best compounding practices will not build quality and suitability into the final product. The compounded drug may be contaminated, super-potent or sub-potent, non-sterile, or at risk of an unusually short shelf life. A pharmacist may have confidence in her ability to accurately measure or weigh individual ingredients and extend this confidence as a quality measure for the finished compound. But if the pharmacist is starting with an adulterated or counterfeit chemical that would go unrecognized in a pharmacy setting (as opposed to a manufacturing facility with the capacity to test the quality of ingredients and overseen by federal regulators), accurate measurement of chemicals cannot remedy an already adulterated or otherwise unsafe product with respect to identity, purity, potency, or harmful contamination. Despite a pharmacist's best efforts, there are parameters beyond her professional control that build risk and uncertainty into all compounded products.[34]

II. MISSISSIPPI'S PLAN TO USE AN ANESTHETIC PRODUCED BY NON-TRADITIONAL PHARMACY COMPOUNDING POSES CONSTITUTIONALLY UNACCEPTABLE RISKS.

A. The Three-Drug Protocol Presents Substantial Risks of Serious Harm. Thus, the Majority of Executing States Have Abandoned This Method.

In recent years, the majority of executing states, and the majority of executions, have proceeded without the use of a paralytic agent or potassium chloride. According to Dr. Heath, of

[33] Sasich Decl. at ¶ 28, quoting Statement of Dennis Baker, *available at* http://www.hhs.gov/asl/testify/t000608a.html.

[34] Sasich Decl. at ¶¶ 35-36.

the 7 states that conducted executions in 2014, only 2 (Florida and Oklahoma) still adhered to the classic triple drug lethal injection protocol. And of the 35 executions conducted in 2014, only 11 used a triple drug protocol.[35] Thus far, in 2015, of the 14 executions by lethal injection, 12 used single-drug barbiturate-only methods; only 2 used a triple drug protocol with a paralytic agent and potassium chloride.[36] Dr. Heath concludes:

> Thus, the dominant form of lethal injection in the United States has become an "anesthetic-only" procedure, in which prisoners are simply administered a lethal overdose of a sedative-anesthetic drug.[37]

The use of an FDA-approved barbiturate in a single-drug execution protocol effectively addresses the serious risk found to be "undisputed" in all three opinions in *Baze*. As Chief Justice Roberts put it: "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." *Baze*, *supra*, 553 U.S. at 53, 128 S.Ct. at 1533 (Roberts, C.J.). By removing the latter two drugs, the majority of executing states have eliminated this substantial and unacceptable risk for serious harm and severe pain.

Thus, Dr. Heath points out that "the states which have adopted a single-drug anesthetic-only barbiturate technique have done so to reduce the substantial risk of serious harm and severe pain presented by the use of a paralytic agent and potassium chloride in a three-drug series."[38] He explains further:

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[35] Heath Decl. at ¶ 20.

[36] Heath Decl. at ¶¶ 21. These numbers have been updated to reflect current data as of the date of this filing. The data is maintained by the Death Penalty Information Center, and *available at* http://www.deathpenaltyinfo.org/executions-united-states.

[37] Id. at ¶ 22.

[38] Id. at ¶ 16.

> The great majority of executions using the anesthetic-only technique use a single drug, either sodium thiopental or pentobarbital.[39] These drugs are both barbiturates, and in massive overdose they ablate consciousness, ablate respiration, and produce hemodynamic collapse.[40] The combination of not breathing and hemodynamic collapse causes rapid death. Because the prevention of breathing and the hemodynamic collapse only occurs with the successful administration of a high dose of barbiturate, and because the dose required for these effects is higher than the dose required to produce unconsciousness, any person who dies from respiratory cessation and hemodynamic collapse caused by barbiturates will necessarily have been unconscious and thus incapable of experiencing anything, including pain or suffering.
>
> From the above, it should be clear that the single-drug anesthetic-only barbiturate technique has repeatedly achieved the states' goal of producing a rapid and painless death. As a matter of historical fact, multiple executions using the single-drug protocol with FDA-approved barbiturates have been conducted by multiple states without anomaly, incident, or complaint.
>
> The success of the barbiturate-only protocol demonstrates conclusively that the inclusion of a paralytic drug and potassium chloride in a lethal injection protocol is unnecessary to achieve the governmental purpose of producing a rapid painless execution.[41]

Dr. Heath describes the torturous pain caused by the three-drug protocol if the first drug fails to sufficiently anesthetize the prisoner:

> [T]he neuromuscular blocking agents proposed by the MDOC for use as the second drug (the "chemical paralytic agent" in the Mississippi statute) do not cause unconsciousness in the way that an anesthetic drug does. **Rather, if administered alone or after an insufficient dose of anesthetic,** a lethal dose of pancuronium bromide or vecuronium bromide would cause a condemned inmate to lose consciousness only after he or she had endured the excruciating experience of suffocation. **The paralytic agent would totally immobilize the inmate by paralyzing all voluntary muscles (including the diaphragm), causing the inmate to suffocate to death while experiencing an intense, conscious, and desperate desire to breath.**

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[39] Two of the anesthetic-only executions used a combination of midazolam and hydromorphone. These prisoners died, but it took much longer than other executions. The use of midazolam is currently under review by the United States Supreme Court. Heath Decl. at ¶ 24, n.3.

[40] Hemodynamic collapse is a steep decline in blood pressure and cardiac function. Heath Decl. at ¶ 24, n.4.

[41] Heath Decl. at ¶¶ 24-26.

> Ultimately, consciousness would be lost, but it would not be lost as an immediate and direct result of the pancuronium bromide or vecuronium bromide. Rather, the loss of consciousness would be due to suffocation, which would be preceded by the torment and agony caused by suffocation. This period of torturous suffocation would be expected to last at least several minutes and would only be relieved by the onset of suffocation-induced unconsciousness.
>
> The experience, in onset and duration and character, would be very similar to that of being suffocated by having one's nose and mouth blocked off. However, **there would be the additional element of being unable to move or writhe or communicate the agony.**
>
> **There is no medical dispute that intravenous injection of concentrated potassium chloride solution,** such as that administered by the MDOC as the third drug in its execution series, **causes excruciating pain.** The vessel walls of veins are richly supplied with sensory nerve fibers that are highly sensitive to potassium ions.
>
> Thus, in comparison to the single-drug anesthetic-only barbiturate technique, the use of a paralytic drug and potassium chloride in a three-drug protocol presents a substantial risk of causing an agonizing, painful, and cruel death, while otherwise serving no legitimate purpose. Conscious paralysis is not simply a bad way to die, it is one of the worst ways to die. **Chemical entombment and suffocation, combined with the excruciating pain caused by the injection of concentrated potassium chloride, is difficult to surpass in terms of agony.**[42]

The botched execution of Clayton Lockett by Oklahoma in April 2014 provides further evidence as to the substantial risks associated with the three-drug protocol which are effectively addressed by the use of a single-drug anesthetic-only protocol.[43] Dr. Heath explains:

> The Lockett execution used a three-drug protocol with a paralytic agent and potassium chloride, and resulted in an excruciatingly agonizing death by chemical entombment and suffocation. The execution team, despite including a physician, was not able to competently insert a catheter into the lumen of a vein. After multiple failed attempts, the team inserted a catheter into Mr. Lockett's groin, but the catheter tip was not inside the femoral vein and the drugs infiltrated into the tissues surrounding the vein. The paralytic drug is rapidly absorbed into the circulation and gradually causes increasing weakness and ultimately suffocation via paralysis of the respiratory muscles. By contrast, the anesthetic drug (in this case midazolam)

[42] Heath Decl. at ¶¶ 27-31 (emphasis added).

