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

RICHARD JORDAN and RICKY CHASE,	)	
Plaintiffs,	)	
THOMAS EDWIN LODEN, Jr.,	)	
Intervenor,	)	
v.	)	**Civil Action No. _____**
MARSHALL L. FISHER, Commissioner, Mississippi Department of Corrections, in his Official Capacity; EARNEST LEE, Superintendent, Mississippi State Penitentiary, in his Official Capacity; THE MISSISSIPPI STATE EXECUTIONER, in his Official Capacity; and UNKNOWN EXECUTIONERS, in their Official Capacities,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT

NATURE OF ACTION

1. Plaintiffs[1] bring this action pursuant to 42 U.S.C. § 1983 for violations and threatened violations of their rights to due process and to be free from cruel and unusual punishment under the First, Eighth, and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14, 24, and 28 of the Mississippi Constitution.

[1] In this First Amended Complaint, the term "Plaintiffs" will be used to refer collectively to named Plaintiffs Richard Jordan and Ricky Chase, as well as Intervenor Thomas Edwin Loden, Jr.

2. On July 28, 2015, Defendants gave notice to this Court of a change to the Mississippi Department of Corrections' lethal injection protocol. The July 2015 protocol now provides that – in the event of the unavailability of a sufficient quantity of sodium thiopental or pentobarbital – the Department will substitute 500 milligrams of midazolam as the first drug in its three-drug series. No other changes were made to the protocol. The amended protocol continues to call for pentobarbital to be used as the first drug in the series when available.

3. Under the direction of the Defendants named herein, the Mississippi Department of Corrections ("MDOC") intends to execute Plaintiffs with compounded drugs that may be counterfeit, expired, contaminated, and/or sub-potent, creating a substantial risk of serious harm to the Plaintiffs. The decision of the Defendants to use compounded drugs, specifically a compounded anesthetic that has not been tested or approved by the United States Food and Drug Administration ("FDA") and the production of which was not under the supervision or regulation of the FDA, substantially risks that Plaintiffs may be conscious throughout their executions and will experience a torturous death by suffocation and cardiac arrest.

4. In the event compounded pentobarbital is unavailable to be used in Mississippi's lethal injection series, MDOC intends to execute Plaintiffs using midazolam as the first drug. Midazolam is a benzodiazepine, an entirely different class of drugs than barbiturates such as sodium thiopental or pentobarbital. Benzodiazepines are not pharmacologically equivalent to barbiturates. There is a substantial risk that midazolam will not render Plaintiffs sufficiently anesthetized and insensate to pain prior to the administration of the second and third drugs in the series, subjecting them to a torturous death by suffocation and cardiac arrest.

5. Further the Defendants intend to execute Plaintiffs using drugs which do not comply with the directive of the Mississippi legislature that death sentences be carried out by the

continuous intravenous administration of "an ultra short-acting barbiturate or other similar drug." Neither compounded pentobarbital nor midazolam are ultra short-acting barbiturates or other similar drugs. Plaintiffs have a life and liberty interest in being punished only to the extent of the statutory authority conferred upon MDOC by the Mississippi legislature. The decision of the Defendants to execute Plaintiffs using a drug that is neither an ultra short-acting barbiturate nor other similar drug impermissibly violates the prescribed form and manner of punishment provided for by the Mississippi legislature, and thereby violates Plaintiffs' due process guarantees.

6. The entirety of the lethal injection protocol promulgated by MDOC is not at issue in this lawsuit. Rather, this civil action challenges the use of compounded drugs (including but not limited to compounded pentobarbital) and midazolam in lethal injection executions conducted by MDOC. Further this civil action specifically challenges the use of a three-drug lethal injection procedure. Lastly this civil action challenges MDOC's intent to have the raw ingredients for pentobarbital compounded into an injectable solution on the grounds of the Mississippi State Penitentiary at Parchman, where there is no pharmacy suitable for compounding sterile drugs.

7. The June 22, 2015 declaration of Defendant Commissioner Marshall Fisher asserts that the Department has destroyed all pentobarbital sodium in its possession, and that the Department has been unable to obtain a new supply of pentobarbital in any form. However, the Department's current protocol still provides for the use of pentobarbital in the event of the unavailability of sodium thiopental. Midazolam is only to be substituted as the first drug in the event of the unavailability of pentobarbital.

8. Other state departments of corrections have obtained and used compounded pentobarbital in 18 executions this year to date. In just the last week of September 2015, the Texas

Department of Criminal Justice provided three (3) vials of compounded pentobarbital to its counterpart in Virginia to be used in a scheduled execution.

9. Furthermore, while Commissioner Fisher declares that all pentobarbital in the custody of the Department has been destroyed, counsel for Plaintiffs have sought records as to the disposition of five (5) vials (of the 14 total vials) of pentobarbital sodium purchased by the Department in 2012. Defendants have failed to account for the whereabouts of these vials.

10. For the reasons set forth in ¶¶ 7 through 9, the allegations and causes of action pled herein with reference to compounded pentobarbital are not moot.

11. MDOC first ordered compounded drugs for purposes of lethal injection executions on May 20, 2012. That purchase instituted a policy, practice, or custom of using compounded drugs in MDOC executions.

12. MDOC first provided for the use of midazolam in lethal injections (in the event of the unavailability of pentobarbital) when it filed notice with this Court of an amendment to its protocol on July 28, 2015. That notice of amended protocol instituted a policy, practice, or custom of using midazolam in MDOC executions.

13. Plaintiffs seek permanent injunctive relief to prevent the Defendants from inflicting cruel and unusual punishment upon them during their executions, and from otherwise violating Plaintiffs' federal and state constitutional rights.

14. Plaintiffs also seek a preliminary injunction against the use of midazolam and compounded pentobarbital in their executions. This Court issued preliminary injunctive relief on August 26, 2015, preserving the status quo pending final adjudication of this civil action. Defendants have sought expedited appeal of this Court's ruling.

JURISDICTION AND VENUE

15. Plaintiffs' claims arise under the Constitution and laws of the United States, as well as under the Constitution of the State of Mississippi. This Court has original federal question jurisdiction over those claims arising under the Constitution and laws of the United States pursuant to 28 U.S.C. §§ 1331, 1343.

16. This Court has the authority to grant declaratory and injunctive relief under 28 U.S.C. § 2201-2202 and FED.R.CIV.P. 57 and 65. The federal rights asserted by Plaintiffs are enforceable under 42 U.S.C. § 1983.

17. Venue is proper in the Southern District of Mississippi under 28 U.S.C. §§ 1391(b)(1) and 1391(c)(2). With respect to Section 1391(b)(1), Defendant Marshall Fisher, Commissioner, Mississippi Department of Corrections, in His Official Capacity, is located in Jackson, Hinds County, Mississippi. With respect to Section 1391(c)(2), all Defendants in this action shall be served with process by service on the Attorney General of Mississippi in Jackson, Hinds County, Mississippi, pursuant to MISS.R.CIV.P. 4(D)(5), incorporated through FED.R.CIV.P. 4(e)(1).

PARTIES

18. Plaintiff Richard Jordan is a United States citizen, currently incarcerated under a sentence of death at the Mississippi State Penitentiary in Parchman, MS. Richard Jordan filed for relief under the MDOC Administrative Remedy Program on October 15, 2014. The request for relief gave MDOC notice and an opportunity to resolve the issues set forth in this Complaint. MDOC rejected the request for relief on October 23, 2014.

19. Plaintiff Ricky Chase is a United States citizen, currently incarcerated under a sentence of death at the Mississippi State Penitentiary in Parchman, MS. Ricky Chase filed for

relief under the MDOC Administrative Remedy Program on October 26, 2014 (received October 29, 2014). The request for relief gave MDOC notice and an opportunity to resolve the issues set forth in this Complaint. MDOC rejected the request for relief on October 30, 2014.

20. Intervenor Thomas Edwin Loden, Jr. is a United States citizen, currently incarcerated under a sentence of death at the Mississippi State Penitentiary in Parchman, MS. Thomas Loden filed for relief under the MDOC Administrative Remedy Program on December 15, 2014. The request for relief gave MDOC notice and an opportunity to resolve the issues set forth in this Complaint. MDOC rejected the request for relief on January 1, 2015.

21. Defendant Marshall L. Fisher is the Commissioner of the Mississippi Department of Corrections.

22. The MDOC is the state agency charged with the incarceration, care, custody, and treatment of all state prisoners, including prisoners sentenced to death. Miss. Code Ann. §§ 47-5-10(a); 47-5-23.

23. Commissioner Fisher is the chief executive, administrative, and fiscal officer of MDOC, establishes the general policy of MDOC, and oversees the administration of all affairs within MDOC. Miss. Code Ann. §§ 47-5-20(a); 47-5-23; 47-5-24(1).

24. As the Commissioner of the MDOC, Mr. Fisher must perform "[a]ll duties and necessary acts pertaining to the execution of a convict . . . except where such duties and actions are vested in the state executioner." Miss. Code Ann. § 99-19-13. *See also* Miss. Code Ann. § 99-19-55.

25. Commissioner Fisher is responsible for ensuring that all prisoners committed to the custody of MDOC are treated in accordance with the United States and Mississippi Constitutions.

26. At all relevant times, Commissioner Fisher has been acting under the color of law and as the agent and official representative of MDOC, pursuant to MDOC's official policies and procedures. Commissioner Fisher is sued in his official capacity only.

27. Defendant Earnest Lee is the Superintendent of the Mississippi State Penitentiary in Parchman, MS, the prison that houses all male death row inmates, and the prison where all executions take place in the State of Mississippi. Miss. Code Ann. § 99-19-55(1).

28. Superintendent Lee is responsible for implementing MDOC's policies and procedures governing executions, managing the preparations for an execution, and for turning over the execution site to the State Executioner to perform the execution.

29. Superintendent Lee is also responsible for protecting the constitutional rights of all persons incarcerated at the Mississippi State Penitentiary in Parchman, and/or transported to Parchman for an execution.

30. At all relevant times, Superintendent Lee has been acting under color of law and as the agent and official representative of the Mississippi State Penitentiary and MDOC. He is sued in his official capacity only.

