

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

OSCAR SMITH, BYRON BLACK, HENRY )  
HODGES, FARRIS MORRIS, and )  
PERVIS PAYNE, )

Plaintiffs, )

V. )

No. 3:19-cv-01138

TONY PARKER, in his official capacity )  
As Tennessee's Commissioner of )  
Correction, )

TONY MAYS, in his official capacity )  
As Warden of Riverbend Maximum )  
Security Institution, )

Defendants. )

**FIRST AMENDED  
COMPLAINT**

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## I. INTRODUCTION

Plaintiff Oscar Smith seeks relief pursuant to 42 U.S.C. § 1983 for injunctive and declaratory relief, attorney fees, and cost of suit against the Defendants.

Defendants intend to execute Mr. Smith by use of a lethal injection protocol that violates the Eighth Amendment. The State's current three-drug protocol is sure or very likely to cause serious illness and needless suffering. Mr. Smith has identified a feasible and readily implemented alternative method of execution—a single-drug pentobarbital protocol—which the State refuses to adopt without a legitimate reason, even though it would significantly reduce a substantial risk of severe pain.

State prison officials previously represented that pentobarbital was not available, but that is no longer the case. Several states and now the federal government have found a domestic source of the active pharmaceutical ingredient (API) and compounding pharmacies that are willing and able to compound pentobarbital using this API. In addition, the Office of Legal Counsel recently issued an opinion that the Food and Drug Administration has no jurisdiction to regulate lethal injection chemicals, such that state prison officials are now free to import pentobarbital. A single-drug administration of pentobarbital was part of the State's lethal injection protocol from 2013 until July 2018, and state prison officials have stated that they would use pentobarbital if it were available.

In *Bucklew v. Precythe*, 139 S. Ct. 1112 (2019), the Supreme Court clarified that “[d]istinguishing between constitutionally permissible and impermissible degrees of pain . . . is a *necessarily* comparative exercise. To decide whether the

State has cruelly ‘superadded’ pain to the punishment of death isn’t something that can be accomplished by examining the State’s proposed method in a vacuum, but only by ‘compar[ing]’ that method with a viable alternative.” *Id.* at 1126 (citing *Glossip v. Gross*, 135 S. Ct. 2726, 2737-38 (2015); *Baze v. Rees*, 553 U.S. 35, 61 (2008)) (alterations in original). This clarification unified that which had previously be considered as two separate prongs of analysis under *Glossip*. Under *Bucklew*, any method of execution involving a substantial risk of serious harm is constitutionally impermissible if there is a viable alternative that involves less risk of pain and suffering.

## II. JURISDICTION AND VENUE

1. This action arises under 42 U.S.C. §1983 for violations of the Eighth and Fourteenth Amendments to the United States Constitution. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question); §1343 (civil rights violations and equitable relief under an act of Congress); §2201 (declaratory relief); and §2202 (preliminary and permanent injunctive relief).

2. This court has personal jurisdiction over Defendants, as they are residents of the State of Tennessee, are presently located in the State of Tennessee, and are elected or appointed officials of the State of Tennessee or otherwise acting on behalf of the State of Tennessee.

3. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391. Plaintiff is incarcerated at Riverbend Maximum Security Institution (RMSI), in Davidson County, and the Defendants intend to execute him in Davidson County.

Accordingly, the events giving rise to this complaint have occurred and will occur in this county.

4. Plaintiff is not required to exhaust administrative remedies, because any administrative process is futile. Further, Plaintiff attempted to exhaust administrative remedies. Upon notice that Tennessee had adopted a lethal injection protocol including midazolam as the putative analgesic, Plaintiff filed a grievance objecting to the use of the midazolam-based protocol (then called "Protocol B"). Defendants took no action on Plaintiff's grievance. Defendants' inaction regarding Plaintiff's grievance while at the same time seeking his execution demonstrates the futility of such a process.

### **III. STATEMENT OF INCORPORATION**

5. All allegations in this Complaint are incorporated in all sections as if fully set forth therein.

### **IV. PARTIES**

6. Plaintiff Oscar Smith is a United States citizen and a resident of the State of Tennessee.

7. Smith is sentenced to death in the state of Tennessee and housed at RMSI in Nashville, Davidson County, Tennessee. Mr. Smith is in the custody of the Tennessee Department of Correction (TDOC).

8. The Attorney General and Reporter for the State of Tennessee has filed a motion requesting that the Tennessee Supreme Court set an execution date for Mr. Smith.

9. Defendant Tony Parker is the Commissioner of the Tennessee Department of Correction, a state agency located in Nashville, Tennessee. As head of the TDOC, Commissioner Parker adopted and will implement the Lethal Injection Protocol at issue in this litigation. In his capacity as Commissioner, Mr. Parker will oversee Mr. Smith's execution at RMSI. Plaintiff sues Commissioner Parker in his official capacity. The commissioner is a state actor, acting under color of state law in executing Plaintiff; his efforts to do so violate Mr. Smith's constitutional rights as described below.

10. Defendant Tony Mays is the Warden of RMSI where Mr. Smith is in custody and where the state of Tennessee intends to execute him. Plaintiff sues Mr. Mays in his official capacity as he is a state actor, acting under color of state law in executing Mr. Smith. Defendant Mays is directly in charge of carrying out the lethal injection protocol that violates Mr. Smith's rights as described below.

## **V. FACTS**

### **A. Procedural History and Statutory Framework**

11. On July 23, 1990, a Davidson County jury sentenced Plaintiff to "death by electrocution."

12. In 1998, the Tennessee legislature changed the method of execution to lethal injection for all crimes committed after January 1, 1999:

For any person who commits an offense for which the person is sentenced to the punishment of death, the method for carrying out this sentence shall be by lethal injection.