[43] Heath Decl. at ¶ 33.

> takes much longer to enter the circulation and produce anesthetic concentrations in the blood and brain.
>
> The Lockett execution clearly demonstrates the perils of the triple drug protocol. Even when a physician is present and personally inserts the IV catheter, if the catheter is misplaced then the prisoner will die a slow and agonizing death. The paralytic drug will produce its excruciating influence before the sedative/anesthetic produces unconsciousness.[44]

Dr. Heath further notes that "[t]he execution of Angel Diaz in Florida in 2006 was botched in exactly the same way – specifically, all three drugs were infiltrated, and as expected from their known pharmacological behavior, the paralytic drug caused paralysis and suffocation before the anesthetic could render Mr. Diaz unconscious."[45]

B. The Use of Lethal Injection Drugs Produced by Non-Traditional Pharmacy Compounding Creates a Substantial Risk of Serious Harm.

Specifically because of the torturous pain described above, Chief Justice Roberts found that "a substantial, constitutionally unacceptable risk" is created if "a proper dose of sodium thiopental that would render the prisoner unconscious" is not administered. *Baze*, *supra*, 553 U.S. at 53, 128 S.Ct. at 1533 (Roberts, C.J.). And Defendants admit that administration of an "ultra short-acting barbiturate or other similar drug" is a crucial step in the execution procedure under Mississippi's current lethal injection protocol.[46]

However, where the anesthetic to be used in the three-drug series is produced by non-traditional pharmacy compounding, the likelihood that the prisoner will be injected with a contaminated or sub-potent chemical, incapable of rendering the prisoner sufficiently anesthetized, is a substantial risk of constitutional significance.

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[44] Heath Decl. at ¶¶ 34-35.

[45] Id. at ¶ 35.

[46] Defendants' Answer (Doc. 19) at ¶ 135.

For example, on January 10, 2014, Oklahoma prisoner Michael Lee Wilson was executed under a three-drug protocol that used pentobarbital sodium injection produced by an unknown compounding pharmacy. It was reported that within 20 seconds of receiving the injection Mr. Wilson cried that he felt his "whole body burning."[47] As Dr. Heath explains, "Barbiturate injection into a vein should not be palpable or painful, and should not produce a burning sensation. Mr. Wilson's statement is therefore consistent with a painful reaction to the injection of contaminated pentobarbital."[48] Dr. Sasich concurs:

> It is my opinion that Mr. Wilson's reaction is consistent with a contaminated pentobarbital sodium injection. Because of common problems with safety procedures of compounding pharmacies and testing laboratories, and the lack of adequate oversight by federal and state authorities, the injection used in Mr. Wilson's execution likely contained cross-contaminates that he was allergic to, bacteria and endotoxins. The injection could have had an altered pH due to contaminates or inadequate procedures used in the preparation of the drug. Additionally, because of this lack of oversight described above, no one knows for sure what was injected into Mr. Wilson.[49]

The South Dakota execution of Eric Robert on October 15, 2012 used pharmacy compounded pentobarbital. According to reports, Mr. Robert appeared to clear his throat, gasped heavily and snored. Over a ten-minute period his skin turned a blue-purplish hue. During the course of his execution, he opened his eyes and they remained open until his death. It took 20 minutes for the state to declare Mr. Robert dead. Mr. Robert's heart continued to beat ten minutes after he

[47] Sasich Decl. at ¶ 69.

[48] Heath Decl. at ¶ 39.

[49] Sasich Decl. at ¶ 70. Dr. Heath points out, "as Michael Wilson was paralyzed as part of the three-drug injection, it is not possible to know from the external observations of witnesses whether his death was humane or cruel." Heath Decl. at ¶ 39.

stopped breathing.[50] Dr. Sasich is of the opinion that Mr. Robert's execution is "consistent with the administration of a compounded drug that was contaminated or sub-potent."[51]

1. Compounding Drugs for Intravenous Administration is Complex.

The process of compounding drugs intended for intravenous administration is fraught with difficulty:

> The manufacture of sterile drugs intended for intravenous administration, such as pentobarbital sodium, is acknowledged by pharmaceutical manufacturers and the FDA alike to be one of the most difficult of all pharmaceutical processes to execute. The preparation of sterile drugs is unavoidably complex, often involving many steps and manipulations. Each step poses an opportunity for error, including unintended introduction of potentially dangerous cross contaminants, and the possibility of a problematic osmolality or imbalanced pH.[52]

Despite the complexity of producing a sterile compounded anesthetic for injection, Mississippi has no plan for exactly how or where to compound pentobarbital for use in executions. The Roderick & Solange MacArthur Justice Center has repeatedly requested MDOC to produce, under the Mississippi Public Records Act, all documents related to lethal injection drugs. The documents produced to date indicate there is no contract, purchase order, protocol, or other document indicating any agreement for a qualified pharmacy to compound pentobarbital sodium API into the injectable drug.[53]

Moreover, as Dr. Sasich testifies, Mississippi offers its execution team no guidance on how to compound pentobarbital sodium API into an injectable drug:

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[50] Sasich Decl. at ¶ 71.

[51] Id. at ¶ 72.

[52] Id. at ¶ 23.

[53] See Doc. 21-5, MDOC Response to MacArthur Justice Center Request for Public Records of November 20, 2014. Additional requests for this information have similarly been answered without providing any protocol, policy, contract, communication, or other information regarding the actual compounding of pentobarbital sodium API.