31. The State Executioner of the State of Mississippi is appointed by the Governor and shall supervise and inflict the punishment of death pursuant to Miss. Code Ann. § 99-19-53. The name of the State Executioner is withheld from the public by the State of Mississippi.

32. The names of Defendants Unknown Executioners are unknown to Plaintiffs, but they include the State Executioner, his or her designee, and members of the State Execution Team. On information and belief, the Unknown Executioners will participate in the process of the execution by virtue of their roles in designing, implementing, carrying out, and/or

supervising the lethal injection process, including the procurement and storage of lethal injection drugs and materials. Miss. Code Ann. § 99-19-53, 99-19-55(2).

33. At all relevant times, Defendants State Executioner and Unknown Executioners have been acting under the color of law. There are sued in their official capacities only.

RELEVANT PROCEDURAL BACKGROUND

34. Plaintiffs filed their original complaint on April 16, 2015 (Doc. 1). Defendants filed their answer on May 28, 2015 (Doc. 19).

35. Plaintiffs moved for preliminary injunction on June 3, 2015 (Doc. 21). Defendants moved to dismiss on June 22, 2015 (Doc. 22), arguing that Plaintiffs claims were simultaneously moot and unripe as the Department had recently destroyed its supply of pentobarbital sodium active pharmaceutical ingredients ("API"), and the Department had been unsuccessful at obtaining any new supply of pentobarbital.

36. Argument on these motions was scheduled for July 29, 2015 at 9:30 a.m.

37. On July 28, 2015, at 6:38 p.m., Defendants filed notice of an amended execution protocol (Doc. 38). The amended protocol (Doc. 38-2) provides for the use of midazolam as the first drug in the three-drug series in "the event of the unavailability of a sufficient quantity of Pentobarbital."

38. Following continued argument on July 31, 2015, this Court denied Defendants' motion to dismiss, and granted Plaintiffs' motion for preliminary injunction (Doc. 42).

FACTUAL ALLEGATIONS

A. MISSISSIPPI'S THREE-DRUG LETHAL INJECTION PROTOCOL

39. 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 by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.

40. MDOC's lethal injection protocol calls for the serial administration of three drugs to put a prisoner to death.

41. The first drug, pentobarbital,[2] a short-acting or intermediate-acting barbiturate, is intended to sufficiently anesthetize the prisoner so that he is both unconscious and insensate when the executioner injects the second and third drugs, vecuronium bromide[3] and potassium chloride, respectively.[4]

42. In the event of the unavailability of pentobarbital, the July 2015 protocol now calls for the use of midazolam, a drug in the benzodiazepine class such as Valium, Xanax, or Klonopin, as the first drug.

43. Pentobarbital is not "an ultra short-acting barbiturate or other similar drug" as required by Mississippi law.

44. Midazolam is not "an ultra short-acting barbiturate or other similar drug" as required by Mississippi law.

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[2] MDOC's current protocol, promulgated July 28, 2015, calls for the use of Sodium Pentothal as the first drug in the series, but provides for the use of pentobarbital "[i]n the event of an unavailability of a sufficient quantity of sodium pentothal from available sources." As discussed *infra*, Sodium Pentothal is no longer available to MDOC. Sodium Pentothal is the trademarked name for sodium thiopental. The MDOC's execution protocols have never expressly authorized or referenced the use of compounded drugs in executions. "In the event of the unavailability of a sufficient quantity of Pentobarbital from available sources," the recently amended protocol now provides for the use of midazolam as the first drug in the series.

[3] The July 2015 protocol calls for the use of pavulon as the second drug in the series, but provides for the use of vecuronium bromide "[i]n the event of unavailability of a sufficient quantity of pavulon from available sources."

[4] MDOC purchased its current supply of vecuronium bromide in July 2014. The supply of vecuronium bromide will expire on October 1, 2015. MDOC purchased a supply of potassium chloride in October 2014. That supply of potassium chloride expired on September 1, 2015. MDOC has not indicated whether this expired supply has been destroyed and whether it has purchased any new supplies of vecuronium bromide or potassium chloride.

45. The second drug, vecuronium bromide, is a neuromuscular blocking agent that paralyzes all of the prisoner's voluntary muscles, including the muscles used for respiration, but *does not* suppress sensation, consciousness, cognition, or the ability to feel pain and suffocation. It is used by MDOC to be the "chemical paralytic agent."

46. There is no legitimate penological justification for the use of a neuromuscular blocking agent or other chemical paralytic agent in an execution by lethal injection.

47. Neuromuscular blocking agents are not necessary to produce death, and do not diminish the prisoner's awareness or ability to feel pain.

48. One hundred (100) executions have been accomplished in other jurisdictions in the United States without the use of a neuromuscular blocking agent or other chemical paralytic agent. In each of these executions, the prisoner died.

49. The only purpose of the neuromuscular blocking agent in Mississippi's lethal injection protocol is to mask the gasping and physical convulsions produced by injection of the final drug, potassium chloride.

50. The neuromuscular blocking agent is thus used to make the execution appear serene and peaceful where the State may have in fact failed to sufficiently anesthetize the prisoner against pain and suffering.

51. The third and final drug in Mississippi's lethal injection protocol is potassium chloride – a chemical that disrupts the electrical signals in the heart, paralyzes the cardiac muscle, and kills the prisoner by cardiac arrest.

52. Provided that a lethal dose of a barbiturate is administered, there is no legitimate penological justification for the use of potassium chloride in an execution by lethal injection.

53. One hundred (100) executions have been accomplished in other jurisdictions in the United States without the use of potassium chloride. In each of these executions, the prisoner died.

54. Midazolam is not in the barbiturate class of drugs, and has never been used by any jurisdiction in a single-drug execution protocol, unlike sodium thiopental and pentobarbital.[5] Benzodiazepines are not pharmacologically equivalent to barbiturates.

55. Where there is a substantial risk that the first drug injected in a three-drug series will not be administered correctly, will not be sufficiently potent, pure, and rapid in onset, and is not chemically capable of rendering the prisoner unconscious and insensate so he does not feel the painful effects of the second and third drugs, the execution will cause severe, torturous pain for the prisoner, in violation of the Eighth and Fourteenth Amendments.

B. KNOWN RISKS OF THE DRUGS USED IN MISSISSIPPI'S LETHAL INJECTION PROTOCOL

56. The drugs used in Mississippi's lethal injection protocol have known and documented risks about which the Defendants are, or should be, aware.

57. The first risk is associated with the administration of vecuronium bromide, the drug currently stockpiled by MDOC to serve as the paralytic agent required by the Mississippi statute and protocol.

58. Vecuronium bromide causes the paralysis of all voluntary muscles, including the lungs and diaphragm.

[5] Only two states have experimented with the use of midazolam as the first drug in a two-drug lethal injection series (to be followed by hydromorphone, an opioid). These experiments produced grisly results. On January 2014, Dennis McGuire's execution in Ohio (using a two-drug injection of midazolam and hydromorphone) took twenty-six (26) minutes. Mr. McGuire appeared to gasp for air and gag throughout the execution. The same protocol (midazolam and hydromorphone) was later used in Arizona's execution of Joseph Wood in July 2014, with even more troubling results. Mr. Wood gasped and gulped in the death chamber as prison officials injected 15 doses of lethal injection chemicals into his body for nearly two (2) hours before he was pronounced dead. While Oklahoma and Ohio previously provided for the use of midazolam in a two-drug series, those states have since amended their protocols to eliminate this option.

59. If vecuronium bromide is administered to a prisoner who is still conscious and able to feel pain, he will suffocate to death while experiencing the agonizing and conscious urge to breath.

60. Thus, if a prisoner is injected with the paralytic agent vecuronium bromide before he is fully anesthetized and before he is rendered insensate, he will experience conscious paralysis and suffocation.

61. However, because the prisoner is completely paralyzed and unable to talk, move, or make facial expressions as a result of being paralyzed, his agony will be completely masked and concealed to observers.

62. The second known risk associated with the drugs used in the Mississippi lethal injection protocol is associated with the third and final drug in the series, potassium chloride.

63. There is no medical dispute that the injection of potassium chloride into an individual who has not been adequately anesthetized will cause excruciating pain.

64. Potassium chloride induces an intense burning sensation throughout the blood vessel walls running through a prisoner's body. If a prisoner is not fully anesthetized prior to the injection of potassium chloride, then he will consciously experience the agony of cardiac arrest.

65. The two risks set forth in ¶¶ 57 to 64 above create a substantial risk of severe pain and serious harm, particularly where MDOC *will not be* administering an FDA-approved,[6] ultra short-acting barbiturate in sufficient dosage and potency to ensure that the prisoner is completely anesthetized prior to the injection of the paralytic agent and of potassium chloride.

[6] As used in this Complaint, the term "FDA-approved" includes both the drug itself (i.e. that the drug's formula is approved for distribution to consumers) and the process for manufacturing the drug. An "FDA-approved" drug thus refers to the specific batch or supply of a medication after manufacture.

66. There is no penological justification for the use of a paralytic agent and potassium chloride in an execution by lethal injection. Executions may be carried out through the use of a single-drug anesthetic-only injection, a protocol now used in most executions nationwide and which has proven effective in executing over one hundred (100) prisoners to date.

67. An execution conducted by MDOC which continues to use a three-drug protocol, thereby refusing to adopt the feasible and readily implemented alternative of a single-drug protocol (which significantly reduces the substantial risks of severe pain and serious harm posed by the use of a chemical paralytic agent and potassium chloride), violates the Eighth Amendment.

C. Recent History of Lethal Injection Executions in Other States Demonstrates the Severity of the Risk of Extreme Pain and Torture Where the Potency and Dosage of the Anesthetic Are Insufficient

68. Reflecting their revulsion against the use of their medications to execute prisoners in the United States, many pharmaceutical manufacturers have ceased production of drugs commonly used in American executions, have refused to sell them to corrections departments that may use them in executions, or have conditioned the sale of such drugs on "end-user agreements" which forbid the resale or use of the drugs for purposes of lethal injection executions.

69. In March 2015, the American Pharmacists Association, the largest association of pharmacists in the United States, voted to adopt a policy which discourages "pharmacist participation in executions on the basis that such activities are fundamentally contrary to the role of pharmacists as providers of health care." Just a week prior to this announcement, the top trade group representing compounding pharmacists in the United States, the International Academy of Compounding Pharmacists, similarly "discourag[ed] its members from participating in the preparation, dispensing, or distribution of compounded medications for use in legally authorized executions."