Tenn. Code Ann. § 40-23-114(a); *see also* 1998 Tenn. Laws Pub. Ch. 982.

13. Individuals, such as Mr. Smith, who committed an offense before January 1, 1999, and “were sentenced to the punishment of death may elect to be executed by electrocution by signing a written waiver waiving the right to be executed by lethal injection.” Tenn. Code Ann. § 40-23-114(b).

14. Mr. Smith has not— and will not— elect a method of execution. He believes that to do so would constitute participation in a murder, rendering him guilty of a crime (to wit: accessory to murder or suicide). Accordingly, under Tennessee Code Annotated § 40-23-114(a) and (b), the death sentence will be carried out by lethal injection.

15. If a court finds the State’s execution protocol unconstitutional, state statute allows for execution “by any valid method”:

[A]ll persons sentenced to death for a capital crime shall be executed by any constitutional method of execution. No sentence of death shall be reduced as a result of a determination that a method of execution is declared unconstitutional under the state constitution or the Constitution of the United States. In any case in which an execution method is declared unconstitutional, the death sentence shall remain in force until the sentence can be lawfully executed by any valid method of execution.

Tenn. Code Ann. § 40-23-114(d).

16. State statute provides that the State will execute inmates by electrocution if a court finds the lethal injection protocol unconstitutional or the commissioner of correction certifies to the governor that “one (1) or more of the ingredients essential to carrying out a sentence of death by lethal injection is unavailable through no fault of the department.” Tenn. Code Ann. 40-23-114(e).

17. In September 2013, TDOC revised its lethal injection protocol to a one-drug, pentobarbital protocol:

Pentobarbital: An intermediate-acting barbiturate. A lethal dose of 100 ml of a 50 mg/ml solution (a total of 5 grams) is administered during the execution process.

18. TDOC next revised its lethal injection protocol in January 2018, at which time it retained the pentobarbital protocol (labeled “Protocol A”) and added the current three-drug protocol (500 milligrams of midazolam, 100 milligrams of vecuronium bromide, and 240 mEq potassium chloride) (labeled “Protocol B”).

19. On July 5, 2018, TDOC again amended its lethal injection protocol, removing “Protocol A,” and leaving only the three-drug protocol. Hereafter, all references to “the Lethal Injection Protocol” are to the July 5, 2018 protocol currently in effect.

## **B. Tennessee’s Lethal Injection Protocol**

### **1. Midazolam**

20. Midazolam is a benzodiazepine.

21. Midazolam is a sedative.

22. Sedation is a state of calm or sleep.

23. Midazolam is used for induction of anesthesia.

24. Induction is a stage that precedes achieving and maintaining a plane of general anesthesia.

25. During the induction stage, an induction agent induces a state of sedation in which the patient is calm but arousable when subjected to noxious stimuli. The eyes generally closed in the induction stage.

26. At the induction stage, a person remains sensate to pain.
27. The depth of midazolam's inhibitory effect on the central nervous system is limited; midazolam cannot induce or maintain a state where a person is fully unaware of or insensate to pain.
28. Midazolam affects the central nervous system by facilitating the activity of gamma amino-butyric acid (GABA) receptors, the primary effect of which is to reduce anxiety.
29. GABA is a primary neurotransmitter that inhibits central nervous system activity.
30. When inhibitory neurons of the brain release GABA onto other brain neurons, GABA binds to GABA-specific receptors. This binding causes chloride ion channels to open on the recipient neuron.
31. The influx of chloride ions through the channels causes those neurons to become more quiescent, to decrease electrical activity, and to decrease the likelihood of neuronal firing, resulting in neuronal inhibition and central nervous system depression.
32. Midazolam promotes the binding of GABA to GABA-A receptors, which are ion channels with multiple binding sites that can be opened by GABA.
33. Midazolam's mechanism of action is inherently limited by the finite number of GABA-A receptors in the brain.
34. Once each of the GABA-A receptors has been bound with the midazolam, activating the inhibitory response of the neural pathway,

administration of additional quantities of midazolam does not provide any greater sedative effect. This phenomenon is known as the “ceiling effect.”

35. Because of the ceiling effect, 500 mg of midazolam is no more effective than the minimum dose of midazolam required to bind the available GABA receptors.

36. Regardless of dose, midazolam cannot produce a plane of general anesthesia.

37. Midazolam has a negligible analgesic effect.

38. There is no dose of midazolam that can sufficiently inhibit the severe pain and needless suffering caused by vecuronium bromide and potassium chloride.

39. Midazolam cannot reliably serve as general anesthesia, as barbiturates (including pentobarbital) can.

40. Barbiturates and benzodiazepines are different classes of drugs that work via different mechanisms.

41. Barbiturates do not have a “ceiling effect,” can quiet all brain activity, and can cause a coma or brain death in a way that midazolam cannot.

42. Condemned inmates have responded during lethal injections after being injected with 10, 50, 500, 700, and 1,000 mg of midazolam.

43. There exists a substantial and unjustifiable risk that the use of midazolam as required by the Lethal Injection Protocol will not prevent Plaintiff from experiencing the severe pain and needless suffering of involuntary paralysis and suffocation caused by vecuronium bromide.

44. There exists a substantial and unjustifiable risk that the use of midazolam as required by the Lethal Injection Protocol will not prevent the Plaintiff from experiencing the severe pain and needless suffering of potassium chloride as it passes through his veins and causes cardiac arrest.

45. The consciousness check contained in the Lethal Injection Protocol is insufficient to determine whether Plaintiff will experience the severe pain and needless suffering of the second and third drugs in the Protocol.

46. An eyelash brush is not a sufficient consciousness check, as it is not a noxious stimuli.

47. A trapezius pinch is not a sufficient consciousness check, as it is not comparable to the noxious stimuli created by the sensation of suffocation from vecuronium bromide or as the sensations caused by the potassium chloride.

