

IN THE CHANCERY COURT OF HINDS COUNTY, MISSISSIPPI
FIRST JUDICIAL DISTRICT

FILED
MAR 28 2014
EDDIE JEAN CARR, CHANCERY CLERK
BY [Signature] D.C.

MICHELLE BYROM and
CHARLES CRAWFORD,

Plaintiffs,

v.

CHRISTOPHER EPPS, 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.

Civil Action No. C-2014-424
TJ

COMPLAINT FOR EQUITABLE AND INJUNCTIVE RELIEF

NATURE OF ACTION

1. Plaintiffs bring this action pursuant to 42 U.S.C. § 1983 and Mississippi law for violations and threatened violations of their rights to due process and to be free from cruel and unusual punishment under the First, Fifth, Eighth, and Fourteenth Amendments to the United States Constitution and art. 3, sections 14, 24 and 28 of the Mississippi Constitution. The Mississippi Department of Corrections ("MDOC") intends to execute Plaintiffs with compounded drugs that may be counterfeit, expired, contaminated, and/or sub-potent, which creates a substantial risk of serious harm to the Plaintiffs. MDOC's decision to use compounded drugs, specifically a compounded anesthetic that has not been tested or approved by the United States

Food and Drug Administration (“FDA”), means that Plaintiffs may be conscious throughout their executions and will experience a tortuous death by suffocation and cardiac arrest. Plaintiffs seek permanent injunctive relief to prevent the Defendants from inflicting cruel and unusual punishment upon them during their executions.

JURISDICTION AND VENUE

2. Because Plaintiffs seek equitable relief, this Court has jurisdiction over this action pursuant to Article VI, §159(a) of the Mississippi Constitution. This action arises under the First, Fifth, Eighth, and Fourteenth Amendments to the United States Constitution, article 3, Sections 14, 24, and 28 of the Mississippi Constitution, and under 42 U.S.C. § 1983.

3. Venue is proper in the First Judicial District of Hinds County pursuant to Miss. Code Ann. §11-5-1 and MISS.R.CIV.P. 4(d)(5), because Defendant Christopher Epps, as Commissioner of the Mississippi Department of Corrections, may be found in Jackson, Hinds County, Mississippi, all of the defendants are officers of the State of Mississippi and may be sued in Hinds County, the seat of state government.

PARTIES

4. Plaintiff Michelle Byrom is a United States citizen, currently incarcerated under a sentence of death at the Central Mississippi Correctional Facility in Pearl, MS.

5. Plaintiff Charles Crawford is a United States citizen, currently incarcerated under a sentence of death at the Mississippi State Penitentiary in Parchman, MS.

6. Defendant Christopher Epps is the Commissioner of the Mississippi Department of Corrections.

7. 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.

8. Commissioner Epps 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).

9. As the Commissioner of the MDOC, Mr. Epps 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 § 99-19-53. *See also* § 99-19-55.

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

11. At all relevant times, Commissioner Epps 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 Epps is sued in his official capacity only.

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

13. 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.

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

15. 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.

16. 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.

17. 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).

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

FACTUAL ALLEGATIONS

A. MISSISSIPPI'S THREE-DRUG LETHAL INJECTION PROTOCOL

19. 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.

20. The lethal injection protocol promulgated by the MDOC under the supervision of Defendant Epps calls for the serial administration of three drugs to put a prisoner to death.

21. The first drug, pentobarbital, a short-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 and potassium chloride, respectively.

22. 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 affect sensation, consciousness, cognition, or the ability to feel pain and suffocation.

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

24. The purpose of the neuromuscular blocking agent in Mississippi's lethal injection protocol is to mask the gasping and physical convulsions produced by the final drug, potassium chloride, and to make the execution appear serene and peaceful.

25. 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.

26. The humaneness and constitutionality of the lethal injection process hinges on whether the entire dose of pentobarbital is administered correctly, and whether the drug is of sufficient potency and purity, to ensure that the prisoner is unconscious so he does not feel the torturous effects of the second and third drugs. If the first drug administered fails to work as intended, the execution will be torturous for the prisoner.

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

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

28. The first risk is associated with the administration of vecuronium bromide, the paralytic agent required by the Mississippi protocol

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

30. 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 desire to inhale.

31. 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.

32. 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.

33. 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.

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

35. 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.