Sodium Thiopental

70. Hospira, Inc., the American manufacturer of the anesthetic sodium thiopental, stopped making sodium thiopental in 2011, after the drug's use in executions interfered with Hospira's ability to enter into manufacturing contracts in Europe. Hospira elected to stop making the drug entirely because it could not prevent the drug from getting into the hands of departments of corrections. Although sodium thiopental is manufactured in other countries, the FDA has not approved its importation into the United States.

71. Some states – including Georgia – resorted to violating federal law in order to procure sodium thiopental.[7] Georgia illegally imported the drug from an English pharmaceutical distributor that operated out of the back of a driving school in London.

72. In May of 2011, the United States Drug Enforcement Agency ("DEA") seized the illegal sodium thiopental from the Georgia Department of Corrections; however Georgia had already executed two individuals with the illegal substance.

73. The compromised drug used in these Georgia executions failed to perform its necessary function of rendering the prisoners unconscious and insensate, causing the two prisoners to experience significant and unnecessary pain and suffering.

74. Thus, when Brandon Rhode was executed in September 2010 with the illegally-imported sodium thiopental, his eyes remained open for the entirety of his execution, indicating consciousness during the process.

[7] In May 2015, the governor of Nebraska announced the state's purchase of sodium thiopental from a broker in India, despite statements from the FDA that it is unlawful for Nebraska to import the drug and that the FDA would refuse the drug's admission into the United States.

75. Similarly, when Emmanuel Hammond was executed in January 2011 with the illegally-imported sodium thiopental, his eyes also remained open, and he grimaced and appeared to be trying to communicate throughout his execution.

76. Mississippi's lethal injection protocol calls for the use of Sodium Pentothal (a trademarked name for sodium thiopental) as the first drug in its series (except in the event of the unavailability of a sufficient quantity of the drug).

77. The last execution in Mississippi using Sodium Pentothal as the anesthetic drug given first in the three-drug series was on July 21, 2010. Since that time Mississippi has been unable to legally obtain Sodium Pentothal for use in executions.

Nembutal: Pentobarbital Sodium Manufactured by Lundbeck

78. Where Sodium Pentothal is unavailable for use as the first drug in the series, the Mississippi execution protocol allows the administration of pentobarbital in its place.

79. There is only one manufacturer of FDA-approved injectable pentobarbital sodium, sold under the name-brand Nembutal.

80. In July 2011, Lundbeck, the manufacturer of Nembutal, announced that it would no longer sell the drug to departments of corrections, and required purchasers of its drug to enter into end-user agreements by which they agreed not to sell or transfer the drugs to prisons in states that still use capital punishment.

81. In December 2011, Lundbeck sold the rights to Nembutal to Akorn, Inc. and, as part of the agreement, Akorn agreed to maintain the restricted distribution program.

82. Any Nembutal sold prior to the July 2011 agreement would have expired no later than November 2013.

83. The last time MDOC purchased Nembutal was on March 23, 2011.

84. Any unused drugs from MDOC's purchase of Nembutal have expired.

85. By the March 23, 2011 transaction, MDOC purchased 12 units of Nembutal (50 mg/mL). It is unclear from the receiving report disclosed by MDOC what total volume of Nembutal was purchased.

86. The supply of Nembutal obtained by MDOC in March 2011 was utilized by MDOC in executions conducted in May 2011, and in executions conducted between February and June 2012.[8]

87. The State of Mississippi has not executed any prisoner since June 20, 2012.

88. Mississippi no longer has any legally-obtained, FDA-approved, and unexpired pentobarbital to use in executions.

Experimentation with Anesthetics Previously Not Used in Executions

89. Due to this nation-wide shortage of FDA-approved sodium thiopental and pentobarbital for use in executions, some states (including Florida, Ohio, Arizona, and Oklahoma) have executed prisoners with drugs never previously used for lethal injection.

90. In Florida, Ohio, and Arizona executions using these experimental drugs caused the prisoners to remain conscious for an unacceptable length of time.

91. Since October 2013, Florida has executed prisoners using a three-drug protocol featuring midazolam hydrochloride, a paralytic agent, and potassium chloride. William Happ's execution in Florida – the first using this new series – took twice the amount of time as prior executions, and he continued to make body movements after he was injected with an untested drug, midazolam hydrochloride.

[8] As discussed *infra*, MDOC did not purchase any additional legally-obtained, FDA-approved, and unexpired pentobarbital after March 2011. Rather in May 2012, MDOC purchased the active pharmaceutical ingredients to compound pentobarbital. This supply was not received by MDOC until June 13, 2012, according to receiving reports disclosed by MDOC. The State of Mississippi has only conducted one execution – that of Gary Simmons on June 20, 2012 – since this date of receipt. MDOC utilized Nembutal still in its possession from the March 2011 purchase in the execution of Mr. Simmons. MDOC has never used pentobarbital sodium API in any execution in the state.

92. In January 2014, Dennis McGuire's execution in Ohio (using a two-drug injection of midazolam and hydromorphone) took twenty-six (26) minutes, and he gasped for air and gagged throughout the execution.

93. The same protocol (midazolam and hydromorphone) was later used in Arizona's execution of Joseph Wood in July 2014, with even more troubling results. Mr. Wood gasped and gulped in the death chamber as prison officials injected *15 doses of lethal injection chemicals* into his body for *nearly two (2) hours* before he was pronounced dead.

94. A three-drug protocol featuring midazolam hydrochloride was subsequently tried by Oklahoma in April 2014 with torturous results in the botched execution of Clayton Lockett. Mr. Lockett was observed writhing on the execution table and attempting to speak, even after having been declared unconscious.

95. An investigation following Mr. Lockett's execution discovered numerous failures, from the placement of the IV to the lack of procedural safeguards which would have detected or deterred serious problems in the administration of the drugs. The Oklahoma Department of Corrections has since revised its protocol extensively, seeking to address the problems highlighted by Mr. Lockett's execution. It is this revised protocol which is the subject of litigation in the federal courts in the *Glossip* challenge to Oklahoma's method of execution.

Experimentation with Compounded Drugs

96. Some states have responded to the unavailability of Nembutal by turning to the "gray market" of unregulated compounded drugs and unregulated active pharmaceutical ingredients to obtain compounded pentobarbital for use in executions.

97. This type of pharmacy compounding is a deviation from the traditional practice of pharmacy compounding, which involved the mixing of small batches of drugs in response to a

physician's prescription to meet the unique needs of an individual patient when an FDA-approved drug is not suitable for the patient.

98. Compounded drugs are not FDA-approved and have not been evaluated for effectiveness and safety. Until recently, the FDA did not regulate compounded drugs and compounding pharmacies at all, and even now, the FDA does not have regulatory authority over all compounding pharmacies.

99. Compounded drugs are created without producing the data on safety and efficacy that the FDA requires for new drugs, and without the requirement that they follow good manufacturing practice regulations which insure their identity, strength, quality and purity. Thus the FDA has noted "quality problems with various compounded drugs, including sub-potency, super-potency, and contamination."

100. State regulation of compounding pharmacies varies substantially, but no state regulates compounding pharmacies in a manner that would replicate the FDA's regulation of pharmaceutical manufacturers. Without unified standards and regulations there is no way to guarantee that drugs from a compounding pharmacy are what they purport to be and are safe and effective.

101. In recent years, a substandard compounding drug industry has emerged wherein compounding pharmacies create and market copies of FDA-approved drugs for general distribution. These drugs are developed and sold without the testing required by the FDA to ensure that the drugs are potent, pure, safe, and effective.

102. Additionally, there is a significant risk that compounded drugs are manufactured with counterfeit or substandard ingredients purchased from a range of manufacturers that operate outside of FDA supervision and regulation.

103. For these reasons, among others, the FDA has called the proliferation of compounded drugs a "troubling trend" because it has resulted in individuals taking harmful, contaminated, counterfeit, sub-potent, and/or super-potent drugs.

104. This is not a speculative risk. The 2012 outbreak of fungal meningitis caused by contaminated steroid injections from a compounding pharmacy in New England drew national attention to the regulatory vacuum within which compounding pharmacies operate, and the substandard and harmful products that these pharmacies can market to the public. Two senior executives of the New England pharmacy have since been indicted on charges of racketeering and murder. The compounded drugs responsible for the meningitis outbreak had been "tested" and found potent by a laboratory purporting to be "independent."

105. Further, Oklahoma executed Michael Lee Wilson with compounded pentobarbital on January 9, 2014. After Mr. Wilson spoke his final words, and after the executioner administered the first drug, Mr. Wilson spoke again and stated: "I feel my whole body burning."

106. The burning sensation relayed by Mr. Wilson during his execution is consistent with an excruciatingly painful reaction to the injection of contaminated pentobarbital.

D. MISSISSIPPI'S DECISION TO USE COMPOUNDED DRUGS IN LETHAL INJECTION EXECUTIONS

107. Because MDOC can no longer obtain the FDA-approved form of pentobarbital, the Defendants, jointly and/or severally, obtained pentobarbital sodium API for use in lethal injections from a compounding pharmacy in Grenada, Mississippi that otherwise markets its expertise in herbal supplements.

108. On or around May 20, 2012, MDOC purchased $3,150 worth of pentobarbital sodium from H&W Compounding Pharmacy d/b/a Brister Brothers ("Brister Brothers"), a compounding pharmacy in Grenada, MS. According to a receiving report disclosed by MDOC,

this supply was received by the Department on June 13, 2012.[9] Brister Brothers purchased the pentobarbital sodium API from Professional Compounding Centers of America, Inc. ("PCCA"), in Houston, Texas.

109. Defendants did not purchase Nembutal or another sterile, injectable pentobarbital from Brister Brothers on or around May 20, 2012 or at any time thereafter.

110. Specifically Defendants purchased 70 grams of raw materials or active pharmaceutical ingredients from Brister Brothers. These 70 grams were packaged as 14 vials containing 5 grams each.

111. Of the 14 vials purchased in May 2012, MDOC has provided documentation that nine (9) vials were destroyed in June 2015, once the pentobarbital sodium API had passed its expiration date.