48. Unresponsiveness to an eyelash brush or to the trapezius pinch fails to demonstrate that Plaintiff will not experience serious pain and needless suffering when more noxious stimuli are introduced into the body.

## **2. Vecuronium Bromide**

49. Vecuronium bromide is a neuromuscular blocking agent that produces paralysis, including of the respiratory muscles.

50. A neuromuscular blocking agent blocks the receptor sites in muscle tissue that receive nerve impulses.

51. When these sites are blocked, the nerve impulses have no effect on the muscle tissue, which means that the muscle tissue will no longer contract, thus causing paralysis.

52. A neuromuscular blocking agent has no effect on the central nervous system, and consequently it has no effect on awareness or the sensation of pain and suffering.

53. Vecuronium bromide is a noxious stimuli.

54. Vecuronium bromide has no analgesic properties.

55. The vecuronium bromide is unnecessary to cause death and is not the cause of death from the Lethal Injection Protocol.

56. The vecuronium bromide will cause Plaintiff to be completely unable to move; he will not be able to respond by breathing, by moving, or by facial or vocal expressions.

57. When the diaphragm and other muscles that control breathing are paralyzed, Plaintiff will experience the sensation of suffocation without being able to respond.

58. The use of vecuronium bromide will prevent execution team members, correctional staff, and witnesses from observing Plaintiff's pain responses.

59. Vecuronium bromide serves no purpose in the protocol other than to act as a chemical veil that prevents witnesses from observing signs that an inmate is aware and able to feel the searing pain caused by the administration of potassium chloride.

60. Midazolam will not prevent the Plaintiff from experiencing the pain and suffering of suffocation caused by Defendants' use of vecuronium bromide.

61. When Plaintiff experiences the pain and suffering of suffocation, his body will respond with an immediate and extreme spike in adrenaline and other stress hormones.

62. Administration of vecuronium bromide to any sensate human produces the terrifying sensation of being buried alive.

63. A human being's biological response to the administration of vecuronium bromide is sure or very likely to overcome the sedative effect of midazolam.

64. Though vecuronium bromide would, without medical intervention, cause death through suffocation after sufficient time for oxygen deprivation to cause brain death, the Lethal Injection Protocol provides for the inmate to be killed by administration of potassium chloride before death by vecuronium bromide can occur.

65. As Plaintiff is sure or very likely to be conscious enough to experience the serious pain, unnecessary suffering, and terror caused by suffocation, the Lethal Injection Protocol is unconstitutional.

66. Because the injection of vecuronium bromide as set forth in the Lethal Injection Protocol takes two minutes to administer, removing the vecuronium bromide from the Lethal Injection Protocol would hasten death by two minutes.

67. Defendants have admitted that vecuronium is unnecessary to cause death.

### **3. Potassium Chloride**

68. Potassium chloride, the third drug in the Lethal Injection Protocol, is a metal halide salt composed of potassium and chloride.

69. Given midazolam's lack of analgesic properties, Plaintiff is sure or very likely to experience serious pain and needless suffering from an intravenous injection of potassium chloride, which will cause a searing, burning, sensation in his veins.

70. Death by potassium chloride does not occur instantaneously.

71. Potassium chloride causes death by interference with the electrical activity of the heart resulting in cardiac arrest.

72. Though the heart stops beating, consciousness may continue for as long as 3 minutes until brain death.

73. Given midazolam's lack of analgesic properties, Plaintiff is sure or very likely to be aware and experience serious pain and needless suffering caused by searing, burning sensation in his veins and the heart attack induced by potassium chloride.

74. The use of potassium chloride as part of a lethal injection protocol is unnecessary.

75. The serious pain, needless suffering, and terror caused by potassium chloride violates the Eighth Amendment.

### C. Factual Amendments

76. The State executed Donnie Johnson by lethal injection on May 16, 2019.

77. Defendants followed the July 5, 2018 midazolam-based lethal injection protocol in carrying out Donnie Johnson's execution.

78. Mr. Johnson began to sing after the warden had given the signal for the administration of chemicals to begin.

79. Mr. Johnson's singing lasted for nearly three minutes.

80. Mr. Johnson opened his eyes after the midazolam had been administered.

81. Mr. Johnson's mouth moved after the midazolam had been administered.

82. Defendant Mays and the associate deputy warden for security blocked the view of Mr. Johnson's head, upper torso, and lower extremities during the consciousness check.

83. Mr. Johnson made choking noises until the paralytic took effect.

84. Mr. Johnson made a barking noise approximately 39 seconds after the paralytic began to be administered.

85. Mr. Johnson ceased making any noise approximately 54 seconds after the paralytic began to be administered.

86. Approximately three minutes after the paralytic began to be administered Mr. Johnson's face turned to grey, then blue, then purple, then

ashen.

87. An August 8, 2010 email between state prison officials indicates that the potassium chloride (KCl) “was falling out of solution.”

From: [REDACTED]  
To: [REDACTED]  
Subject: [EXTERNAL] Suitability Test  
Date: Thursday, August 8, 2019, 11:45:26 AM  
Attachments: [REDACTED]

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Here is the suitability/methodology test for the KCl that was falling out of solution.

88. The term “falling out of solution” indicates the use of a compounded drug.

89. The use of the term “was” indicates a past event.

90. No person in Tennessee has been executed by lethal injection since May 16, 2019.

91. Defendants’ protocol provides that the compounded potassium be thawed 24 hours in advance of a scheduled execution.

92. On August 8, 2019, the next scheduled execution was August 15, 2019.

93. Defendants did not disclose the fact that the potassium chloride was falling out of solution to Mr. Johnson’s counsel prior to his execution.

94. On August 1, 2019, undersigned counsel served a public records request on counsel for Defendants, Ms. Debra K. Inglis. Ms. Inglis responded to that request on August 30, 2019. The August 8, 2019 email (as well as a number of

emails dated May 9-August 9) were not provided even though they were responsive to the request.