> Mississippi's protocol for lethal injection does not contemplate use of compounded drugs such as compounded pentobarbital. The protocol provides no guidance or instruction as to who will be responsible for compounding the pentobarbital sodium API into a sterile injection, where this compounding process is to take place, when the pentobarbital will be compounded in advance of an execution, and how the compounded drug will be transported and stored once it is prepared. MDOC has provided no other records that detail a protocol for compounding of the pentobarbital sodium API. The process for compounding an API into a sterile injection is much more complex and technical than the process MDOC would have conducted to obtain commercial Sodium Pentothal or Nembutal (pentobarbital) for use in executions.[54]

Dr. Sasich continues: "Doing this outside of a facility designed for sterile compounding would be reckless. In my opinion, to a reasonable degree of scientific certainty, this practice presents a substantial risk of serious harm and severe pain to any Mississippi prisoner who would be executed by such compounded drugs."[55]

2. MDOC's Only Supply of Pentobarbital Sodium API Has Expired.

Defendants admit that the expiration date of the pentobarbital obtained by MDOC in 2012 was May 20, 2015.[56] They further admit that Mississippi has not purchased any additional pentobarbital since May 20, 2012.[57] Thus, the only API for compounding pentobarbital currently possessed by MDOC expired on May 20, 2015.

As Dr. Heath explains, the expiration of pentobarbital sodium API is the point at which the deterioration of the quality of the raw ingredients has passed a critical stage. Even before the listed expiration date, such deterioration raises concerns about the quality and potency of the API:

> It is important to understand that even a small level of contamination or small deviation in the preparation process will, over time, lead to increasing deterioration of the quality of the batch. Because the MDOC's batch of pentobarbital sodium API

[54] Sasich Decl. at ¶ 95.

[55] Sasich Decl. at ¶ 98.

[56] Defendants' Answer (Doc. 19) at ¶ 120.

[57] Defendants' Answer (Doc. 19) at ¶ 93.

> is at the brink of expiry, a small problem with the initial preparation may well have progressed, over time, into a severe problem that will cause an anomaly or botch. Any contamination, sub-potency, or super-potency in the original preparation may be enhanced as the batch ages closer to its expiration date.[58]

3. MDOC Improperly Stores its Execution Drugs and API.

Mississippi's protocol, which pre-dates its decision to purchase pentobarbital sodium API, is silent on the storage conditions of lethal injection drugs:

> Based on the materials provided to counsel by MDOC, the hospital on the grounds of the Mississippi State Penitentiary at Parchman does not appear to have a pharmacy. Instead it has a drug room, a storage facility which is allowed to be used by hospitals in Mississippi which do not have registered pharmacies.
>
> However, the MDOC materials also indicate that the pentobarbital sodium API and other execution drugs are stored at Unit 17, which is not the prison hospital, but is the unit historically used to house death-sentenced prisoners, and is used now only to house a prisoner facing imminent execution. It also contains the actual execution chamber where lethal injection is carried out.
>
> There is nothing in Mississippi's lethal injection protocol to indicate that MDOC is storing the pentobarbital sodium API properly, nor policies and procedures as to how a compounded injection will be properly prepared from the API.[59]

The Mississippi State Penitentiary at Parchman does not operate its own licensed pharmacy.[60] The Defendants admit that MDOC's lethal injection drugs were kept at Unit 17,[61] the building in which Death Row was formerly housed but which is used now only during the execution of a prisoner. Defendants state that their lethal injection drugs have "recently" been moved to the drug room at the Mississippi State Penitentiary hospital.[62]

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[58] Heath Decl. at ¶¶ 44-45.

[59] Sasich Decl. at ¶¶ 92-94. The standards for storage of high-risk compounded sterile products, including pharmacy-compounded pentobarbital produced from APIs, are discussed in Sasich Decl. at ¶¶ 81-86.

[60] Defendants' Answer (Doc. 19) at ¶ 95.

[61] Id. at ¶ 96.

[62] Id.

The attempted execution of Kelly Gissendaner in Georgia in March 2015 demonstrates how improper storage of API or compounded drugs creates risks in lethal injection executions. As Dr. Heath explains:

> The scheduled execution of Ms. Gissendaner was postponed because the compounded pentobarbital solution was cloudy (definitive evidence of a major problem with the drug, rendering it unfit for use). The Georgia Department of Corrections has now cited to failures in the handling and storage of the compounded drug as the cause. Based on the information presently available, the Department not only failed to maintain a proper temperature during the transport and storage of the drug, but also failed to conduct any research as to the appropriate storage temperature and to develop a handling protocol accordingly.[63]

The events in Georgia demonstrate that Mississippi's careless approach to storage of APIs or lethal injection drugs presents serious risks to Mr. Jordan and Mr. Chase:

> [G]iven the Georgia experience with the planned execution of Kelly Gissendaner, there is reason for concern that MDOC's storage of the pentobarbital sodium API and/or the compounded injectable solution will cause degradation of the drug planned for use as the critical element to assure that the prisoner will not consciously experience the excruciating pain and agony caused by the use of the second and third drug in the Mississippi execution protocol.[64]

4. Summary of the Risks Involved in the Mississippi Plan

Dr. Heath summarizes the risks of MDOC's plan to use compounded pentobarbital as the first of a three-drug series which is to be completed by a chemical paralytic agent and potassium chloride:

> Mississippi's use of compounded pentobarbital, near its expiration date, likely to be compounded by MDOC staff or the state executioner, and maintained under an unknown or nonexistent handling and storage protocol, as the sole bulwark to protect the prisoner from the agony of a paralytic drug and potassium chloride, presents more than a substantial risk of severe pain and serious harm. It is, rather, a foreseeable recipe for an egregious botch causing an agonizing death for the condemned prisoner.

[63] Heath Decl. at ¶ 42.

[64] Heath Decl. at ¶ 51.

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> For these reasons, it is my opinion, to a reasonable degree of medical certainty, that Mississippi's planned use of compounded pentobarbital as the first drug in a three-drug series which is completed with the continuous intravenous administration of a chemical paralytic agent and potassium chloride, creates a substantial risk of serious harm and severe pain to the condemned prisoner. The single-drug anesthetic-only barbiturate technique which is in use in other jurisdictions, using an FDA-approved ultra short-acting barbiturate, significantly reduces this substantial risk of severe pain.[65]

Dr. Sasich concurs:

> It is my opinion, to a reasonable degree of scientific certainty, that there is a substantial risk that the compounded drugs planned for use in lethal injections in Mississippi will be sub-standard in a manner that will cause severe pain upon or shortly after injection. These include the risk that the compounded drug will be sub-potent, expired, contaminated, contain unintended additives, or will contain a substantial level of particulates.[66]

III. COMPOUNDED PENTOBARBITAL IS NOT AN "ULTRA SHORT-ACTING BARBITURATE OR OTHER SIMILAR DRUG" AS REQUIRED BY MISSISSIPPI'S LETHAL EXECUTION STATUTE.

Mississippi plans to use compounded pentobarbital in Plaintiffs' executions, despite the fact that, unlike most other states, the Mississippi method of execution statute specifies the use of "an **ultra short-acting barbiturate** or other similar drug . . . ." Miss. Code Ann. § 99-19-51 (emphasis added).

Defendants admit that Pentothal (the anesthetic in use when Mississippi first implemented lethal injection) is classified as an ultra short-acting barbiturate, based on the drug's speed of onset and duration of effect.[67] However, the same is not true of pentobarbital:

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[65] Heath Decl. at ¶¶ 49, 52.