112. MDOC has not accounted for the disposition of the other five (5) vials of pentobarbital sodium API (containing 25 grams total) purchased in May 2012. Therefore, according to the documentation provided to Plaintiffs' counsel by MDOC, these drugs remain in the Department's possession.

113. If MDOC does not, in fact, possess the unaccounted for vials of pentobarbital sodium API, then, on information and belief, these vials have been transferred and/or sold by MDOC to departments of corrections in other jurisdictions.

114. Defendants have not purchased any pentobarbital sodium API since May 20, 2012.

[9] MDOC also purchased vecuronium bromide and potassium chloride from the Brister Brothers pharmacy but this supply expired in 2014 and has since been destroyed. MDOC has subsequently purchased new supplies of vecuronium bromide and potassium chloride (reported to expire in fall 2015). MDOC refuses to disclose the provider of its current supply of vecuronium bromide and potassium chloride. This failure to disclose the identity of lethal injection drug suppliers is the subject of ongoing litigation between the MacArthur Justice Center and MDOC under the Mississippi Public Records Act. A chancery court has ordered the disclosure of the identity of the drug supplier but MDOC has appealed this ruling to the Mississippi Supreme Court.

115. The pentobarbital sodium API which Defendants purchased from Brister Brothers were not compounded prior to the shipment from Brister Brothers to the grounds of the Mississippi State Penitentiary at Parchman. Any pentobarbital sodium API purchased by Defendants will have to be compounded before its use in any execution in Mississippi.

116. According to the records of the Mississippi State Board of Pharmacy, there is no registered or licensed pharmacy at the Medical/Dental Facility at Parchman (Mississippi State Department of Health License No. 11-317). Drugs administered to prisoners are kept in the Drug Room at the Medical/Dental Facility at Parchman.

117. Until May 2015, drugs used for lethal injection were not kept in the Drug Room, but at Unit 17, the building where death-sentenced prisoners were once incarcerated, and which is now used exclusively to house a condemned prisoner the days before his scheduled execution and to house the death chamber where he will be executed.

118. MDOC has never used pentobarbital sodium API in an execution.

119. Defendants have never compounded raw pentobarbital into a sterile injection. There is no public record of MDOC sending pentobarbital sodium API to a compounding pharmacy to prepare an injectable form of pentobarbital for use in an execution. Additionally, an affidavit executed by Special Assistant Attorney General Jim Norris on March 10, 2014 describes the pentobarbital sodium purchased in May 2012 as being in a "powder" form.

120. Upon information and belief, Defendants intend to compound pentobarbital on the grounds of the Mississippi State Penitentiary at Parchman; or in the alternative, Defendants intend to send pentobarbital sodium API to a yet undisclosed location to prepare the drug for an execution.

121. If Mississippi proceeds with their executions, Plaintiffs will be among the first prisoners in Mississippi to be executed with compound pentobarbital.

E. CONSTITUTIONAL, PHARMACEUTICAL, AND MEDICAL RISKS PRESENTED BY DEFENDANTS' USE OF COMPOUNDED PENTOBARBITAL

122. Where Mississippi intends to use a three-drug series in its executions, there is a substantial risk that the first drug administered (whether it be compounded pentobarbital or midazolam) will fail to render the prisoner unconscious and insensate prior to the administration of the second and third drugs, resulting in a painful and torturous death.

123. When compounded pentobarbital is used as the first drug in a three-drug series, risks are introduced to the execution procedure which serve no valid penological purpose. Compounded drugs are not FDA-approved, so they carry no guarantees of the identity, purity, or potency of the drug.

124. Compounding pharmacies such as Brister Brothers generally do not have the facilities to test chemicals for identity, potency, purity, and contamination.

125. It is not possible for the testing of API to eliminate the risks posed by impurities, contaminants, particulate matter, and/or an improper pH balance. Testing only provides a very provisional indication of an API's suitability for compounding given the unknowns about the chemical's integrity, storage, and custody in the timeframe from testing to pharmacy compounding and use.

126. Testing of non-sterile API by laboratories contracting with a distributor has proven unreliable. Poorly regulated, if regulated at all, contract-testing laboratories are supposed to test compounded drugs for safety and effectiveness. Too often, however, these laboratories are themselves substandard, and many are established to serve the financial interests of the pharmacies for which they are doing the testing. Five laboratories that test compounded drugs have had enforcement actions taken against them by the FDA.

127. Where the compounded pentobarbital is in any way sub-optimal, it poses a substantial risk of serious harm to the condemned prisoner either by inflicting pain and suffering itself or by failing to adequately anesthetize the prisoner, who then would experience conscious paralysis and the pain of potassium chloride, followed by cardiac arrest.

128. Moreover, each injection of compounded pentobarbital used in executions in Mississippi will be a new product, so the effectiveness of one dose does not demonstrate the effectiveness of the next.

The Department's Lack of Safeguards to Insure the Integrity of Active Pharmaceutical Materials Held for Use in Executions

129. MDOC's lethal injection protocol does not include any means for verifying the integrity of the MDOC's supply of active pharmaceutical ingredients. There is a substantial risk that such raw ingredients are counterfeit, contaminated, or substandard.

130. The Defendants have not revealed the source of the active pharmaceutical ingredients that were purchased in 2012 for compounding pentobarbital.

131. PCCA's source for the pentobarbital sodium API purchased by MDOC in 2012 is not a matter of public record and is unknown to Plaintiffs.

132. Defendants themselves do not know the source of the pentobarbital sodium API sold by PCCA to Brister Brothers, and from Brister Brothers to MDOC.

133. PCCA expressly disclaimed any warranties in its sale of pentobarbital sodium API to Brister Brothers in 2012.

The Questionable Process for the Compounding of Mississippi's Execution Drugs

134. The Defendants refusal to disclose critical facts surrounding the compounding process separately creates a substantial risk of serious harm to Plaintiffs.

135. In order to properly and safely compound the raw ingredients for pentobarbital into a sterile injectable, the compounding must be done in a sterile compounding laboratory with very specific and sophisticated physical requirements.

136. Under State law, a pharmacy or medical facility must be registered with the Mississippi State Board of Pharmacy in order to manufacture pentobarbital or another controlled substance. The pharmacy or facility cannot manufacture any controlled substance not authorized by its registration. Miss. Code Ann. §41-29-125, 41-29-141(2). Manufacture, in this context, includes compounding. Miss. Code Ann. §41-29-105(q).

137. As stated above, the State Board of Pharmacy does not list the Medical/Dental Facility at Parchman as a facility with a licensed pharmacy. The State Board of Pharmacy does not list the Medical/Dental Facility at Parchman as a facility registered to compound controlled substances.

138. There are a limited number of compounding laboratories in Mississippi, and MDOC has not revealed to Plaintiffs where or how they intend to compound pentobarbital sodium API into a sterile injectable solution.

139. The compounding of pentobarbital or any other drug on the grounds of the Mississippi State Penitentiary creates substantial risks that a drug so manufactured may be contaminated during compounding, and/or the compounding process may be flawed, resulting in the production of a sub-potent and ineffective drug.

The Risk That the Pentobarbital Is Degraded or Expired

140. The expiration dates for FDA-approved drugs are based on rigorous testing in a controlled and regulated environment. The same testing is not performed on compounded drugs,

resulting in an unacceptable risk that the drug may be degraded and sub-potent by the time it is used, and unable to perform its designated anesthetic function.

141. According to the March 10, 2014 affidavit of MDOC attorney Jim Norris and records from PCCA, the batch of pentobarbital sodium API purchased by MDOC in May 2012 has an expiration date of May 20, 2015. Defendants have provided documentation as to the destruction of nine (9) vials of the API in June 2015. However Defendants have failed to account for the disposition of the other five (5) vials purchased in May 2012. These vials of pentobarbital sodium API have now passed their expiration date.

142. 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. 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 and past its expiration date.

143. Other records provided by MDOC indicate that the vecuronium bromide possessed by the Defendants will expire on October 1, 2015, and the potassium chloride possessed by the Defendants expired on September 1, 2015.

The Risk of Counterfeit API

144. One of the purposes of FDA regulation is to ensure that the drugs and narcotics used by Americans are true and genuine. The risk of counterfeit or "watered-down" drugs is a substantial part of the FDA's justification for prohibiting Americans from purchasing narcotics and drugs from foreign pharmacies or sources.

145. Because Defendants have not procured drugs for lethal injections from an FDA-approved source, there is a risk that the materials which Defendants claim to be pentobarbital,

vecuronium bromide, and potassium chloride are, in fact, nothing of the sort. The materials in Defendants' possession may be "watered-down" or wholly counterfeit.

Compounded Pentobarbital Is Not an Ultra Short-Acting Barbiturate or Other Similar Drug

146. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "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 by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.

147. Unable to obtain Sodium Pentothal or Nembutal, MDOC purchased pentobarbital sodium API to be compounded into an injectable solution to be used as the first drug in the three-drug series.

148. Compounded pentobarbital *is not* an ultra short-acting barbiturate like Sodium Pentothal. Rather pentobarbital is classified as a short- or intermediate-acting barbiturate.

149. This classification system refers to the rate of onset and length of duration for a given class of barbiturates. Those barbiturates classified as ultra short-acting have the fastest rate of onset, producing their anesthetic effect more quickly than all other classes of barbiturates. By contrast, short- or intermediate-acting barbiturates have a slower rate of onset than those barbiturates classified as ultra short-acting, taking longer to produce any anesthetic effect upon injection.

150. As there is substantial risk that compounded pentobarbital may be sub-potent, the onset rate of compounded pentobarbital would be even slower than that of FDA-approved pentobarbital.

151. An understanding of this classification system is of the utmost importance when a barbiturate is planned for use as the first drug in three-drug protocol for execution by lethal injection. Where the first drug does not act swiftly and effectively to anesthetize the prisoner such that he is both unconscious and insensate *before* the executioner injects the second and third drugs, there is a substantial risk of severe pain and suffering.

152. It was with this understanding in mind that the Mississippi legislature specifically directed the use of an ultra short-acting barbiturate for use in lethal injections. Furthermore any chemical which does not mirror the ultra short-acting property of the drug class explicitly prescribed for use by the statute cannot be considered an "other similar drug."