95. On September 24, 2019, undersigned counsel served a public records request on counsel for Defendants, Ms. Debra K. Inglis. Ms. Inglis responded to that request on August 30, 2019. The August 8, 2019 email (as well as a number of emails dated May 9-August 9) were not provided even though they were responsive to the request.

96. On December 17, 2019, undersigned counsel served a public records request on counsel for Defendants, Ms. Debra K. Inglis. Ms. Inglis responded to that request on January 15, 2020. The August 8, 2019 email was disclosed for the first time as part of a packet of emails dating back to May 9, 2019. The public records production on January 15, 2020 is heavily redacted and fails to provide a number of attachments which are responsive to the lawfully served request for public records.<sup>1</sup>

97. Defendants intend to use compounded potassium chloride to execute Plaintiffs.

98. Defendants intend to use compounded midazolam to execute Plaintiffs.

99. Compounded potassium chloride is a high-risk sterile injectable. See U.S.P. 797, <https://www.usp.org/compounding/general-chapter-797> (last checked January 28, 2019).

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<sup>1</sup> Defendants regularly and routinely withhold information regarding their execution protocols that is responsive to public records disclosure under the Tennessee Public Records Act. Tenn. Code. Ann. § 10-7-501, *et seq.* This pattern and practice not only violates the law, it also interferes with a death row defendant's ability to litigate method of execution challenges and to exercise his right under the law to choose between lethal injection and electrocution.

100. Compounded midazolam is a high-risk sterile injectable.

101. “Falling out of solution” is a known problem with the administration of high-risk sterile injectables.

102. The administration of compounded chemicals that have fallen out of solution is exceedingly painful.

103. The administration of compounded chemicals that have fallen out of solution has been described as injecting rocks into the veins. This pain is in addition to the searing, burning pain caused by virtue of the chemical properties of potassium chloride.

104. Compounded potassium chloride that has fallen out of solution might not reach the heart because it will not circulate through the body as intended.

105. Compounded potassium chloride that has fallen out of solution is extremely painful upon injection and may clog the IV line.

106. If the compounded potassium chloride does not reach the heart, the executed inmate will continue to slowly suffocate. The cause of death will be suffocation from the vecuronium bromide, which will take longer than the time contemplated by the protocol as written and will result in more protracted suffering than if the potassium chloride were to work as intended by the protocol.

107. Defendants were aware of the problem with the potassium “falling out of solution” prior to the scheduled execution of Stephen West.

108. Defendants did not inform Mr. West, or his counsel, that they had experienced problems with the potassium falling out of solution prior to his

scheduled execution.

109. On or about July 15, 2019, Defendants presented Mr. West with an affidavit regarding method of execution which asked Mr. West to elect between lethal injection or electrocution.

110. Defendants did not inform Mr. West, or his counsel, that they had experienced a problem with the potassium falling out of solution prior to asking him to waive his legal rights to challenge lethal injection or electrocution.

111. On August 14, 2019, Mr. West elected to be executed by electrocution.

112. On or about November 5, 2019, Defendants presented Mr. Leroy Hall with an affidavit regarding method of execution.

113. Defendants did not inform Mr. Hall, or his counsel, that they had experienced a problem with the potassium falling out of solution prior to asking him to waive his legal rights to challenge lethal injection or electrocution.

114. On or about November 5, 2019, Mr. Hall elected to be electrocuted.

115. An email dated November 21, 2019, from the compounding pharmacist to Defendants states, "I am still having a difficult time sourcing the Vecuronium. However, I can source Rocuronium as an API from one of our vendors and compound it. It is used in place of Vecuronium in Ohio, Virginia, and Florida. I've included some additional info below. Of course it would mean changing the protocol." The heavily redacted email, which the State has only recently disclosed through public records requests, follows:

From: [REDACTED]  
To: [REDACTED]  
Subject: [EXTERNAL] Alternatives  
Date: Thursday, November 21, 2019 12:21:36 PM

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[REDACTED]

I'm still having a difficult time sourcing the Vecuronium. However, I can source Rocuronium as an API from one of our vendors and compound it. It is used in place of Vecuronium in Ohio, Virginia, and Florida. I've included some additional info below. Of course it would mean changing the protocol.

[REDACTED]

Regards,

[REDACTED]