36. The two risks set forth in paragraphs 27 to 36 above create a substantial risk of serious harm in violation of the Eighth Amendment, unless the short-acting barbiturate is

administered 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.

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 IS INSUFFICIENT

37. Over the past several years, many pharmaceutical manufacturers have ceased production of drugs commonly used in executions in the United States, have refused to sell them to states 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.

Sodium Thiopental

38. The American manufacturer of the anesthetic sodium thiopental, Hospira, Inc., 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 corrections’ departments.

39. Although sodium thiopental is manufactured in other countries, the FDA has not approved its importation into the United States.

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

41. 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.

42. The compromised drug used in 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.

43. Thus, when Brandon Rhodes was executed with the illegally imported sodium thiopental, his eyes remained open for the entirety of his execution, indicating consciousness during the process.

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

Nembutal: Pentobarbital Sodium Manufactured by Lundbeck

45. The Mississippi execution protocol requires the administration of pentobarbital.

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

47. 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 their drug to enter into end-use agreements by which they agreed not to sell or transfer the drugs to prisons in states that still use capital punishment. 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. Any Nembutal sold prior to the July 2011 agreement would have expired no later than November 2013.

48. The last time MDOC purchased Nembutal was on March 23, 2011 and any unused drugs from this purchase will have expired.

49. Consequently, Mississippi, along with every other state that uses pentobarbital to carry out executions, no longer has any legally-obtained and unexpired Nembutal to use in executions.

50. The last execution that took place in Mississippi occurred on June 20, 2012.

Experimentation With Anesthetics Previously Not Used in Executions

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

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

53. William Happ's execution in Florida 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.

54. Dennis McGuire's execution in Ohio with midazolam and hydromorphone took twenty-six (26) minutes, and he gasped for air and gagged throughout the execution -- signs that he was being suffocated to death.

Experimentation With Compounded Drugs

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

56. This type of pharmacy compounding is a gross deviation from the traditional practice of pharmacy compounding, which involves 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.

57. 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.

58. 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.

59. 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.

60. 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.

61. 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.

62. The 2012 outbreak of fungal meningitis from compounded steroid injections resulted in several fatalities, and has drawn increased attention to the risks associated with the practice of compounding drugs for general distribution.

63. 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."

64. The burning sensation related 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

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

66. On or around May 20, 2012, MDOC purchased \$3,150 worth of Pentobarbital Sodium from Brister Brothers Compounding Pharmacy in Grenada, MS.

67. MDOC also purchased \$685 worth of Vecuronium Bromide on or around May 20, 2012, and \$200 of Potassium Chloride from Brister Brothers on or around May 8, 2013. MDOC purchased another \$200 of Vecuronium Bromide from Brister Brothers on or around December 17, 2013.

68. Upon information and belief, Defendants did not purchase Nembutal or another sterile, injectable pentobarbital from Brister Brothers Pharmacy on or around May 20, 2012.

69. Specifically, Defendants purchased 70 vials of raw materials or active pharmaceutical ingredients (“API”), which will have to be compounded to create an injectable form of pentobarbital.

70. Upon information and belief, Defendants have not yet compounded the raw pentobarbital.

71. There is no public record of MDOC sending the raw pentobarbital to a compounding pharmacy.

72. Additionally, an affidavit executed by Special Assistant Attorney General Jim Norris on March 10, 2014 describes the pentobarbital sodium as being in a “powder” form.

73. Upon information and belief, the Defendants intend to compound the pentobarbital on the grounds of the Mississippi State Penitentiary; or in the alternative, the Defendants intend to send the raw pentobarbital to a yet undisclosed compounding pharmacy to prepare the drug for an execution.

74. Mississippi has never resorted to compounded pentobarbital in the past, and if Mississippi proceeds with their executions, Plaintiffs will be the first prisoners in Mississippi to be executed with compounded pentobarbital.

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

75. Because Mississippi will use a three-drug formula in its executions, the humaneness and the constitutionality of the procedure depends entirely on the first drug working as intended and deeply anesthetizing the prisoner.

76. When a compounded pentobarbital is used as the first drug in the three-drug formula, new, gratuitous risks are introduced to the execution procedure. Compounded drugs are not FDA approved, so they carry no guarantees of the identity, purity, or potency of the drug. And

while it is possible for the compounding pharmacy to test the drug to ensure that it is pentobarbital, it is not possible for testing to eliminate the risks posed by impurities, contaminants, particulate matter and an improper pH balance.