153. The current MDOC execution protocol does not account for the difference between an ultra short-acting barbiturate and other classes of barbiturates. The protocol simply substitutes pentobarbital for Sodium Pentothal with no other changes to the procedure.

154. According to execution logs produced by MDOC, the intervals between the administration of the anesthetic and paralytic drugs have not been lengthened as a result of substituting pentobarbital for the ultra short-acting barbiturate required by the Mississippi statute.

Summary of Risks Presented by Defendants' Conduct

155. For the reasons set forth above, there is a high risk that either: (a) the Defendants intend to use a degraded form of compounded pentobarbital for the execution of the Plaintiffs; (b) the Defendants have obtained only the raw ingredients for pentobarbital and intend to compound the pentobarbital at the Mississippi State Penitentiary; or (c) the Defendants have devised some other unknown and heretofore untested method of making pentobarbital.

156. The administration of pure and potent pentobarbital is a crucial step in the execution process to ensure that a condemned prisoner does not consciously experience the agonizing pain of live suffocation and cardiac arrest.

157. Defendants' decision to use a non-FDA-approved form of pentobarbital made with unknown and potentially contaminated or counterfeit ingredients is nothing short of human experimentation and presents an unacceptable risk that Plaintiffs will experience unnecessary pain and suffering if and when they are executed.

158. Defendants' decision to use a new and experimental lethal injection protocol without adequate assurances that the pentobarbital is manufactured according to accepted pharmaceutical practices and with pure and potent ingredients presents an unacceptable risk that MDOC will attempt to execute Plaintiff with an expired, contaminated, degraded, or sub-potent form of pentobarbital, resulting in the infliction of cruel and unusual punishment.

Defendant's Policy of Secrecy

159. Over the past two years, counsel for Plaintiffs have submitted public records requests to MDOC pursuant to Miss. Code Ann. § 25-65-1 et seq., wherein counsel requested documents and correspondence pertaining to MDOC's lethal injection protocol, and where and how MDOC procured its lethal injection drugs.[10]

160. In response to a November 20, 2014 request, MDOC provided 10-pages of heavily-redacted documents, stating that MDOC would not disclose any information that could identify the supplier or manufacturer of their lethal injection drugs out of fear that such disclosure of public information would negatively affect MDOC's supply of such drugs.

[10] Counsel for Plaintiffs first submitted a request to MDOC on February 7, 2014, requesting public documents pertaining to MDOC's lethal injection protocol and lethal injection drugs. After receiving records redacted for the identity of the supplier of MDOC's lethal injection drugs, the MacArthur Justice Center filed suit against MDOC for violations of the Mississippi Public Records Act (filed March 3, 2014). This lawsuit was ultimately mooted when the MacArthur Justice Center was able to determine the identity of MDOC's lethal injection drug supplier – the Brister Brothers – through information make publically-available by the MDOC on the state's Transparency website (as operated by the Department of Finance and Administration pursuant to the Mississippi Accountability and Transparency Act of 2008).

161. MDOC's failure to comply with the Mississippi Public Records Act and disclose public records related to their supply of lethal injection drugs is currently the subject of litigation between the MacArthur Justice Center and MDOC. The trial court has ruled in favor of the MacArthur Justice Center, ordering MDOC to provide un-redacted records as to their purchase of lethal injection drugs, awarding attorneys' fees, costs, and expenses, and denying a stay of this ruling pending appeal. MDOC has filed for appeal with the Mississippi Supreme Court.

162. In response to a February 20, 2015 request, MDOC again provided redacted records, claiming the ongoing litigation between the MacArthur Justice Center and MDOC as the basis for the denial.

163. Importantly, in the records provided on April 14, 2015, in response to the February 20 request, MDOC redacted *even more* information from records which have previously been made available to the MacArthur Justice Center. Specifically, MDOC redacted the month from records as to the date of purchase of the pentobarbital sodium API, and provided records of the six (6) executions carried out by Mississippi in 2012 in response to an inquiry about the disposition of five (5) vials of the pentobarbital sodium API that may have left the possession of the MDOC since June 2012.

164. By these calculated redactions of documents produced in response to a specific request for information about the use, disposal, or transfer of MDOC's pentobarbital sodium API, MDOC seeks to mislead the public to believe that several vials of the pentobarbital sodium API in MDOC's possession were used in the executions the state conducted in 2012. This is impossible given the fact – known through records MDOC previously disclosed – that the API was not in

MDOC's possession until *after* five (5) of the six (6) executions carried out in 2012 had already occurred.[11]

165. In response to requests for records submitted from May through July 2015, MDOC claimed attorney client privilege and work product doctrine protect the disclosure of records responsive to the requests.

166. Counsel for Plaintiffs were previously able to identify the supplier of MDOC's lethal injection drugs through their own investigation, *see* footnote 10 *supra*, but MDOC has since purchased new vecuronium bromide and potassium chloride (the second and third drugs in the execution series), and the identity of the supplier of these drugs is unknown.

167. Further, in response to an August 5, 2015 request for public records, MDOC provided 16 pages of redacted records indicating that the Department purchased 290 bottles of midazolam (containing 50mg/10mL each) from a supplier sometime in 2015. The name and all other identifying information regarding the supplier(s) is redacted. The date of purchase and/or receipt of the midazolam is redacted from all records except for the year.[12]

168. MDOC maintains a policy of secrecy with regard to where and from whom they purchase lethal injection drugs, and how and where those drugs are prepared for use in executions.

[11] The April 13, 2015 MDOC Public Records Act response was also inconsistent with the statement of counsel for the MDOC in a March 2, 2015 hearing in the chancery court case brought by the MacArthur Justice Center against MDOC. Counsel asserted then that the unaccounted-for pentobarbital sodium API had been destroyed because it had passed its expiration date. All documents produced by MDOC, however, demonstrate that all of the sodium pentobarbital API purchased from Brister Brothers had the same expiration date – May 20, 2015.

[12] A redacted "supply inventory form" provided by MDOC appears to indicate "29 boxes" as the "amount received" of midazolam on July 27, 2015, but the purchase and receipt date is redacted from the receiving form and invoice provided by MDOC.

169. States continue to have difficulty purchasing lethal injection drugs. Consequently, Defendants may change their protocol or purchase different drugs or active pharmaceutical ingredients from different manufacturers before the next scheduled execution.

170. No execution is currently scheduled in the State of Mississippi. MDOC has repeatedly asserted in pleadings in the Chancery Court for the First Judicial District of Hinds County, Mississippi and in the Mississippi Supreme Court that Plaintiffs' counsel in this case has no immediate need for unredacted records related to its supply of lethal injection drugs because there are no current execution dates and the pentobarbital sodium API was set to expire on May 20, 2015.

171. On July 28, 2015, minutes after Defendants noticed this Court of an amended lethal injection protocol, the State moved the Mississippi Supreme Court to set an execution date for Plaintiff Richard Jordan within 30 days. The Mississippi Supreme Court has taken no action on the motion.

172. Defendants have never compounded pentobarbital sodium API into a sterile injectable form, and Defendants have never used compounded drugs in an execution. Plaintiffs' executions may be the first in which Defendants use compounded pentobarbital.

173. Defendants have failed to disclose any information as to their ability to or history of successfully compounding pentobarbital sodium API into a sterile injectable form for use in executions.

174. Defendants have also failed to disclose what information, if any, they have researched, gathered, or relied upon to evaluate the efficacy or effect of compounded pentobarbital or midazolam when used for an execution.

175. A request for public records submitted by counsel for Plaintiffs to MDOC on August 5, 2015 sought (among other items) any records as to whether midazolam is "ultra short-acting barbiturate or other similar drug" in Miss. Code Ann. § 99-19-51 and any records as to all drugs MDOC has contemplated for use as the first drug in its lethal injection protocol. The Department did not disclose any records responsive to these paragraphs of the request.

176. Defendants' failure to disclose the manufacturer of active pharmaceutical ingredients deprives Plaintiffs of any means to assess the purity of the API from which the injectable form of pentobarbital has or will be made; whether the API has been diluted with any substances which could impact the potency of the final product; whether the API is contaminated with either particulate foreign matter or a microbial biohazard that could lead to a severe allergic or neurotoxic reaction upon injection and several other similar issues.

177. Defendants will not disclose to Plaintiffs where and when they plan to compound lethal injection drugs, or the training and qualifications of the individuals who will participate in and supervise the compounding process. Plaintiffs have no way to assess the qualifications of the compounding pharmacy, whether the facility is actually equipped to make sterile injectable drugs such as pentobarbital, or whether the facilities are equipped to conduct any testing on the identity and/or purity of the API.

178. Defendants' policy of secrecy, their refusal to disclose to Plaintiffs the manufacturer and/or supplier of active pharmaceutical ingredients and other lethal injection drugs purchased for use in executions, and their failure to disclose where, how, and when they intend to try to compound API into a sterile injectable form violates Plaintiffs' rights to be free from cruel and unusual punishment, to due process, and to access to the courts.

F. MISSISSIPPI'S DECISION TO USE MIDAZOLAM IN LETHAL INJECTION EXECUTIONS

179. On July 28, 2015, Defendants filed notice with this Court of a change to their lethal injection protocol. The amended protocol is identical to the March 2012 protocol save for the provision that, in the event of the unavailability of pentobarbital, 500 milligrams of midazolam will be substituted as the first drug in the three-drug series.

180. During ongoing litigation regarding violations of the state public records act by MDOC (see ¶ 161), the presiding Chancery Judge questioned MDOC's attorney regarding the steps MDOC would have to take in the event the Department could no longer obtain pentobarbital. MDOC counsel answered: "Well, our statute says ultra short-acting barbiturate or other similar drug. We are already limited." In the same colloquy, MDOC counsel stated, "counsel for the state is not interested in using [midazolam] right now and that's not an option for this counsel at this point, which means that you've got to find something else and there's a whole process that would be involved in trying to find an alternative anesthetic."

181. A request for public records submitted by counsel for Plaintiffs to MDOC on August 5, 2015 sought (among other items) any records as to whether midazolam is "ultra short-acting barbiturate or other similar drug" in Miss. Code Ann. § 99-19-51 and any records as to all drugs MDOC has contemplated for use as the first drug in its lethal injection protocol. The Department did not disclose any records responsive to these paragraphs of the request, and have provided no records as to any research, assessment, consultation, or other actions taken by the Department prior to amending its protocol to provide for the use of midazolam.