[66] Sasich Decl. at ¶ 100.

[67] Defendants' Answer (Doc. 19) at ¶ 173.

> Pentobarbital sodium is classified as a short-acting barbiturate. It is not an ultra short-acting barbiturate. This classification is indicated on the Food and Drug Administration approved professional product label for the drug.
>
> It is my opinion, to a reasonable degree of scientific certainty, that pentobarbital sodium is not a "similar drug" to an ultra short-acting barbiturate for purposes of lethal injection. The properties of an ultra short-acting barbiturate relevant to a three-drug lethal injection series are the drug's rate of onset and the degree of anesthetic depth induced by the drug. Pentobarbital has a slower rate of onset than do the drugs in the "ultra short-acting barbiturate" classification.[68]

Dr. Heath concurs with this opinion[69], and elaborates on the point:

> Sodium thiopental is classified among the ultra short-acting barbiturates. Pentobarbital, by contrast, is classified either as a short-acting barbiturate or an intermediate-acting barbiturate.
>
> Barbiturates are classified both in terms of their speed of onset and their duration of action, but these properties are linked. Ultra short-acting barbiturates (referring to their duration of action) are also ultra fast-acting (referring to their speed of onset). By contrast, short-, intermediate-, and long-acting barbiturates do not possess the quality of being ultra fast-acting, and their speed of onset is observably slower than an ultra fast-acting barbiturate.
>
> While there is some flexibility as to the classification of barbiturates as short, intermediate-, or long-acting, there is a sharp boundary between those barbiturates that are ultra fast- and ultra short-acting, and everything else. Barbiturates that are classified as short- or intermediate-acting (such as pentobarbital) have a slower speed of onset than an ultra short- or ultra fast-acting barbiturate (such as sodium thiopental), and thus do not achieve anesthetic depth in a patient as rapidly as an ultra short-acting barbiturate.[70]

The distinction between an ultra short-acting barbiturate and pentobarbital is significant, because in four (4) of the last six (6) executions in Mississippi, the paralytic drug was "pushed" a

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[68] Sasich Decl. at ¶¶ 13-14.

[69] Heath Decl. at ¶ 59.

[70] Heath Decl. at ¶¶ 53-55. Dr. Heath points out that "[t]he significance of the term "ultra short-acting barbiturate" in the Mississippi statue is highlighted by the fact that the statute also requires a "continuous intravenous injection" of the execution drug. The instruction for this continuous application of the drug underscores the legislative intent that the barbiturate be ultra short-acting; there would be less need to employ a continuous injection for a barbiturate (such as a short-acting or an intermediate-acting barbiturate) with a longer duration of effect." Id. at ¶ 56.

mere two to three minutes after the anesthetic.[71] It is exactly the "speed of onset" – which Defendants admit is one of the defining characteristics of an ultra short-acting barbiturate – that is critical in the role of the first drug in the three-drug series. Dr. Heath explains:

> By definition, an "ultra short-acting barbiturate" such as sodium thiopental takes effect much more quickly than does a "short- or intermediate-acting barbiturate" such as pentobarbital. Given the risks discussed above, the difference in the speed with which the two classes of drugs take effect is significant. Where the barbiturate used as the first drug in a three-drug protocol has a slower speed of onset, there is a substantial risk that the drug's anesthetic properties will not have taken effect when the paralytic agent and potassium chloride are injected.[72]

Moreover, "[t]his difference is magnified when, as planned by MDOC, compounded, rather than FDA-approved, pentobarbital is employed . . . [g]iven the substantial risk that compounded pentobarbital could be contaminated, sub-potent, or even counterfeit."[73]

LAW AND ARGUMENT

I. STANDARD FOR GRANTING PRELIMINARY INJUNCTION

The criteria for determining whether a preliminary injunction should be granted were established in the Fifth Circuit in *Canal Authority of State of Fla. v. Callaway*, 489 F.2d 567, 572 (5th Cir. 1974):

> A substantial likelihood that plaintiff will prevail on the merits; a substantial threat that irreparable injury will result of the injunction is not granted; that the threatened injury outweighs the threatened harm to defendant, and that granting the preliminary injunction will not disserve the public interest.

Mississippi Power & Light v. United Gas Pipe Line Co., 760 F.2d 618, 621 (5th Cir. 1985) (*quoting Callaway*); *Google, Inc. v. Hood*, 2015 WL 1546160 (S.D. Miss., March 27, 2015) at *7. *See also*

[71] Heath Decl. at ¶ 57.

[72] Id.

[73] Heath Decl. at ¶ 58.

Winter v. Natural Resources Defense Council, Inc., 129 S.Ct. 365, 374 (2008). Plaintiffs meet these criteria and a preliminary injunction should be granted.

II. SUBSTANTIAL LIKELIHOOD OF SUCCESS ON THE MERITS

In this case, Plaintiffs have advanced three separate legal theories to support their claim for injunctive relief:

Count I (Complaint ¶¶ 152-169) asserts that Mississippi's plan for executing Plaintiffs presents "a substantial risk of serious harm and severe pain" and therefore constitutes cruel and unusual punishment forbidden by the Eighth Amendment as interpreted in *Baze*.

Count II (Complaint ¶¶ 170-180) challenges the use of compounded pentobarbital under the Eighth and Fourteenth Amendments and Mississippi statutory law as that anesthetic is not an "ultra short-acting barbiturate or other similar drug" as required by Miss. Code Ann. §99-19-51 (1972).

Count III (Complaint ¶¶ 181-195) challenges Mississippi's continued use of the three-drug protocol for lethal injection executions where that protocol has been abandoned by the majority of executing states, representing the evolving standards of decency which underpin the Eighth Amendment.

Plaintiffs need only succeed on one of these counts in order to secure permanent injunctive relief. Thus, if this Court finds that there is a substantial likelihood of success on the merits of at least one of these counts, this criterion has been satisfied.

A. Plaintiffs Are Likely to Prevail on the Merits of Count I: The Mississippi Execution Protocol Creates a Substantial Risk of Serious Harm and Severe Pain in Violation of the Eighth Amendment as Interpreted in *Baze*.

It is well-established that a challenge to a state's method of execution is cognizable under 42 U.S.C. § 1983. *Hill v. McDonough*, 547 U.S. 573, 126 S.Ct. 2096 (2006).[74]

To date, *Baze v. Rees*, 553 U.S. 35, 128 S.Ct. 1520 (2008), is the Supreme Court's leading, substantive decision on whether a particular manner of execution constitutes cruel and unusual punishment as forbidden by the Eighth Amendment. Seven justices concluded that the lethal injection protocol then used by Kentucky was not unconstitutional; however, no opinion garnered a majority of the Court.