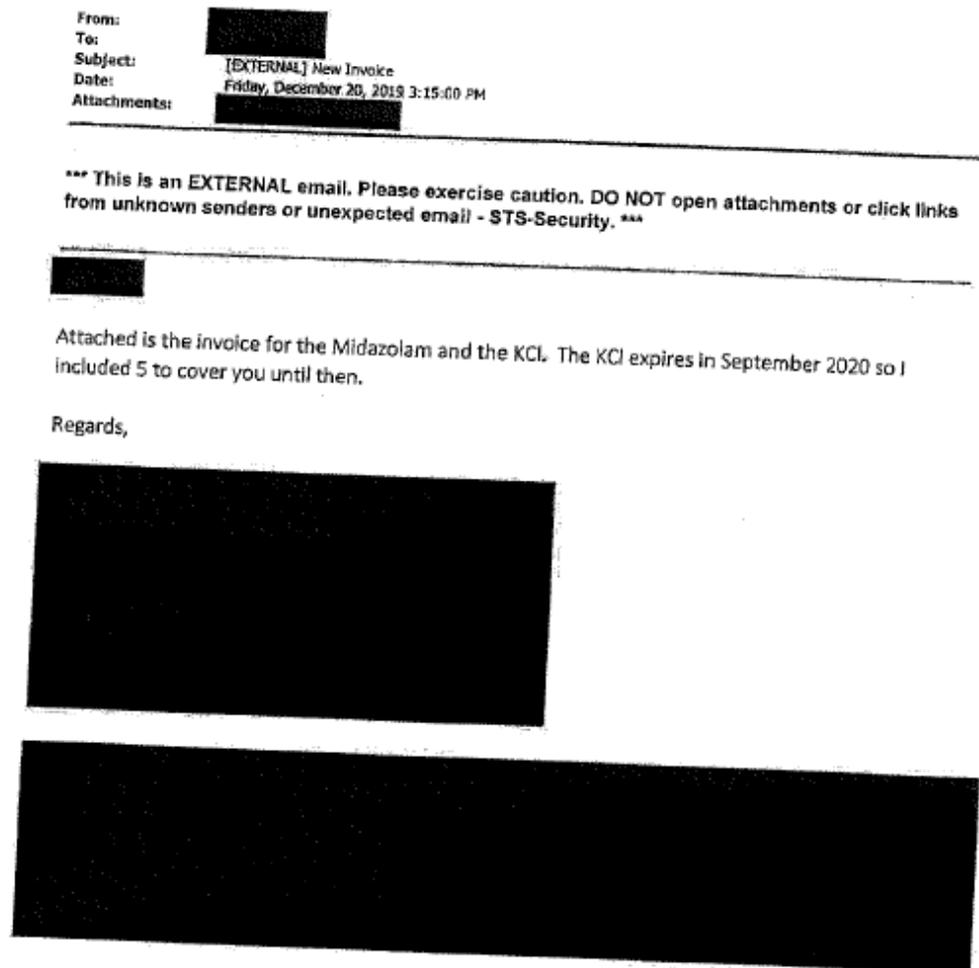
[REDACTED]

116. By November 5, 2019, the Defendants' supply of manufactured vecuronium bromide had expired. On November 5, 2019, the Department had no known source of vecuronium bromide.

117. If Mr. Hall had not elected to be electrocuted, Defendants would have been forced to inform him that they could not carry out his execution by lethal injection, paving the way for Mr. Hall to challenge the constitutionality of Tennessee's electric chair.

118. Defendants procured a waiver of rights from Mr. Hall without disclosing all relevant information to him or his counsel.

119. On December 20, 2019, the compounding pharmacist billed Defendants for midazolam and potassium. The heavily redacted email, which the State recently provided in response to a public records request, follows:



120. It does not appear that Defendants have procured a new supply of vecuronium bromide or any other paralytic.

121. On or about January 20, 2020, Defendants presented death row inmate Nicholas Sutton with an affidavit regarding method of execution.

122. Defendants did not inform Mr. Sutton, or his counsel, that they had experienced a problem with the compounded potassium falling out of solution.

123. Defendants did not inform Mr. Sutton, or his counsel, that they do not currently have the necessary chemicals to carry out a lethal injection.

124. Mr. Sutton had vigorously challenged the Midazolam-based lethal injection protocol in this Court. *Sutton v. Parker*, 3:19-cv-00005.

125. This Court dismissed Mr. Sutton's complaint on September 5, 2019. *Id.*, D.E. 32. Mr. Sutton appealed. *Sutton v. Parker*, 19-6135.

126. Defendants did not inform the United States Court of Appeals for the Sixth Circuit that they did not have sufficient chemicals to carry out a lethal injection pursuant to their protocol.

127. Defendants did not inform the United States Court of Appeals for the Sixth Circuit that they did had experienced a problem with the potassium falling out of solution.

128. On January 15, 2019, the United States Court of Appeals for the Sixth Circuit denied Mr. Sutton's motion for stay of execution. *Id.*, D.E. 13.

129. Mr. Sutton elected to executed by electrocution, thus waiving his legal right to challenge electrocution.

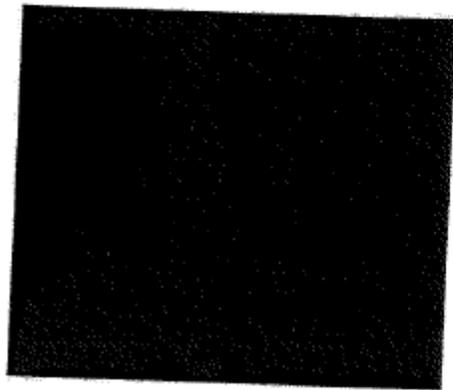
130. Within the past 8 months, Defendants have considered alternatives to the current Midazolam-based lethal injection protocol.

131. A June 26, 2019 an internal email with the subject line "Proposed Alternative" states "Midazolam, Digozin, Morphine Sulfate, & Propranolol." The

email contains an attachment which the State did not disclose in response to a public records request, in violation of state statute. The heavily-redacted email, which the State recently provided in response to a public records request, appears below.

From: [REDACTED]  
To: [REDACTED]  
Subject: Proposed Alternative  
Date: Wednesday, June 26, 2019 12:19:00 PM  
Attachments: [REDACTED]

Midazolam, Digoxin, Morphine Sulfate, & Propranolol



132. An October 30, 2019 email indicates that Defendants are considering importing pentobarbital.

133. The October 30, 2019 email indicates that Defendants believe that they are able to obtain the pentobarbital from a known source.

134. The October 30, 2019 email indicates that Defendants believe that there is a “loop hole” that will allow them to import pentobarbital because it is not “readily available” in the United States.

135. An image of the heavily redacted email is below.

From: [REDACTED]  
To: [REDACTED]  
Subject: [EXTERNAL] RE: API  
Date: Wednesday, October 30, 2019 11:07:20 AM  
Attachments: [image003.png](#)

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It's possible we could order it but getting it imported would be the issue. It's a schedule II drug and the DEA has already advised us that they do not allow the importation of drugs that are considered "readily available" in the US. There may be a loop hole in there given that the product is technically not "readily available."