182. MDOC has made no amendments to its lethal injection protocol to account for the important differences in pharmacology and physical effect between sodium thiopental, the manufactured ultra short-acting barbiturate originally used in lethal injections in the state, and

compounded pentobarbital (a non-FDA-approved, short- or intermediate-acting barbiturate) or midazolam (a drug in a wholly different class, benzodiazepines).

183. The Mississippi protocol does not provide for any procedural safeguards which have been added to the revised lethal injection protocols of other jurisdictions in an effort to reduce the substantial risk of serious harm that results from failures in the administration of lethal injection drugs. Importantly the MDOC protocol does not provide any instruction, timeline, procedure, or training for assessing the level of anesthetic depth of the prisoner prior to the administration of the second and third drug in the three-drug series.

184. Aside from providing for the use of midazolam as the first drug in a three-drug series, the Mississippi protocol in no way resembles the Chart D protocol that Oklahoma's Department of Corrections has adopted (following the botched execution of Mr. Lockett), which is the subject of litigation in federal court in Oklahoma and was the subject of the United States Supreme Court opinion in *Glossip v. Gross*.

185. Furthermore, the July 2015 protocol only provides for the use of midazolam in executions conducted by MDOC where a sufficient quantity of pentobarbital is unavailable.

186. Defendants have stated that MDOC is unable to obtain pentobarbital in any form.

187. However, other state departments of corrections continue to obtain and utilize compounded pentobarbital in lethal injection executions. The States of Texas and Missouri, not to mention Georgia,[13] have had no difficulty obtaining pentobarbital or using it to carry out executions by lethal injection.

[13] Since 2014, Georgia has conducted four (4) executions using pentobarbital in a single-drug lethal injection protocol, most recently in January 2015.

188. Texas and Missouri each carried out more executions than any other state in 2014 (10 executions each), and combined, these two states account for 80 percent of the executions in 2015 to date (16 of the 20 executions). All executions conducted by Texas and Missouri in 2014 and 2015 have involved the use of pentobarbital in a single-drug lethal injection protocol.

189. Furthermore, Texas is known to have twice obtained new supplies of pentobarbital just this year, first in March 2015, and as recently as May 2015.

190. In just the last week of September 2015, the Texas Department of Criminal Justice provided three vials of compounded pentobarbital to its counterpart in Virginia to be used in a scheduled execution. On information and belief, it is not unusual for departments of corrections in the executing states to transfer, exchange, or sell execution drugs to each other.

Pharmacology of Midazolam

191. Unlike sodium thiopental and pentobarbital, both classified as barbiturates, midazolam is classified as a benzodiazepine, a class of drugs including Valium, Xanax, and Klonopin that are commonly used in the treatment of anxiety and panic disorders. Midazolam is incapable of inducing a "deep, comalike unconsciousness." Midazolam acts to depress the activity of the central nervous system ("CNS"), but the depth of that depression is limited, and even a large dose of midazolam will not result in unconsciousness or general anesthesia.

192. There is no pharmacological equivalency between benzodiazepines and barbiturates when evaluated using the criteria of chemical (atomic) structures, mechanisms of action, magnitude of pharmacological effect produced (considering partial versus full effects, as well as ceiling effects), approved and known therapeutic uses, or drug abuse and dependence properties.

193. This lack of pharmacological equivalency between benzodiazepines and barbiturates is also reflected by the different scheduling of these drugs by the DEA.

194. Both benzodiazepines and barbiturates act upon the same type of receptor complex in the brain, the $GABA_A$ receptor-chloride ion channel complex ("GABA receptor"). When the GABA receptor is acted upon, chloride ion channels open. The influx of chloride ions from the outside of the neuron to the inside causes a decrease in electrical activity of the neuron, neuronal inhibition, and ultimately CNS depression.

195. However benzodiazepines and barbiturates exhibit different mechanisms of action upon the receptor complex. These different mechanisms significantly impact the form and extent of the effect of these two drug classes on the GABA receptor.

196. Benzodiazepines (such as midazolam) require the presence of GABA, an inhibitory neurotransmitter in the brain, to exhibit any effect on the GABA receptor. GABA is a limited resource as it is made and released by inhibitory neurons, which are finite in number. GABA must be released and must act upon the GABA receptor at the same time as the benzodiazepine for drugs like midazolam to produce an inhibitory neuronal effect. Further, the presence of a benzodiazepine only increases the frequency at which the GABA receptor complex opens, not the duration of that opening. As a result of their mechanism of action, benzodiazepines can only produce a partial pharmacological effect.

197. In contrast, barbiturates do not require the presence of GABA to act upon the GABA receptor. Barbiturates can cause neuronal inhibition even when GABA is not present. Further, unlike benzodiazepines, barbiturates increase the duration of opening at the GABA receptor such that activity of the neuron is completely shut down, resulting in electrical silence.

198. Midazolam has a ceiling effect that is not present in barbiturates. A ceiling effect refers to a limit on the magnitude of the produced effect of a drug as the dose is increased. Midazolam's ceiling effect is a direct result of the mechanism of action described above, and explains why benzodiazepines are incapable of rendering a person unconscious and insensate to pain.

199. Injection of an IV bolus of 500 milligrams of midazolam, as called for by the July 2015 MDOC protocol, would produce a brain concentration many times higher than the concentration at which the ceiling effect is observed.

200. However, increasing the dose of midazolam above the amount necessary to reach the ceiling effect will have no additional effect on the neurons.

201. Thus even at concentrations of midazolam at or above the concentration at which the ceiling effect is observed, the drug cannot be relied upon to render a person anesthetized and insensate to pain.

Midazolam Is Not an Ultra Short-Acting Barbiturate or Other Similar Drug

202. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "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 by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.

203. Unable to obtain Sodium Pentothal or Nembutal, and having declared its inability to obtain pentobarbital sodium API, MDOC has now purchased midazolam to be used as the first drug in the three-drug series.

204. Midazolam is not an ultra short-acting barbiturate like Sodium Pentothal. Midazolam is not a short- or intermediate-acting barbiturate like pentobarbital. Midazolam is not a barbiturate at all. Rather midazolam belongs to the benzodiazepine class of drugs.

205. An understanding of the pharmacological differences between barbiturates and benzodiazepines is of the utmost importance when a benzodiazepine like midazolam is planned for use as the first drug in a three-drug protocol for execution by lethal injection. Where the first drug does not act swiftly and effectively to anesthetize the prisoner such that he is both unconscious and insensate before the executioner injects the second and third drugs, there is a substantial risk of severe pain and suffering.

206. It was with this understanding in mind that the Mississippi legislature specifically directed the use of an ultra short-acting barbiturate or other similar drug for use in lethal injections.

207. There is no pharmacological equivalency between midazolam and ultra short-acting barbiturates when evaluated using the criteria of chemical (atomic) structures, mechanisms of action, magnitude of pharmacological effect produced (considering partial versus full effects, as well as ceiling effects), approved and known therapeutic uses, or drug abuse and dependence properties (as reflected by the different scheduling of these drugs by the DEA).

208. Any chemical that is not pharmacologically equivalent to an ultra short-acting barbiturate cannot serve as a valid pharmacological substitute.

209. The current MDOC execution protocol does not account for the difference between an ultra short-acting barbiturate and midazolam, a benzodiazepine. The protocol simply substitutes midazolam for pentobarbital, which is in term substituted for Sodium Pentothal, with no other changes to the procedure.

210. The Mississippi protocol does not provide for any procedural safeguards which have been added to the revised lethal injection protocols of other jurisdictions in an effort to reduce the substantial risk of serious harm that can result from failures in the administration of lethal injection drugs. Importantly the MDOC protocol does not provide any instruction, timeline, procedure, or training for assessing the level of anesthetic depth of the prisoner prior to the administration of the second and third drug in the three-drug series.

CLAIMS FOR RELIEF

Count I.A.: Use of Compounded Pentobarbital in a Three-Drug Lethal Injection Protocol Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution

211. Plaintiffs reallege and incorporate by reference the allegations contained in ¶¶ 39 to 210.

212. Defendants claim they can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is among the ultra short-acting barbiturates authorized by the Mississippi lethal injection statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.

213. Defendants also claim they no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of the Mississippi statute.

214. MDOC's decision to act contrary to the Mississippi statute for method of execution violates Plaintiffs' rights to be free from cruel and unusual punishment and to due process, as guaranteed by the United States and Mississippi Constitutions, and as discussed in claim II *infra*.

215. Defendants plan to use a compounded form of pentobarbital made from active pharmaceutical ingredients of unknown origin that may be counterfeit, contaminated, or ineffective.

216. In the alternative, Defendants intend to compound the drug by some other means pursuant to an unknown process and protocol, and by individuals with unknown qualifications.

217. The Eighth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, and the corresponding provisions of the Mississippi Constitution, prohibit the infliction of unnecessary pain in the execution of a death sentence.

218. Because it is nearly impossible to determine with certainty whether a prisoner will suffer serious and needless pain and suffering during an execution, the question of whether a particular execution procedure will inflict such pain and suffering involves an inquiry as to whether the prisoner is subject to a substantial or intolerable risk of serious harm.

219. Such a substantial or intolerable risk of serious harm may occur when a state lacks a clear protocol for lethal injection, when experience with the procedure demonstrates that there are foreseeable problems, or when it is known that the drugs intended for use in lethal injections will very likely result in the prisoner suffering intense pain that an alternative procedure would not cause.

220. The Defendants' decision to use a previously untried form of pentobarbital created with unknown and unregulated ingredients through an unknown and unregulated compounding process creates a substantial and intolerable risk that the pentobarbital will be counterfeit, contaminated, degraded, expired, or sub-potent, resulting in the infliction of cruel and unusual punishment.

221. The Defendants' untried and untested drugs create a substantial risk that Plaintiffs will suffer unnecessary and excruciating pain either by the injection of the compounded pentobarbital causing a painful reaction itself, or by the compounded pentobarbital failing to work, resulting in a torturous death by life suffocation and cardiac arrest.