Chief Justice Roberts announced the Court's ruling in a plurality opinion joined by Justices Kennedy and Alito. The plurality's analysis is important to this case. It begins by stating that "[o]ur cases recognize that subjecting individuals to a risk of future harm – not actually inflicting pain – can qualify as cruel and unusual punishment." *Baze*, 553 U.S. at 49, 128 S.Ct. at 1530. To prevail on such a claim, under the Chief Justice's plurality opinion, there must exist a "substantial risk of serious harm." *Id*., 553 U.S. at 50, 128 S.Ct. at 1531.[75]

In assessing Kentucky's lethal injection protocol, the plurality concluded 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

[74]In *Hill*, the Court held that Federal constitutional challenges to a state's method of execution may be brought pursuant to 42 U.S.C. § 1983 because these suits deal with "the circumstances of . . . confinement," as opposed to the validity or duration of confinement, which must be challenged through a petition for habeas corpus. 547 U.S. at 579. *See also Nelson v. Campbell*, 541 U.S. 637, 647 (2004) (holding that plaintiff properly used § 1983 to challenge Alabama's planned use of a "cut down" procedure during his lethal injection and that his claims did not need to be presented in a petition for writ of habeas corpus).

[75] Although no opinion in *Baze* commanded a majority, the Fifth Circuit has adopted the Chief Justice's opinion as the standard to be employed in an Eighth Amendment challenge to a method of execution. *See Thorson v. Epps*, 701 F.3d 444, 446-47 (5th Cir. 2012).

and pain from the injection of potassium chloride." *Id*., 553 U.S. at 53, 128 S.Ct. at 1533. But as the plurality also found, "proper administration of the first drug, sodium thiopental, eliminates any meaningful risk that a prisoner would experience pain from the subsequent injections of pancuronium and potassium chloride." *Id*., 553 U.S. at 49, 128 S.Ct. at 1530.

Of particular significance to the case before this Court, the plurality in *Baze* recognized that the process by which the injectable anesthetic is created is critical to a determination of the constitutionality of a lethal injection protocol:

> As for the risk that the sodium thiopental would be improperly prepared . . . [the trial court] specifically found that if the manufacturers' instructions for reconstitution of Sodium Thiopental are followed, there would be minimal risk of improper mixing, . . . that finding is substantiated by expert testimony describing the task of reconstituting powder sodium thiopental into solution form as not difficult at all.

Id., 553 U.S. at 54, 128 S.Ct. at 1533. Thus the availability of FDA-approved manufacturers' instructions for the drug, as well as the lack of complexity in the preparation process, were integral factors to the plurality's assessment of whether any risks posed by the anesthetic in *Baze* rose to constitutionally unacceptable levels.

However, unlike the procedure assessed in *Baze*, Mississippi's current plan for executing the Plaintiffs does not rely on the mere reconstituting of an FDA-approved preparation of sodium thiopental.[76] Rather, the Defendants plan to have the active pharmaceutical ingredients (APIs) for pentobarbital **compounded**.[77] As recognized by the analysis of the plurality in *Baze*, an assessment

[76] Describing the ease with which one may reconstitute powder sodium thiopental, the plurality in *Baze* referenced expert testimony in the trial court: "You take a liquid, you inject it into a vial with powder, then you shake it up until the powder dissolves and, you're done. The instructions are on the package insert." *Baze*, 553 U.S. at 54, 128 S.Ct. at 1533. This process sharply contrasts with the complexity of non-traditional pharmacy compounding. *See* Sasich Decl. at ¶¶ 17, 18, 22-23, 95.

[77] As defined by the Federal Food, Drug, and Cosmetic Act, "the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling." The Federal

of the challenges and uncertainties involved in the compounding of pentobarbital is integral to the determination of whether MDOC's protocol poses a substantial risk of serious harm to the Plaintiffs.[78] The significant distinctions between the reconstitution of an FDA-approved drug and the compounding of APIs makes a difference in this analysis.

First, rather than obtaining an FDA-approved drug from its manufacturer, **Mississippi will use compounded drugs** which, as the FDA has said, "are not FDA approved . . . . This means that **FDA has not verified their quality, safety, and effectiveness**."[79] As discussed at length above, the very identity of the drugs – whether the API is, in fact, pentobarbital sodium API – is open to doubt. "If poor quality ingredients are used, even the best compounding practices will not build quality and suitability into the final product. The compounded drug may be contaminated, super-potent or sub-potent, non-sterile, or at risk of an unusually short shelf life."[80] Here, Defendants admit that they have purchased pentobarbital sodium API without knowing the original source of these raw ingredients.[81]

Second, non-traditional pharmacy compounding is not the same as reconstituting a drug supplied by its FDA-regulated manufacturer. As Dr. Sasich has stated, "**The process for**

Food, Drug, and Cosmetic Act, U.S. Code, Title 21, Chapter 9, Sub-Chapter V, Part A, Section 353a (Pharmacy Compounding), Doc. 21-6.

[78] Because Mississippi has changed its plan to rely on non-traditional pharmacy compounding of pentobarbital, it cannot rely on *Thorson v. Epps*, 701 F.3d 444, 448 (5th Cir. 2012), in which the Fifth Circuit held that Mississippi's protocol – which at that time employed the same three-drug series as was approved in *Baze* – did not violate the Eighth Amendment. Like *Baze*, *Thorson* involved the use of sodium thiopental (purchased from an FDA-approved manufacturer), a drug in the class of ultra short-acting barbiturates, as the anesthetic in Mississippi's three-drug protocol.

[79] 2012 FDA Special Risks, Doc. 21-2, citing Kathleen Anderson, acting director of the Office of Unapproved Drugs and Labeling Compliance in FDA's Center for Drug Evaluation and Research (CDER).

[80] Sasich Decl. at ¶ 36.

[81] Defendants' Answer (Doc. 19) at ¶¶ 109, 111.

compounding an API into a sterile injection is much more complex and technical than the process MDOC would have conducted to obtain commercial Sodium Pentothal or Nembutal (pentobarbital) for use in executions."[82] "The manufacture of sterile drugs intended for intravenous administration, such as pentobarbital sodium, is acknowledged by pharmaceutical manufacturers and the FDA alike to be one of the most difficult of all pharmaceutical processes to execute. The preparation of sterile drugs is unavoidably complex, often involving many steps and manipulations. Each step poses an opportunity for error, including unintended introduction of potentially dangerous cross contaminants, and the possibility of a problematic osmolality or imbalanced pH."[83]

Third, Mississippi has no standard procedure for proper storage of the API or the drugs compounded therefrom. "There is nothing in Mississippi's lethal injection protocol to indicate that MDOC is storing the pentobarbital sodium API properly, nor policies and procedures as to how a compounded injection will be properly prepared from the API."[84] The recent Georgia experience highlights the importance of this deficiency.[85] Defendants admit that the Mississippi State Penitentiary at Parchman does not operate its own licensed pharmacy, and that MDOC's lethal injection drugs have been kept at Unit 17,[86] the former building in which Death Row was housed, which is used now only during the execution of a prisoner. Defendants also admit that their lethal injection drugs have just "recently" been moved to the drug room at the Mississippi State

[82] Sasich Decl. at ¶ 95.