77. If the compounded pentobarbital is in any way sub-optimal, it would pose a substantial risk of 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.

78. Moreover, each batch of compounded pentobarbital used in executions in Mississippi will be a new product, so the effectiveness of one batch will tell us nothing about the effectiveness of the next.

The Questionable Integrity of the Materials in the Possession of the Defendants

79. First, the integrity of the drug's active pharmaceutical ingredients cannot be verified, and the ingredients could very well be counterfeit, contaminated, or substandard.

80. The Defendants have not revealed the source of the active pharmaceutical ingredients that were used or will be used to make the compounded drug.

81. Instead, the Defendants have provided conflicting statements about the pentobarbital it plans to use to execute Plaintiffs.

82. In their February 24, 2014 response to a public records request submitted by Plaintiffs, MDOC stated that the pentobarbital it possesses is currently in a liquid form.

83. If the pentobarbital in the possession of Defendants is in liquid form, then the drug must have already been mixed and compounded for use.

84. If the pentobarbital has been mixed and compounded already, then its expiration date would be uncertain, but shorter than the expiration period for Nembutal.

85. However, in a recent affidavit attesting to the drugs' expiration dates, Special Assistant Attorney General Jim Norris testified that the pentobarbital currently held by Defendants is in a powder form.

86. If the execution drugs held by MDOC and the other Defendants are currently in powder form, then Defendants will need to compound the powder form of pentobarbital into an injectable drug.

87. In either event, Defendants have not revealed the source of the active pharmaceutical ingredients that were used or will be used to make the compounded drug.

88. The integrity of the drug's active pharmaceutical ingredients cannot be verified, and the ingredients could very well be counterfeit, contaminated, or substandard.

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

89. The lack of transparency surrounding the compounding process is also problematic. Pentobarbital is a schedule II narcotic.

90. 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 lab with very specific and sophisticated physical requirements.

91. Upon information and belief, the Mississippi State Penitentiary does not have a sterile compounding lab.

92. There are a limited number of sterile compounding labs in Mississippi, and MDOC has not revealed to Plaintiffs where or how they intend to compound the raw pentobarbital.

93. There are substantial risks that the drug may be contaminated during compounding, and 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

94. 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.

95. In the affidavit provided by the attorney for MDOC, Mr. Norris testified that the pentobarbital sodium possessed by the Defendants will expire on May 20, 2015, the vecuronium bromide possessed by the Defendants will expire in June 2014, and the potassium chloride possessed by the Defendants will expire in October 2014.

96. The expiration date claimed by Defendants for the pentobarbital sodium in their possession is questionable.

97. First, the use of a specific date for expiration is contrary to the FDA practice with respect to pentobarbital. The FDA-approved form of pentobarbital, Nembutal, only provides a month and year for its expiration date, as opposed to the month, day, and year expiration date provided by MDOC.

98. Second, any compounded form of pentobarbital based upon ingredients purchased in 2012 would expire well before 2015.

The Risk of Counterfeit API

99. 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.

100. Because Defendants have not procured the drugs for lethal injection 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.

Summary of Risks Presented by Defendants' Conduct

101. 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.

102. The administration of pure and potent pentobarbital is the 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.

103. 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.

104. 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 Plaintiffs 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

105. On February 7, 2014, counsel for Plaintiffs submitted a public records request 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, where and how MDOC procured its lethal injection drugs, and the expiration dates for the lethal injection drugs.

106. MDOC provided some information and documents, but stated that MDOC would not disclose any information about the supplier or manufacturer of their lethal injection drugs due to "security" concerns.

107. Although Plaintiffs were able to identify the supplier of MDOC's lethal injection drugs through their own investigation, 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.

108. States continue to have difficulty purchasing pentobarbital in any form, and have recently encountered difficulty in purchasing vecuronium bromide. Consequently, Defendants may change their protocol or purchase different drugs or active pharmaceutical ingredients from different manufacturers before the next scheduled execution.

109. Due to Defendants' policy of secrecy, Plaintiffs will not receive notice of any changes that Defendants make to their protocol, nor will they receive notice if and when Defendants change the type or form of drugs they intend to use in a lethal injection.