222. Thus, Mississippi's planned use of compounded pentobarbital as the first drug in a three-drug series, which is completed with the intravenous administration of a chemical paralytic agent and potassium chloride, creates a substantial risk of serious harm and severe pain to Plaintiffs.

223. There is a feasible alternative which could substantially reduce the risk of severe pain and serious harm presented by the continuous intravenous administration of compounded pentobarbital in combination with a chemical paralytic agent and potassium chloride.

224. The use of an FDA-approved, ultra short-acting barbiturate in a single-drug protocol is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure. Other jurisdictions have already moved towards the use of a single-drug anesthetic-only protocol.

225. If no FDA-approved ultra short-acting barbiturate can be legally sold to a department of corrections for use in executions, and only in that event, the use of an FDA-approved short- or intermediate-acting barbiturate in a single-drug protocol is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure.

226. If the alternatives pled in ¶¶ 224 to 225 are not legally available, and only in that event, the use of an ultra short-acting barbiturate, compounded by a duly licensed compounding pharmacy, tested for integrity, purity, and potency by a laboratory unaffiliated with the

compounding pharmacy industry or a department of corrections, and used in a single-drug anesthetic-only protocol (without a paralytic agent or potassium chloride), is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure.

227. If the alternatives pled in ¶¶ 224 to 226 are not legally available, and only in that event, the use of a short- or intermediate-acting barbiturate, compounded by a duly licensed compounding pharmacy, tested for integrity, purity, and potency by a laboratory unaffiliated with the compounding pharmacy industry or a department of corrections, and used in a single-drug anesthetic-only protocol (without a paralytic agent or potassium chloride), is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure.

228. Defendants' refusal to adopt these alternatives for the executions of Plaintiffs, in the face of these documented advantages, without a legitimate penological justification for adhering to its current method of execution, constitutes cruel and unusual punishment prohibited by the Eighth Amendment.

229. To the extent that Defendants' refusal to adopt the single-drug anesthetic-only barbiturate technique is based on the requirements of Miss. Code Ann. §99-19-51, that part of the statute which requires the use of a "chemical paralytic agent" in executions should be held unconstitutional as contrary to the Eighth Amendment.

230. For the reasons set forth above, Defendants are deliberately indifferent to Plaintiffs' constitutional rights.

231. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count I.A.

Count I.B.: Use of Midazolam in a Three-Drug Lethal Injection Protocol Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution

232. Plaintiffs reallege and incorporate by reference the allegations contained in ¶¶ 39 to 231.

233. Defendants claim they can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is among the ultra short-acting barbiturates authorized by the Mississippi lethal injection statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.

234. Defendants also claim they no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of the Mississippi statute.

235. Defendants further claim they have been unsuccessful at obtaining pentobarbital is any form despite the fact that several other jurisdictions have obtained and utilized compounded pentobarbital in lethal injection executions this year.

236. On July 28, 2015, MDOC amended its lethal injection protocol. The current protocol now provides for the use of midazolam as the first drug in the series in the event of the unavailability of pentobarbital. No other changes were made to the protocol.

237. The Eighth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, and the corresponding provisions of the Mississippi Constitution, prohibit the infliction of unnecessary pain in the execution of a death sentence.

238. Because it is nearly impossible to determine with certainty whether a prisoner will suffer serious and needless pain and suffering during an execution, the question of whether a particular execution procedure will inflict such pain and suffering involves an inquiry as to whether the prisoner is subject to a substantial or intolerable risk of serious harm.

239. Such a substantial or intolerable risk of serious harm may occur when a state lacks a clear protocol for lethal injection, when experience with the procedure demonstrates that there are foreseeable problems, or when it is known that the drugs intended for use in lethal injections will very likely result in the prisoner suffering intense pain that an alternative procedure would not cause.

240. The Defendants' decision to use midazolam as the first drug in its lethal injection series in the event of the unavailability of pentobarbital creates a substantial and intolerable risk that the Plaintiff will not be anesthetized and insensate prior to the administration of the second and third drugs, resulting in the infliction of cruel and unusual punishment, a torturous death by life suffocation and cardiac arrest.

241. Midazolam is not a barbiturate. Rather, midazolam is classified as a benzodiazepine, the same class of drugs as Valium, Xanax, and Klonopin.

242. There is no pharmacological equivalency between benzodiazepines and barbiturates when evaluated using the criteria of chemical (atomic) structures, mechanisms of action, magnitude of pharmacological effect produced (considering partial versus full effects, as

well as ceiling effects), approved and known therapeutic uses, or drug abuse and dependence properties (as reflected by the different scheduling of these drugs by the DEA).

243. Unlike barbiturates, benzodiazepines have a ceiling effect. This ceiling effect restricts the magnitude of pharmacological effects that can be produced by midazolam, and is a direct result of benzodiazepines' mechanism of action. Barbiturates have a different mechanism of action and therefore do not exhibit a ceiling effect.

244. Injection of an IV bolus of 500 milligrams of midazolam, as called for by the July 2015 MDOC protocol, would produce a brain concentration many times higher than the concentration at which the ceiling effect is observed.

245. However, increasing the dose of midazolam above the amount necessary to reach the ceiling effect will have no additional effect on the neurons.

246. Thus even at concentrations of midazolam at or above the concentration at which the ceiling effect is observed, the drug cannot be relied upon to render a person anesthetized and insensate to pain.

247. Mississippi's planned use of midazolam as the first drug in a three-drug series, which is completed with the intravenous administration of a chemical paralytic agent and potassium chloride, creates a substantial risk of serious harm and severe pain to Plaintiffs.

248. There is a feasible alternative which could substantially reduce the risk of severe pain and serious harm presented by the continuous intravenous administration of midazolam in combination with a chemical paralytic agent and potassium chloride.

249. The use of a single-drug anesthetic-only protocol as set forth in ¶¶ 224 to 227 above is a feasible and available alternative which would significantly reduce the substantial risk of

severe pain presented by the use of midazolam as the first drug in a three-drug series. Other jurisdictions have already moved towards the use of a single-drug anesthetic-only protocol.

250. Defendants' refusal to adopt these alternatives for the executions of Plaintiffs, in the face of their documented advantages, without a legitimate penological justification for adhering to its current method of execution, constitutes cruel and unusual punishment prohibited by the Eighth Amendment.

251. To the extent that Defendants' refusal to adopt the single-drug anesthetic-only barbiturate technique is based on the requirements of Miss. Code Ann. §99-19-51, that part of the statute which requires the use of a "chemical paralytic agent" in executions should be held unconstitutional as contrary to the Eighth Amendment.

252. For the reasons set forth above, Defendants are deliberately indifferent to Plaintiffs' constitutional rights.

253. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count I.B.

Count II: Failure to Use an Ultra Short-Acting Barbiturate or Other Similar Drug as Directed by Mississippi Statute Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment and Right to Due Process under the Eighth and Fourteenth Amendments to the United States Constitution

254. Plaintiffs reallege and incorporate by reference the allegations contained in ¶¶ 39 to 253.

255. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "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 by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.

256. Plaintiffs have a life and liberty interest created by the requirement of an "ultra short-acting barbiturate or other similar drug" in Section 99-19-51. This interest is protected by the Due Process Clause of the Fourteenth Amendment.

257. Prior to 2011, Defendants used Sodium Pentothal (also known as sodium thiopental) as the first drug in a three-drug lethal injection protocol. Sodium Pentothal is classified as an ultra short-acting barbiturate. This classification is based on the drug's speed of onset and duration of effect.

258. By the enactment of Miss. Code Ann. § 99-19-51, the Mississippi legislature has directed that use of an ultra short-acting barbiturate is necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs. In addition to creating a life and liberty interest protected by the Fourteenth Amendment, the statute's legislative determination of the method of minimizing the risks of torturous harm in Mississippi executions is relevant for Eighth Amendment purposes.

259. Defendants claim they can no longer purchase Sodium Pentothal, as detailed *supra*. As a result, MDOC amended its protocol to allow for the use of pentobarbital as the first drug in the three-drug series where Sodium Pentothal is unavailable.

260. Pentobarbital – even in its FDA-approved form – is not classified as an ultra short-acting barbiturate. Rather it is classified as a short- or intermediate-acting barbiturate. This classification recognizes the slower speed of onset of pentobarbital when compared to an ultra short-acting barbiturate.

261. While the Mississippi statute provides for use of an "ultra short-acting barbiturate or other similar drug," pentobarbital is not sufficiently similar to an ultra short-acting barbiturate as to be considered an "other similar drug" within the meaning of a statute. This is true even for FDA-approved pentobarbital, let alone for compounded pentobarbital made from unknown active pharmaceutical ingredients, as MDOC intends to now use.

262. Defendants have further amended the MDOC protocol to provide for the use of midazolam as the first drug in a three-drug series in the event of the unavailability of pentobarbital.

263. Midazolam is not a barbiturate. Rather, midazolam is classified as a benzodiazepine, the same class of drugs as Valium, Xanax, and Klonopin.

264. There is no pharmacological equivalency between benzodiazepines and barbiturates when evaluated using the criteria of chemical (atomic) structures, mechanisms of action, magnitude of pharmacological effect produced (considering partial versus full effects, as well as ceiling effects), approved and known therapeutic uses, or drug abuse and dependence properties (as reflected by the different scheduling of these drugs by the DEA).

265. MDOC's decision to use compounded pentobarbital or midazolam as the first drug in its upcoming executions is in clear violation of Miss. Code Ann. § 99-19-51. As such this decision violates Plaintiffs' rights guaranteed by the Eighth Amendment to the United States Constitution.

266. MDOC's decision to use compounded pentobarbital or midazolam as the first drug in its upcoming executions further violates Plaintiffs' right, guaranteed by the Fourteenth Amendment to the United States Constitution, to not be executed except in accordance with Section 99-19-51. Mississippi law provides no adequate post-deprivation remedy for the harm that

will be caused by Defendants' denial of Plaintiffs' right to be executed only with the use of an ultra short-acting barbiturate or other similar drug.

267. For the reasons set forth above, MDOC's failure to use an ultra short-acting barbiturate as required by Miss. Code Ann. §99-19-51 creates an unacceptable risk of severe pain and serious harm in violation of the Eighth Amendment, and violates Plaintiffs' due process guarantees under the Fourteenth Amendment.

268. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count II.

Count III: Mississippi's Continued Use of a Three-Drug Protocol in the Face of Evolving Standards of Decency Which Require Abandonment of the Use of a Chemical Paralytic Agent and Potassium Chloride, Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution

269. Plaintiffs re-allege and incorporate by reference the allegations contained in ¶¶ 39 to 268.

270. "The basic concept underlying the Eighth Amendment is nothing less than the dignity of man . . . . The Amendment must draw its meaning from the evolving standards of decency that mark the progress of a maturing society." *Atkins v. Virginia*, 536 U.S. 304, 311-312 (2002) (quoting Trop v. Dulles, 356 U.S. 86 (1958)). The United States Supreme Court has repeatedly looked to legislation enacted by the states as the "clearest and most reliable objective evidence of contemporary values," *id.* at 312 (*quoting Penry v. Lynaugh*, 492 U.S. 302, 331 (1989)), relying on such legislative evidence of evolving trends to narrow the classes of those individuals we seek to punish through the death penalty and to determine the suitability of those methods and protocols by which we carry out such sentences.

271. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Defendants have not used Sodium Pentothal in an execution since 2010.

272. Defendants have amended their lethal injection protocol to provide for the use of pentobarbital in the event that Sodium Pentothal is unavailable. In executions conducted in 2011 and in 2012, MDOC used pentobarbital as the first drug in its three-drug lethal injection protocol, in place of Sodium Pentothal.

273. These eight (8) executions used the FDA-approved form of pentobarbital, marketed as Nembutal and purchased by MDOC in March 2011.

274. Defendants no longer possess an FDA-approved form of pentobarbital. Instead Defendants have purchased pentobarbital sodium API to be compounded into injectable pentobarbital for use in upcoming lethal injections.

275. Defendants have also amended the MDOC lethal injection protocol to provide for the use of midazolam as the first drug in its three-drug series in the event a sufficient quantity of pentobarbital is unavailable. As detailed *supra*, defendants have purchased midazolam from an unknown source on an unknown date.

276. Mississippi's decision to continue use of a three-drug lethal injection protocol runs contrary to the trend towards single-drug anesthetic-only protocols employed successfully by other states in recent years.

277. No state has used pentobarbital in a three-drug protocol this year (with 20 executions having been conducted by five states to date). Only Oklahoma used pentobarbital in a three-drug protocol in 2014, accounting for just two (2) of the 35 executions conducted by seven (7) states last year.

278. The chart below summarizes this evolving trend away from the use of three-drug lethal injection protocols, particularly those involving pentobarbital. The execution methods, protocols, and drugs (as contained in the chart) track the lethal injection statutes propagated by state legislatures, as well as the lethal injection protocols propagated and implemented by state departments of corrections.

	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	18 GA, TX, MO	2 FL, OK	0	0	20 (to date)

279. The trend towards abandonment of the three-drug protocol is evidence of the evolving standards of decency which inform the Eighth Amendment. 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 (29 percent) of the 94 conducted nationwide. Only 14 of these 94 executions used pentobarbital in a three-drug series (15 percent of executions nationwide). Only 13 of these 94 executions used midazolam in a three-drug series (14 percent of executions nationwide).

280. Put another way, forty-seven of the fifty states punish murder without undertaking the risk of conscious, torturous pain and suffocation which is raised by the use of a chemical paralytic agent and potassium chloride in the three-drug protocol.

281. It follows that use of the three-drug protocol by Mississippi constitutes cruel and unusual punishment in violation of the Eighth Amendment.

282. Defendants continued use of a three-drug lethal injection protocol, when other states have abandoned this method in favor of a single-drug, anesthetic-only protocol, violates Plaintiffs' right to be free from cruel and unusual punishment as guaranteed by the United States and Mississippi Constitutions.

283. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count III.

Count IV: Violation of Plaintiffs' Right to Notice of the Defendants' Method of Execution under the Fourteenth Amendment to the United States Constitution and Article 3, Section 14 of the Mississippi Constitution

284. Plaintiffs reallege and incorporate by reference the allegations contained in ¶¶ 39 to 283.

285. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is an ultra short-acting barbiturate, required by Mississippi statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.

286. Defendants also no longer possess an FDA-approved form of pentobarbital.

287. Defendants have obtained active pharmaceutical ingredients from a compounding pharmacy to try to manufacture a sterile injectable form of pentobarbital.

288. Defendants have not disclosed to Plaintiffs where they have compounded, or where they intend to compound the raw ingredients to try to make a sterile injectable form of pentobarbital.

289. Defendants have not disclosed to Plaintiffs the training or qualifications of the individuals responsible for trying to compound the raw ingredients to make a sterile injectable form of pentobarbital.

290. Furthermore, Defendants have obtained midazolam from an unknown source on an unknown date. Defendants have amended the MDOC lethal injection protocol to provide for the use of midazolam as the first drug in the three-drug series in the event of the unavailability of pentobarbital.

291. On information and belief, Defendants intend to execute Plaintiffs with drugs or ingredients that have never been used before in an execution in Mississippi.

292. Under the due process clauses of the United States and Mississippi Constitutions, Plaintiffs are entitled to notice of the Defendants' intended method of execution, including information about the drugs Defendants have obtained and the steps by which any API will be compounded into a sterile injection to be used in executions.

293. Defendants' failure to disclose the manufacturer of the active pharmaceutical ingredients it purchased to make pentobarbital, Defendants' failure to disclose the supplier of its recent purchase of midazolam, and Defendants' failure to disclose how, where, and when they intend to try to compound any raw ingredients into sterile injectable solutions for use in executions violates Plaintiffs' right to due process under the United States and Mississippi Constitutions.

294. For the reasons set forth above, Defendants are deliberately indifferent to Plaintiffs' constitutional rights.

295. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count IV.

Count V: Violation of Plaintiffs' Right of Access to the Courts under the First and Fourteenth Amendment to the United States Constitution and Article 3, Section 14 and 24 of the Mississippi Constitution

296. Plaintiffs reallege and incorporate by reference the allegations contained in ¶¶ 39 to 295.

297. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is an ultra short-acting barbiturate, required by Mississippi statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.

298. Defendants also no longer possess an FDA-approved form of pentobarbital.

299. Due to the unavailability of FDA-approved pentobarbital, Defendants have changed their lethal injection protocol by substituting a compounded form of pentobarbital for the FDA-approved drug Nembutal.

300. Defendants have further amended their protocol to provide for the use of midazolam in the event of the unavailability of pentobarbital.

301. Defendants have purchased the active pharmaceutical ingredients for pentobarbital, and already have, or will in the future, devise a way to try to compound the active pharmaceutical ingredients to create a sterile injectable form of pentobarbital.

302. Defendants have purchased midazolam in an unknown form, from an unknown supplier, on an unknown date.

303. Defendants have asserted that the identity of the manufacturer and supplier of lethal injection drugs is confidential for fear the disclosure of such information would forestall MDOC's ability to obtain lethal injection drugs in the future. MDOC will not tell Plaintiffs who manufactured the active pharmaceutical ingredients, who manufactured or supplied the midazolam, where lethal injection drugs have been or will be compounded, and the training and qualifications of the individuals who have or will compound the drugs. This information is necessary in order for Plaintiffs to more fully determine the risks associated with Defendants' lethal injection drugs.

304. Plaintiffs possess a right to file a legal challenge to enjoin their executions if Defendants' execution procedure presents a substantial risk of serious harm, in violation of the Eighth and Fourteenth Amendments to the United States Constitution.

305. Plaintiffs also possess a right under the First and Fourteenth Amendments to the United States Constitution and Article 3, Section 24 of the Mississippi Constitution to have a reasonable opportunity to present legal claims implicating fundamental constitutional rights to the courts.

306. Defendants' policy of secrecy prevents Plaintiffs from accessing all of the relevant information they need to mount an Eighth Amendment challenge to Defendants' lethal injection protocol, and thus violates their right of access to the courts.

307. For the reasons set forth above, Defendants are deliberately indifferent to Plaintiffs' constitutional rights.

308. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count V.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court:

1. Grant a declaratory judgment that neither pentobarbital nor midazolam are ultra-short acting barbiturates or other similar drugs and are therefore not permitted for lethal injection executions in Mississippi;
2. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs with any drug which is not an ultra short-acting barbiturate;
3. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs with either compounded pentobarbital or midazolam, which are neither ultra-short acting barbiturates nor similar to ultra short-acting barbiturates;
4. Grant a declaratory judgment that the words "in combination with a chemical paralytic agent" in Miss. Code Ann. §99-19-51 violate the Eighth and Fourteenth Amendment to the United States Constitution;
5. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs with compounded drugs;
6. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs with a three-drug series which includes a chemical paralytic agent and potassium chloride;

7. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs until such time as Defendants can demonstrate the integrity, purity, potency, and legality of any and all controlled substances they intend to use for Plaintiffs' executions;

8. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs without providing full and complete information about the drugs that Defendants intend to use in their execution, within sufficient time for Plaintiffs to raise any statutory or constitutional challenges to the use of said drugs.

9. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs until such time as Defendants can demonstrate that measures are in place to allow for Plaintiffs' execution in a manner that complies with the Eighth and Fourteenth Amendments to the United States Constitution;

10. Award costs and attorney's fees pursuant to 42 U.S.C. §1988; and

11. Grant any such other relief that this Court determines to be just and proper in these premises.

Respectfully submitted,

/s/ James W. Craig
James W. Craig, MSB # 7798
Emily M. Washington (pro hac vice)
The Roderick & Solange MacArthur Justice Center
4400 South Carrollton Ave.
New Orleans, LA 70119
(504) 620-2259 (p)
(504) 208-3133 (f)
jim.craig@macarthurjustice.org
emily.washington@macarthurjustice.org

Counsel for Plaintiffs Jordan and Chase

Respectfully submitted,

/s/ Stacy Ferraro
Stacy Ferraro, MSB no. 100263
239 N. Lamar Street, Suite 604
Jackson, MS 39201
(601) 576-2322 (p)
(601) 576-2319 (f)
lifestoryms@gmail.com

Counsel for Intervenor Loden

Dated: September 28, 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 and the Intervenor in this case.

This, the 28th of September, 2015.

/s/James W. Craig