[83] Sasich Decl. at ¶ 23.

[84] Sasich Decl. at ¶ 94.

[85] See discussion of canceled Gissendaner execution, *supra*, at page 22.

[86] Defendants' Answer (Doc. 19) at ¶96.

Penitentiary hospital.[87] The MDOC execution protocol is silent on the storage of API for compounding of lethal injection drugs.

Additionally, the pentobarbital sodium API that Mississippi obtained in June 2012 expired on May 20, 2015.[88] As Dr. Heath explained, the expiration of the API poses additional risks with respect to potential contamination and/or sub-potency in the June 2012 batch.[89]

Plaintiffs' experts testify that these issues associated with the compounding of pentobarbital from API present the substantial risk of serious harm which establishes an Eighth Amendment claim under the *Baze* plurality's standard.

Dr. Heath:

> Mississippi's use of compounded pentobarbital, near its expiration date, likely to be compounded by MDOC staff or the state executioner, and maintained under an unknown or nonexistent handling and storage protocol, as the sole bulwark to protect the prisoner from the agony of a paralytic drug and potassium chloride, presents more than a substantial risk of severe pain and serious harm. It is, rather, a foreseeable recipe for an egregious botch causing an agonizing death for the condemned prisoner.
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> ***
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> For these reasons, it is my opinion, to a reasonable degree of medical certainty, that Mississippi's planned use of compounded pentobarbital as the first drug in a three-drug series which is completed with the continuous intravenous administration of a chemical paralytic agent and potassium chloride, creates a substantial risk of serious harm and severe pain to the condemned prisoner. The single-drug anesthetic-only barbiturate technique which is in use in other jurisdictions, using an FDA-approved ultra short-acting barbiturate, significantly reduces this substantial risk of severe pain.[90]

[87] Id.

[88] Defendants' Answer (Doc. 19) at ¶¶ 70, 98, 120.

[89] Heath Decl. at ¶¶ 44-45.

[90] Heath Decl. at ¶¶ 49, 52.

Dr. Sasich:

> It is my opinion, to a reasonable degree of scientific certainty, that there is a substantial risk that the compounded drugs planned for use in lethal injections in Mississippi will be sub-standard in a manner that will cause severe pain upon or shortly after injection. These include the risk that the compounded drug will be sub-potent, expired, contaminated, contain unintended additives, or will contain a substantial level of particulates.[91]

For these reasons, as amplified by the detailed statement of facts set forth above, Plaintiffs have a substantial likelihood of success on the merits of their *Baze* claim.

B. Plaintiffs Are Likely to Prevail on the Merits of Count II: Mississippi's Plan to Use Compounded Pentobarbital Violates Mississippi State Law and the Eighth and Fourteenth Amendments.

Count Two of Plaintiffs' Complaint relies on both Mississippi statutory law and the Eighth and Fourteenth Amendments. Simply put, the Mississippi Legislature has enacted requirements for the process of lethal injection that Defendants do not plan to follow. Miss. Code Ann. §99-19-51 requires "continuous intravenous administration of a lethal quantity of an **ultra short-acting barbiturate** or other similar drug . . . ." (emphasis added). Defendants admit that Sodium Pentothal, previously used in Mississippi executions, is classified as an ultra short-acting barbiturate, based on the drug's speed of onset and duration of effect.[92] The same cannot be said for pentobarbital.

Pentobarbital is neither an ultra short-acting barbiturate nor a "similar drug." Dr. Heath explains:

> Sodium thiopental is classified among the ultra short-acting barbiturates. Pentobarbital, by contrast, is classified either as a short-acting barbiturate or an intermediate-acting barbiturate.

[91] Sasich Decl. at ¶ 100.

[92] Defendants' Answer (Doc. 19) at ¶ 173.

> Barbiturates are classified both in terms of their speed of onset and their duration of action, but these properties are linked. Ultra short-acting barbiturates (referring to their duration of action) are also ultra fast-acting (referring to their speed of onset). By contrast, short-, intermediate-, and long-acting barbiturates do not possess the quality of being ultra fast-acting, and their speed of onset is observably slower than an ultra fast-acting barbiturate.[93]

Dr. Sasich makes a similar point:

> Pentobarbital sodium is classified as a short-acting barbiturate. It is not an ultra short-acting barbiturate. This classification is indicated on the Food and Drug Administration approved professional product label for the drug.
>
> It is my opinion, to a reasonable degree of scientific certainty, that pentobarbital sodium is not a "similar drug" to an ultra short-acting barbiturate for purposes of lethal injection. The properties of an ultra short-acting barbiturate relevant to a three-drug lethal injection series are the drug's rate of onset and the degree of anesthetic depth induced by the drug. Pentobarbital has a slower rate of onset than do the drugs in the "ultra short-acting barbiturate" classification.[94]

The distinction between these two classes of barbiturates is significant, because it relies on the speed of onset of the drug:

> By definition, an "ultra short-acting barbiturate" such as sodium thiopental takes effect much more quickly than does a "short- or intermediate-acting barbiturate" such as pentobarbital. Given the risks discussed above, the difference in the speed with which the two classes of drugs take effect is significant. Where the barbiturate used as the first drug in a three-drug protocol has a slower speed of onset, there is a substantial risk that the drug's anesthetic properties will not have taken effect when the paralytic agent and potassium chloride are injected.[95]

There are **two procedural vehicles** for the Court to enforce Section 99-19-51. **The first is to rely on the supplemental jurisdiction statute**, 28 U.S.C. §1367. This Court clearly has Federal question jurisdiction over the subject matter of Counts One and Three, as challenges to a method of execution are cognizable under 42 U.S.C. § 1983, and causes of action under the Eighth and

[93] Heath Decl. at ¶¶ 53-54.

[94] Sasich Decl. at ¶¶ 13-14.

[95] Heath Decl. at ¶ 57.

Fourteenth Amendments are enforceable by granting declaratory and injunctive relief pursuant to 42 U.S.C. §1983. *Hill v. McDonough*, 547 U.S. 573 (2006).

This Court therefore has supplemental jurisdiction under over "all other claims" – state or federal – in the same case or controversy as the federal questions presented in Counts One and Three. *See City of Chicago v. International College of Surgeons*, 552 U.S. 156, 164-65, 118 S.Ct. 523, 529-30 (1997). It follows that this Court can enforce the Mississippi state statute by means of a grant of declaratory and injunctive relief prohibiting the use of any anesthetic which is not an "ultra short-acting barbiturate or other similar drug."