[REDACTED]

[REDACTED]

From: [REDACTED]  
Sent: Wednesday, October 30, 2019 9:23 AM  
To: [REDACTED]  
Subject: API

Is this at all a possibility?

[REDACTED]

#### D. Alternatives to Tennessee's Lethal Injection Protocol

136. Mr. Smith identifies two alternative methods of execution: (1) pentobarbital or (2) the omission of vecuronium bromide (the paralytic) from the current protocol. Both are feasible, readily implemented, and would significantly reduce the substantial risk of severe pain presented by the Lethal Injection

Protocol.

**1. Primary Alternative: Pentobarbital**

137. A single dose of five grams of pentobarbital—properly compounded, stored, and administered— is feasible, readily implemented, and significantly reduces the substantial risk of severe pain presented by Tennessee’s current three-drug lethal injection protocol.

**a. Pentobarbital is Feasible and Readily Implemented.**

138. A single, five-gram dose of pentobarbital was Tennessee’s lethal injection protocol from 2013 to July 5, 2018.

139. The Tennessee Supreme Court found that lethal injection with five grams of pentobarbital does not violate the Eighth Amendment or Article I, section 16 of the Tennessee Constitution. *West v. Schofield*, 519 S.W.3d 550, 568 (Tenn. 2017).

140. Pentobarbital is available for purchase by Defendants both domestically and internationally.

141. According to United States Attorney General William Barr, pentobarbital is “widely available.” Katie Benner, *U.S. to Resume Capital Punishment for Federal Inmates on Death Row*, N.Y. TIMES, July 25, 2019.

142. The federal government represented in October 2019 that it possesses pentobarbital for use in executions in pending litigation in the District Court for the United States for the District of Columbia:

As for the supply of pentobarbital, which is a controlled substance, [Bureau of Prisons (“BOP”) selected a domestic bulk manufacturer that is properly registered with the Drug Enforcement Administration (“DEA”). The active pharmaceutical ingredient (“API”) produced by the

manufacturer was subject to quality assurance testing. BOP further selected a compounding pharmacy to store the API and to convert it into injectable form as needed. Compounding pharmacies are those in which a licensed pharmacist or physician combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual. AR 857; *see also* U.S. Food & Drug Administration, *Human Drug Compounding*, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>. The compounding pharmacy is registered with the DEA and has performed its own testing of the injectable form of pentobarbital it produced. Further, two independent laboratories have performed quality testing of the injectable solution produced by the compounding pharmacy. Finally, BOP confirmed with the DEA that the BOP facility in Terre Haute, Indiana—where Lee’s execution will take place—meets the regulatory requirements for storage and handling of pentobarbital.

*In Re: Federal Bureau of Prisons’ Execution Protocol Cases*, D.C.C Case No. 1:19-mc-00145 (TSC), D.E. 16 at 23-24 (10/18/2019 Def. Mem. in Opp. to Mot. for Preliminary Injunction) (record citations omitted).

143. The federal government has procured the API for pentobarbital from a domestic bulk manufacturer.

144. The active pharmaceutical ingredients (API) of pentobarbital are available for sale in the United States and Tennessee for use in executions. *See id.*

145. Five states—Georgia, Idaho, Missouri, South Dakota, and Texas—use a single-drug pentobarbital protocol as the method of execution.

146. States have executed inmates with pentobarbital as recently as December 11, 2019.

147. Since 2012, three of those states—Missouri, South Dakota, and Texas—have conducted a total of 109 executions using this protocol.

148. Pentobarbital was used in nine state executions in 2017, 16 executions

in 2018, and 14 executions so far in 2019.

149. In addition to being available from domestic suppliers, states can also import both the API and finished pentobarbital product from foreign sources.

150. A November 27, 2017 memorandum for the Attorney General reflects that in 2017 the BOP developed a plan to import powdered pentobarbital from a foreign FDA-registered facility and then use a compounding pharmacy to modify the drug into an injectable solution. In so doing, the BOP consulted with the FDA, which indicated that the importation of the pentobarbital would be subject to Food and Drug Administration (FDA) enforcement discretion and “that the shipment should be allowed into the country.”

151. On May 3, 2018, the Office of Legal Counsel (OLC), which provides legal advice to the President and executive branch agencies, issued an opinion stating that the FDA lacks jurisdiction to regulate drugs and devices intended for use in executions. The opinion, which is binding on the FDA, means that the agency has no legal basis to block the importation of pentobarbital from foreign sources for use in executions, thus removing a significant obstacle to importation that previously existed. Ex. 1, OLC Opinion.

152. Pentobarbital from foreign sources is available for import to states that comply with the appropriate process for obtaining that drug, just as it has been to the federal government.

153. As of August 31, 2017, Defendants were aware of ten suppliers who were willing to sell pentobarbital to TDOC. The TDOC staff member responsible for procuring the lethal injection chemicals wrote a note, later provided in response to a

TPRA request by Plaintiff's counsel: "Plenty in Europe & available according [redacted source information] has it. no lawyers." [sic]. *Id.*

154. Defendants chose not to purchase from any of those suppliers.

155. Defendants have not attempted to locate any foreign vendor of pentobarbital for importation.

156. Tennessee has not applied for an importation license.

157. Arizona, and Nebraska have obtained importation licenses for the importation of foreign pentobarbital. Ohio's application for a license to import is pending.

158. If this Court finds Tennessee's current lethal injection protocol unconstitutional, state law allows for execution "by any constitutional method," Tenn. Code Ann. § 40-23-114(d), which would include a reversion to the state's prior pentobarbital method.

**b. A Properly Administered Five Gram Pentobarbital Protocol Will Significantly Reduce the Substantial Risk of Severe Pain and Needless Suffering Presented by Tennessee's Current Three-Drug Lethal Injection Protocol.**

159. Mr. Smith's proposed "Pentobarbital Protocol" consists of the intravenous injection of five grams of pentobarbital—properly compounded, stored, and administered—which does not present a substantial risk of serious pain or needless suffering.