110. Upon information and belief, Defendants have not yet compounded the pentobarbital into a sterile injectable form, and if Plaintiffs are scheduled for an execution, their

executions will be the first in which Defendants use this compounded pentobarbital. Defendants have failed to disclose what information, if any, they have researched, gathered, or relied upon to evaluate the efficacy or effect of this new drug when used for an execution.

111. Defendants' failure to disclose the manufacturer of the active pharmaceutical ingredients deprives Plaintiffs of the means to determine 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.

112. Defendants will not disclose to Plaintiffs where and when they plan to compound the drug, 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 test the identity and the purity of the API.

113. Defendant's policy of secrecy, and their failure to disclose to Plaintiffs the manufacturer of the raw ingredients or API it purchased from Brister Brothers Pharmacy, and where, how, and when they intend to compound the raw ingredients or API into a sterile injectable form of pentobarbital violates Plaintiffs' rights to due process and access to the courts.

CLAIMS FOR RELIEF

Count I: Violation of 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

114. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 20 to 113.

115. Defendants no longer possess an FDA-approved form of pentobarbital – the fast-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.

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

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

118. 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.

119. 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.

120. Because it is nearly impossible to determine with certainty whether a prisoner will suffer unnecessary pain during an execution, the question of whether a particular execution procedure will inflict unnecessary pain and suffering involves an inquiry as to whether the prisoner is subject to an unnecessary risk of unconstitutional pain or suffering.

121. Unnecessary pain and suffering may occur when a state lacks a clear protocol for lethal injection, or experience with the procedure demonstrates that there are foreseeable problems that will result in the prisoner suffering intense pain that an alternative procedure would not cause.

122. 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 an unacceptable risk that the pentobarbital will be counterfeit, contaminated, degraded, expired, or sub-potent, resulting in the infliction of cruel and unusual punishment.

123. The Defendants' untried and untested drugs create an unacceptable risk that Plaintiffs will suffer unnecessary and excruciating pain either by the pentobarbital causing a painful reaction, or by the pentobarbital failing to work, resulting in a torturous death by live suffocation and cardiac arrest.

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

Count II: 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

125. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 20 to 113.

126. Defendants no longer possess an FDA-approved form of pentobarbital – the fast-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.

127. Defendants have obtained raw ingredients or active pharmaceutical ingredients from a compounding pharmacy to make a sterile injectable form of pentobarbital.

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

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

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

131. 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 type of drugs Defendants have obtained and manufactured.

132. Defendants' failure to disclose the manufacturer of the raw ingredients or active pharmaceutical ingredients it purchased to make pentobarbital, and Defendants' failure to disclose how, where, and when they intend to compound the raw ingredients into a sterile injectable form of pentobarbital violates Plaintiffs' right to due process under the United States and Mississippi Constitutions.

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

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

134. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 20 to 113.

135. 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.

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

137. Defendants have asserted that the identity of the manufacturer and supplier of lethal injection drugs is confidential for security reasons, and will not tell Plaintiffs who manufactured the active pharmaceutical ingredients, where the 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 precisely determine the risks associated with Defendants' lethal injection drugs.

138. Defendants' refusal to disclose information about their lethal injection process will also deprive Plaintiffs of notice of future changes that Defendants make to the lethal injection protocol and/or the type and form of drugs used in executions.

139. 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.

140. 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.

141. 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for:

1. 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 and legality of any and all controlled substances they intend to use for Plaintiffs' executions;

2. 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;

3. Permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from withholding from Plaintiffs information about their lethal injection protocol and lethal injection drugs;

4. Timely and meaningful disclosure to Plaintiffs of all information deemed relevant to a determination of the constitutionality of their planned execution;

5. A declaration that Defendants' plan to use an untested, secret, and experimental execution method on Plaintiffs violate their Eighth and Fourteenth Amendment rights under the U.S. Constitution, and Article 3, Sections 14 and 28 of the Mississippi Constitution;

6. A declaration that Defendants' policy of keeping information pertaining to its lethal injection protocol secret violates Plaintiffs' rights under the First and Fourteenth Amendments to the U.S. Constitution and Article 3, Sections 14 and 24 of the Mississippi Constitution;

7. Reasonable attorneys' fees and costs; and

8. Any other such relief as this Court deems just and proper in these premises.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Vanessa Carroll", written over a horizontal line.

James W. Craig, MSB #7798

Vanessa J. Carroll, MSB #102736

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