Additionally, however, **this Court can reach the merits of Count Two under the Fourteenth Amendment's Due Process Clause.** Plaintiffs Jordan and Chase have a substantial and legitimate expectation that they will be executed, if at all, only in the manner authorized by state statute. That expectation confers a liberty and life interest protected by the Due Process Clause. *See Hicks v. Oklahoma*, 447 U.S. 343, 346, 100 S.Ct. 2227, 2229 (1980) (expectation that a convicted defendant will be "deprived of his liberty only to the extent determined by the jury in the exercise of its statutory discretion" is enforceable under the Fourteenth Amendment).

> It is apparent from our decisions that there exists a variety of interests which are difficult of definition but are nonetheless comprehended within the meaning of either "liberty" or "property" as meant in the Due Process Clause. These interests attain this constitutional status by virtue of the fact that they have been initially recognized and protected by state law, and we have repeatedly ruled that the procedural guarantees of the Fourteenth Amendment apply whenever the State seeks to remove or significantly alter that protected status.

Paul v. Davis, 424 U.S. 693, 710-11, 96 S.Ct. 1155, 1165 (1976).

In addition to its procedural guarantees, "the Due Process Clause contains a substantive component that bars certain arbitrary, wrongful government actions regardless of the fairness of the procedures used to implement them." *Zinermon v. Burch*, 494 U.S. 113, 125, 110 S.Ct. 975,

983 (1990). The imposition of unauthorized punishment is one of these "arbitrary, wrongful government actions." *See Rutledge v. United States*, 517 U.S. 292, 297, 116 S.Ct. 1241, 1245 (1996) ("Courts may not prescribe greater punishment than the legislature intended.").

Either directly under Miss. Code Ann. §99-19-51 or by means of the Due Process Clause, Plaintiffs Jordan and Chase have a substantial likelihood of success on the merits of their right to injunctive relief forbidding Defendants from using any anesthetic that is not an "ultra short-acting barbiturate or other similar drug" to execute them.

C. Plaintiffs Are Likely to Prevail on the Merits of Count III: Mississippi's Continued Use of a Three-Drug Lethal Injection Series Does Not Conform to the Evolving Standards of Decency and Violates the Eighth Amendment.

It is well established that "the [Eighth] Amendment draws its meaning from the evolving standards of decency that mark the progress of a maturing society." *Kennedy v. Louisiana*, 554 U.S. 407, 419, 128 S.Ct. 2641, 2649 (2008), *quoting Trop v. Dulles*, 356 U.S. 86, 100-101, 78 S.Ct. 590, 598 (1958) (plurality).

> This is because the standard of extreme cruelty is not merely descriptive, but necessarily embodies a moral judgment. The standard itself remains the same, but its applicability must change as the basic mores of society change.

Graham v. Florida, 560 U.S. 48, 58, 130 S.Ct. 2011, 2021 (2010), *citing Kennedy*, 554 U.S. at 419, 128 S.Ct. at 2649, *quoting Furman v. Georgia*, 408 U.S. 238, 382, 92 S.Ct. 2726 (Burger, C.J., dissenting).

In determining the content of the Eighth Amendment, "the Court has been guided by objective indicia of society's standards, as expressed in legislative enactments and state practice with respect to executions." *Kennedy*, 554 U.S. at 421, 128 S.Ct. at 2650. Such objective indicia may determine "whether there is a national consensus against the sentencing practice at issue." *Graham*, 560 U.S. at 61, 130 S.Ct. at 2022.

Chief Justice Roberts' opinion for the *Baze* plurality took this additional approach with respect to the lethal injection protocol used by Kentucky in 2008:

> Thirty-six States that sanction capital punishment have adopted lethal injection as the preferred method of execution. The Federal Government uses lethal injection as well.
>
> This broad consensus goes not just to the method of execution, but also to the specific three-drug combination used by Kentucky. Thirty States, as well as the Federal Government, use a series of sodium thiopental, pancuronium bromide, and potassium chloride, in varying amounts.

Baze, 553 U.S. at 53, 128 S.Ct. at 1532.

The plurality also found it significant that "[n]o State uses or has ever used the one-drug protocol belatedly urged by petitioners." *Id*. It concluded that:

> [T]he Commonwealth's continued use of the three-drug protocol cannot be viewed as posing an objectively intolerant risk when no other State has adopted the one-drug method and petitioners proffered no study showing that it is an equally effective manner of imposing a death sentence.

Id., 553 U.S. at 57, 128 S.Ct. at 1535.

But as detailed above, the landscape of lethal injection has changed dramatically since *Baze* was decided in 2008. From 2010 to 2012, of the 132 executions conducted nationwide, over 70 percent (94 executions) were conducted using a three-drug protocol. Yet since 2013, just three states have conducted executions using a three-drug protocol, a total of 27 executions (31 percent) of the 88 conducted nationwide. Only 14 of these 88 executions used pentobarbital in a three-drug series (16 percent of executions nationwide). And in 2015 alone, of the 14 executions carried out to date, only two (2) have used a three-drug series (and neither employed pentobarbital as the anesthetic).[96]

[96] The data is maintained by the Death Penalty Information Center, and *available at*: http://www.deathpenaltyinfo.org/executions-united-states. See chart *supra* p. 6.

This demonstrates that the actual practice of the majority of States is to punish homicide by a method other than the three-drug protocol still in use in Mississippi. As Dr. Heath states, "the majority of executing states have abandoned the second and third drugs in the original three-drug protocol, instead executing prisoners by a single overwhelming dose of a barbiturate . . . the states which have adopted a single-drug anesthetic-only barbiturate technique have done so to reduce the substantial risk of serious harm and severe pain presented by the use of a paralytic agent and potassium chloride in a three-drug series. At least eighty (80) executions nationwide have been accomplished with a single-drug barbiturate-only protocol."[97]

This transition to a new national consensus against the use of the three-drug execution protocol answers the question posed by the *Baze* plurality about the effectiveness of anesthetic-only executions. As Dr. Heath states:

> Previously, state departments of corrections had expressed concerns that a barbiturate-only protocol could not efficiently accomplish the execution of a condemned prisoner. But in every single execution in which the "anesthetic-only" technique was used, the prisoner died without the need to administer other classes of drugs. There is thus no evidence to support the idea that lethal injection needs to include the use of a paralytic drug or potassium chloride. As with veterinary euthanasia, which decades ago eschewed and prohibited the use of paralytics and potassium, the goal of causing death has been demonstrated to be achievable in humans by anesthetic-only overdose. This is a matter of historic fact that has been demonstrated and established by the majority of currently-executing states and in the majority of executions.
>
> ***
>
> From the above, it should be clear that the single-drug anesthetic-only barbiturate technique has repeatedly achieved the states' goal of producing a rapid and painless death. As a matter of historical fact, multiple executions using the single-drug protocol with FDA-approved barbiturates have been conducted by multiple states without anomaly, incident, or complaint.
>
> The success of the barbiturate-only protocol demonstrates conclusively that the inclusion of a paralytic drug and potassium chloride in a lethal injection protocol is

[97] Heath Dec. at ¶ 16. This includes Kentucky, the state which was involved in the *Baze* case. Id.