160. Pentobarbital is a barbiturate that acts as a sedative hypnotic drug.

161. A barbiturate like pentobarbital (and sodium thiopental, the first drug in an earlier version of Tennessee's three-drug protocol) reliably induces and

maintains a coma-like state that renders a person insensate to pain. When properly administered, barbiturates eliminate the risk that a prisoner will feel the administration of other lethal drugs.

162. Barbiturates do not have a ceiling effect.

163. Midazolam facilitates the binding of gamma-amino-butyric acid (GABA) to GABA receptors in the brain. GABA is a naturally occurring inhibitory neurotransmitter. GABA inhibits the flow of electrical impulses through the neurons to which it binds. The effect of GABA is useful to healthy brain functioning, for example preventing seizures. But at an extreme, when enough neurons are inhibited by GABA, a person becomes sedated – feeling sleepy and lethargic.

164. Barbiturates, including pentobarbital and sodium thiopental, also facilitate the activity of GABA to inhibit neurons. But barbiturates have an additional, direct effect on GABA receptors that midazolam does not have. Barbiturates bind directly to receptors, mimicking the action of GABA. Thus, even if all the GABA has been bound, barbiturates will bind to additional GABA receptors and inhibit more and more neurons from firing. A large amount of barbiturates will silence brain activity and create a coma.

165. Unlike barbiturates, midazolam does not mimic GABA, bind to receptors, and stop neurons from firing electrical impulses on its own; midazolam needs GABA to affect brain activity. Thus, midazolam's effect is capped by the limited amount of GABA in the brain. Once all GABA has been bound, increasing the dose of midazolam does not further suppress brain activity. This is midazolam's “ceiling effect,” a fundamental and unavoidable pharmacological property shared by

all benzodiazepines, which clinical studies in humans have demonstrated.

166. In other words, although people normally assume that giving twice as much of the drug will cause twice the effect, that's not the case with midazolam or other benzodiazepines. Instead, unlike barbiturates, midazolam's effect is capped ultimately by the body's own production of GABA. Because barbiturates can mimic GABA and bind to GABA receptors, barbiturates have no comparable ceiling effect. Given midazolam's ceiling effect, midazolam cannot provide the deep, coma-like, anesthetized state necessary to avoid responsiveness to pain.

167. Midazolam is not approved or used as a stand-alone anesthetic during painful surgeries, because it is inherently incapable of inducing and maintaining deep, coma-like unconsciousness.

168. The BOP's medical expert, while ethically constrained from advising whether midazolam or pentobarbital would produce a more humane death, answered questions under oath admitting that pentobarbital is able to achieve a "deeper level" of unconsciousness than midazolam.

169. A Pentobarbital Protocol will repress the brain's respiratory impulses, causing the body to become oxygen deficient and resulting in the cessation of cardiac activity.

170. A Pentobarbital Protocol functions as both a method of death and as an anesthetic, rendering the prisoner unaware and insensate to any pain before death occurs.

171. A Pentobarbital Protocol will result in a quick and complete loss of consciousness.

172. In contrast, the current three-drug protocol causes terror, severe pain, and needless suffering because (a) midazolam has no pain-relieving properties, (b) midazolam will not protect Mr. Smith from awareness or sensation of the paralytic and potassium; (c) vecuronium bromide causes paralysis and suffocation; and (d) potassium chloride causes severe pain upon intravenous injection and at the time of cardiac arrest.

173. Defendant Parker has stated under oath that he would prefer to execute inmates with pentobarbital.

174. Defendants have previously relied upon an expert, Dr. Li, who testified that “there is a negligible risk that a condemned inmate to whom five grams of pentobarbital is properly administered . . . will experience any pain and suffering associated with the execution process.” *West v. Schofield*, 519 S.W.3d 550, 560 (Tenn. 2017).

175. Dr. Li’s written report, which Defendants introduced into evidence in previous state proceedings, includes the following:

4. In the execution context, the dose and rate of administration [of the pentobarbital] will have a rapid and profound effect on consciousness, respiratory and circulatory functions. The inmate will quickly lose consciousness and become comatose. Respiration and circulation will be depressed resulting in death. Unconsciousness is a state when the ability to maintain an awareness of self and the environment is lost. In this state, the inmate completely lo[ses] responsiveness to people and other environmental stimuli.

5. It is my opinion, to a reasonable degree of medical certainty, in the execution context, that the intravenous administration of 5 grams of pentobarbital will render the inmate unconscious within seconds and, for an average human being will result in death within minutes and that the Protocol's contingency provision for the administration of an additional 5 grams of pentobarbital will certainly result in death.

6. It is my opinion, to a reasonable degree of medical certainty, that

there is a negligible risk that a condemned inmate to whom 5 grams of pentobarbital is properly administered pursuant to the Protocol will experience any pain and suffering associated with the execution process.

*Id.* at 560-61 (alterations in original).

176. Intravenous injection of five grams of pentobarbital, properly compounded and properly administered, would constitute a significant reduction of the substantial risk of severe pain, needless suffering, and terror that is present in the Lethal Injection Protocol.

## **2. Secondary Alternative: Omission of Vecuronium Bromide from the Lethal Injection Protocol**

177. Omitting vecuronium bromide (the paralytic) from the current three-drug protocol is feasible, readily available, and significantly reduces the substantial risk of severe pain presented by Tennessee's current three-drug lethal injection protocol.

### **a. The Omission of Vecuronium Bromide from the Lethal Injection Protocol Is Feasible and Readily Available.**

178. Omitting the vecuronium bromide (the paralytic) from the Lethal Injection Protocol is feasible and readily available, as it would require no additional work or effort by Defendants. In fact, it is less work for the Defendants as there is one fewer injection to administer.