> unnecessary to achieve the governmental purpose of producing a rapid painless execution.[98]

Discussing the possibility of an anesthetic-only execution protocol, the *Baze* plurality set forth a standard that Plaintiffs Jordan and Chase have met:

> [T]he proffered alternatives must effectively address a substantial risk of serious harm. To qualify, the alternative procedure must be feasible, readily implemented, and in fact significantly reduce a substantial risk of severe pain. If a State refuses to adopt such an alternative in the face of these documented advantages, without a legitimate penological justification for adhering to its current method of execution, then a State's refusal to change its method can be viewed as cruel and unusual under the Eighth Amendment.

Baze, 553 U.S. at 52, 128 S.Ct. at 1532.

The evolving standards of decency – the national consensus – now reject the risks presented by the use of a chemical paralytic agent and potassium chloride in lethal injection executions. That consensus instead embraces an anesthetic-only procedure which eliminates the potential for serious harm from chemical entombment, suffocation, and internal burning. The approach employed by the majority of executing states proves conclusively that there is no penological justification for the use of the second and third drugs in MDOC's execution protocol. Mississippi's refusal to change its method of execution in light of this consensus threatens Plaintiffs Jordan and Chase with cruel and unusual punishment in violation of the Eighth Amendment.

Thus, Plaintiffs have established a substantial likelihood of success on Count Three of the Complaint.

III. IRREPARABLE HARM

An injury is "irreparable" if it cannot be redressed through monetary remedies. *Deerfield Medical Center v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. 1981). Thus it is a well-

[98] Heath Decl. at ¶¶ 23, 26-27.

recognized principle in the district courts of the Fifth Circuit that "constitutional rights violations constitute irreparable harm." *New Orleans Home for Incurables, Inc. v. Greenstein*, 911 F.Supp.2d 386, 407 (E.D. La. 2012).

Nor is this doctrine limited to First Amendment claims. In *Cohen v. Coahoma County, Miss.*, 805 F.Supp. 398, 406 (N.D. Miss. 1992), a case challenging physically coercive interrogations in a county jail, the district court held, "It has repeatedly been recognized by the federal courts at all levels that violation of constitutional rights constitutes irreparable harm as a matter of law."

In any event, it cannot be seriously disputed that Plaintiffs are threatened with irreparable harm by Mississippi's plan to execute them with a three-drug series, beginning with compounded pentobarbital. Simply put, once they are executed, no legal nor equitable remedy can compensate or redress Plaintiffs for the torture visited upon them by Defendants. As the Eleventh Circuit has succinctly stated with respect to a threatened execution, "We consider the irreparability of the injury that petitioner will suffer in the absence of a stay to be self-evident." *In re Holladay*, 331 F. 3d 1169, 1177 (11th Cir. 2003). In a similar case, the district court in *Cooey v. Taft*, 430 F.Supp.2d 702, 708 (S.D. Ohio 2006), held, "there is an unacceptable and unnecessary risk that [the plaintiff] will be irreparably harmed absent the injunction, i.e., that [he] could suffer unnecessary and excruciating pain while being executed in violation of his Eighth Amendment right not to be subjected to cruel and unusual punishment." The same is true here.

IV. BALANCE OF EQUITIES AND THE PUBLIC INTEREST

In Section 1983 challenges to unconstitutional State practices, the last two elements of the preliminary injunction standard often fit together:

> The third (the threat and injury to plaintiff outweighs the threat and harm to defendant) and fourth (the preliminary injunction will not disserve the public

> interest) prerequisites normally address separate concerns and thus must ordinarily be considered separately. However, where preliminary injunctive relief is sought "... against public institutions and against public servants charged with the enforcement of the law ...," *Spiegel v. City of Houston*, 636 F.2d 997, 1002 (5th Cir. 1981), it is proper for the court to consider them together.

Cohen v. Coahoma County, supra, 805 F.Supp. at 407-08. *Accord, Herdahl v. Pontotoc County Sch. Dist.*, 887 F.Supp. 902, 911 (N.D. Miss. 1995) ("The court finds that the public interest will not be disserved by enjoining the unconstitutional practices of the District.").

As the district court in *Cooey* explained, the interplay between these factors in a Section 1983 method-of-execution case is similar:

> The Court notes that the irreparable injury a constitutional violation presents is clear and favors a stay. *Bonnell v. Lorenzo*, 241 F.3d 800, 809 (6th Cir. 2001) (explaining that "if it is found that a constitutional right is being threatened or impaired, a finding of irreparable injury is mandated" and "a successful showing on the first factor mandates a successful showing on the second factor-whether the plaintiff will suffer irreparable harm").
>
> This Court is not persuaded that issuance of injunctive relief will cause substantial harm to the State or others by comparison. The Court also recognizes that the public interest only is served by enforcing constitutional rights and by the prompt and accurate resolution of disputes concerning those constitutional rights.

Cooey v. Kasich, 801 F.Supp.2d 623, 656-57 (S.D. Ohio 2011).

This Court should likewise find that Plaintiffs Jordan and Chase will be irreparably harmed in the absence of the requested injunction, that this threat of harm outweighs any harm to Defendants in modifying (but not completely prohibiting) their method of execution, and that the public interest will be served by requiring Defendants to follow Miss. Code Ann. §99-19-51 and the Eighth and Fourteenth Amendments.

CONCLUSION

This is an unusual case regarding the death penalty, for it neither challenges the institution of capital punishment nor the method of lethal injection. Put another way, this case does not challenge **whether** Mississippi may inflict capital punishment by means of lethal injection, but only **how** it may do so. For the reasons set forth above, and/or as demonstrated to the Court at an evidentiary hearing, Plaintiffs request that this Court enter a preliminary injection, pending entry of a final judgment, enjoining the Defendants during the execution of the Plaintiffs, including any intervening party to this suit, from:

A. administering any anesthetic that is not in the statutorily-mandated class of "ultra short-acting barbiturates";

B. administering any drug that is not manufactured under the regulation of the Food and Drug Administration (FDA);

C. administering any drug that is produced by means of "non-traditional pharmacy compounding" as that term is used by the FDA;

D. administering any drug which has passed its expiration date; and

E. administering (1) any chemical paralytic agent and (2) any drug for stopping the heart, including but not limited to potassium chloride.

Respectfully submitted,

/s/ James W. Craig
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Dated: June 3, 2015

CERTIFICATE OF SERVICE

I hereby certify that I have filed this pleading with the Electronic Case Filing System of the United States District Court for the Southern District of Mississippi, and have thereby served counsel of record for the Defendants in this case.

This, the 3rd of June, 2015.

/s/James W. Craig