179. Vecuronium bromide is not the cause of death in the Lethal Injection Protocol.

180. The use of vecuronium bromide is unnecessary to cause Plaintiff's death.

**b. The Omission of Vecuronium Bromide from the Lethal Injection Protocol Will Significantly Reduce the Substantial Risk of Severe Pain and Needless Suffering Presented by Tennessee's Current Three-Drug Lethal Injection Protocol.**

181. None of the drugs in the Lethal Injection Protocol has analgesic properties.

182. A human being's biological response to the administration of vecuronium bromide—which causes severe suffering through suffocation—is sure or very likely to overcome the sedative effect of midazolam. *See Baze v. Rees*, 553 U.S. 35, 53 (2008) (“ It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride.”).

183. Under the Lethal Injection Protocol, administration of vecuronium bromide is followed immediately by the administration of potassium chloride.

184. Under the Lethal Injection Protocol, the inmate is still alive and sensate at the time of the administration of the potassium chloride.

185. The potassium chloride independently stops the inmate's heart and death results.

186. The vecuronium bromide, while eventually toxic, takes longer to cause death than the potassium chloride, and is therefore unnecessary to cause death and is not the cause of death from the Lethal Injection Protocol.

187. The torture inherent in the administration of potassium chloride is unaffected by vecuronium bromide. The paralytic does nothing to ameliorate the

pain of the potassium, so the omission of the paralytic only affects the amount of pain in the procedure by shortening the time of the entire ordeal and removing the agony inherent in suffocation and paralysis.

188. Because the administration of vecuronium bromide in the Lethal Injection Protocol requires, at a minimum, two minutes, omission of vecuronium bromide from the Lethal Injection Protocol would hasten the inmate's death by two minutes and spare him from experiencing the severe pain and needless suffering of suffocation caused by the noxious stimuli of vecuronium bromide, which will cause Plaintiff to experience the terrifying sensation of being buried alive.

## VI. CAUSE OF ACTION

### Count 1: **Tennessee's Lethal Injection Protocol Constitutes Cruel and Unusual Punishment in Violation of the Eighth and Fourteenth Amendments to the United States Constitution.**

189. Tennessee's Lethal Injection Protocol violates the Eighth and Fourteenth Amendments to the United States Constitution.

190. The Eighth Amendment prohibits cruel and unusual punishment, for example, executions which "involve the unnecessary and wanton infliction of pain," *Gregg v. Georgia*, 428 U.S. 153, 173 (1976), or which "involve torture or a lingering death." *In re Kemmler*, 136 U.S. 436, 447 (1890) (citing *Wilkinson v. Utah*, 99 U.S. 130, 135 (1878)); accord *Gregg*, 428 U.S. at 170.

191. Subjecting individuals to a future risk of harm, such as the improper administration of lethal injection chemicals, can qualify as cruel and unusual punishment. *Baze v. Rees*, 553 U.S. 35, 49 (2008). To prevail on an Eighth Amendment claim there must be a "substantial risk of serious harm," or an

“objectively intolerable risk of harm.” *Id.* at 50.

192. Whether any method of execution involves a constitutionally impermissible risk of pain necessarily involves comparing that protocol with whatever alternative the Plaintiff proffers. *Bucklew v. Precythe*, 139 S. Ct. 112, 1126 (2019). If a challenged protocol involves a comparatively substantially greater risk of severe pain or suffering, a plaintiff has shown that the protocol violates the Eighth Amendment. *Id.*

193. The Protocol presents a risk that is sure or very likely to cause serious illness and needless suffering, and Plaintiff “has identified a feasible and readily implemented alternative methods of execution”—5 mg of pentobarbital or the omission of the vecuronium bromide from the Lethal Injection Protocol—which “the State refuse[s] to adopt without a legitimate reason, even though it would significantly reduce a substantial risk of severe pain.” *Bucklew*, 139 S. Ct. at 1129.

194. As the Supreme Court clarified in *Bucklew*, the assessment of the risk of pain is necessarily a comparative analysis; a lethal injection protocol violates the Eighth Amendment if it involves a comparatively substantially greater risk of pain and suffering than a readily available alternative. *Bucklew*, 139 S. Ct. at 1126.

195. Plaintiff does not allege that the Constitution prohibits a risk of *any* amount of pain during execution, but instead that this Protocol gives rise to sufficiently imminent dangers that he will experience severe pain and unnecessary suffering due to pulmonary edema resulting from the dose of 500 mg midazolam, from suffocation and terror of paralysis from the vecuronium bromide, and from the searing pain of the potassium chloride.

## VII. PRAYERS FOR RELIEF

196. Plaintiffs respectfully requests that this Court declare the Tennessee Lethal Injection Protocol unconstitutional and enjoin Defendants from using the Lethal Injection Protocol to kill them.

197. In the event that the protocol is not enjoined in its entirety, Plaintiffs respectfully requests that this Court enjoin Defendants and their officers or agents from administering vecuronium bromide, which serves no legitimate purpose and paralyzes the prisoner causing severe pain and unnecessary suffering in the forms of suffocation and terror.

198. Any further relief that this Court finds necessary and just.

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I certify that on January 28, 2020, a copy of the foregoing First Amended Complaint was filed and served by operation of the Court's CM/ECF filing system upon opposing counsel, Scott Sutherland, Deputy Attorney General, Rob Mitchell, Asst. Attorney General, Charlotte M. Davis, Asst. Attorney General, Miranda Jones, Asst. Attorney General, Office of the Attorney General and Reporter, Law Enforcement and Special Prosecutions Division, P.O. Box 20207, Nashville, Tennessee 37202-0207.

*/s/ Kelley J. Henry*

Counsel for Plaintiffs