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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Joseph Rudolph Wood III, Graham S. Henry, David Gulbrandson, Todd Smith, Charles M. Hedlund, Eldon Schurz, Plaintiffs, v. Charles L. Ryan, Director of the Arizona Department of Corrections; Ron Credio, Warden, ASPC – Eyman; Lance Hetmer, Warden, ASPC – Florence; and John Does, Unknown ADC Personnel, in their official capacities as Employees, Contractors, and/or Agents of the Arizona Department of Corrections, Defendants.	Case No. _____ COMPLAINT FOR EQUITABLE, INJUNCTIVE, AND DECLARATORY RELIEF [42 U.S.C § 1983]

Nature of Action

1. This action is brought pursuant to 42 U.S.C. § 1983 for violations and threatened violations by the Arizona Department of Corrections ("ADC") of Plaintiffs' First Amendment right to petition the government for redress of grievances; their First

Amendment right of access to governmental proceedings in the execution context; their right to due process under the Fourteenth Amendment; and their right not to be executed by a State acting contrary to federal law, in violation of Article VI of the United States Constitution.

2. Plaintiffs seek equitable, injunctive, and declaratory relief to prevent Defendants from carrying out Plaintiffs' executions in violation of the Constitution.

3. This Complaint does not challenge Plaintiffs' underlying capital conviction or sentence of death, nor does it allege that lethal injection as a form of execution is per se unconstitutional.

Jurisdiction and Venue

4. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1343 (civil-rights violations), 28 U.S.C. § 2201 (declaratory relief), and 28 U.S.C. § 2202 (injunctive relief). Plaintiffs invoke this Court's jurisdiction pursuant to Article III of the United States Constitution, the First and Fourteenth Amendments to the United States Constitution, and 42 U.S.C. § 1983.

5. Venue is proper pursuant to 28 U.S.C. § 1391(b). Plaintiffs are currently incarcerated at the Arizona State Prison Complex ("ASPC")–Eyman, Browning Unit, 4374 East Butte Avenue, Florence, Arizona, located in this District.

6. All executions conducted by ADC occur at the Central Unit at ASPC–Florence. The events giving rise to this Complaint have occurred and/or will occur in this District.

The Parties

7. Plaintiff Joseph Rudolph Wood III is a United States citizen and a resident of the State of Arizona. He is currently subject to a sentence of death imposed by the Superior Court of Pima County. Plaintiff is incarcerated at ASPC-Eyman, Browning Unit, in Florence, Arizona.

8. Plaintiff Wood is under a warrant of execution. His execution has been scheduled for July 23, 2014. Plaintiff Wood refuses to choose his method of execution;

therefore, ADC must use lethal injection to execute him. His execution is scheduled to take place at the Central Unit at ASPC-Florence within the State of Arizona and within this judicial district.

9. Plaintiff Graham S. Henry is a United States citizen and a resident of the State of Arizona. He is currently subject to a sentence of death imposed by the Superior Court of Mohave County. Plaintiff is incarcerated at ASPC-Eyman, Browning Unit, in Florence, Arizona.

10. Plaintiff David Gulbrandson is a United States citizen and a resident of the State of Arizona. He is currently subject to a sentence of death imposed by the Superior Court of Maricopa County. Plaintiff is incarcerated at ASPC-Eyman, Browning Unit, in Florence, Arizona.

11. Plaintiff Todd Smith is a United States citizen and a resident of the State of Arizona. He is currently subject to a sentence of death imposed by the Superior Court of Coconino County. Plaintiff is incarcerated at ASPC-Eyman, Browning Unit, in Florence, Arizona.

12. Plaintiff Charles M. Hedlund is a United States citizen and a resident of the State of Arizona. He is currently subject to a sentence of death imposed by the Superior Court of Maricopa County. Plaintiff is incarcerated at ASPC-Eyman, Browning Unit, in Florence, Arizona.

13. Plaintiff Eldon Schurz is a United States citizen and a resident of the State of Arizona. He is currently subject to a sentence of death imposed by the Superior Court of Maricopa County. Plaintiff is incarcerated at ASPC-Eyman, Browning Unit, in Florence, Arizona.

14. Defendant Charles L. Ryan is the director of ADC and is being sued in his official capacity for equitable, injunctive, and declaratory relief.

15. Defendant Ron Credio is the Warden of ASPC-Eyman, where Plaintiffs are incarcerated, and is being sued in his official capacity for equitable, injunctive, and declaratory relief.

16. Defendant Lance Hetmer is the Warden of ASPC-Florence, where Plaintiffs will be executed, and is being sued in his official capacity for equitable, injunctive, and declaratory relief.

17. Defendants John Does, Unknown ADC Personnel, are staff or agents of ADC or the State of Arizona who are ADC's officers, successors in office, agents, contractors, and employees, along with those acting in concert with them, who have participated or will participate in Plaintiffs' executions in capacities involving, *inter alia*, setting IV lines, handling drugs that are classified as controlled substances, and developing and implementing ADC's execution procedures—including the protocols governing the preparation and administration of drugs designed to execute people. Plaintiffs are not aware of the true identities of the John Does, but allege that when Plaintiffs discover their identities, Plaintiffs will amend this Complaint accordingly.

Exhaustion of Administrative Remedies

18. Plaintiffs do not believe that exhaustion is necessary under the Prison Litigation Reform Act ("PLRA"), 42 U.S.C. § 1997e, because this suit does not challenge prison conditions, and because there are no available administrative remedies that could address the challenged constitutional violations. Despite the inapplicability of the PLRA, Plaintiffs have exhausted all the remedies available to them in an effort to resolve these issues.

19. On April 22, 2014, the day the State moved for a warrant of execution for Plaintiff Wood, Jeffrey A. Zick, Chief Counsel of the Capital Litigation Section of the Office of the Arizona Attorney General, sent a letter to counsel for Mr. Wood, indicating that ADC intends to use a two-drug protocol with midazolam and hydromorphone to execute Mr. Wood.

20. In that same letter, Mr. Zick stated that if "ADC is able to procure pentobarbital, ADC will provide notice of its intent to use that drug . . . "

21. On April 30, 2014, counsel for Mr. Wood sent Defendant Ryan a letter requesting information about the provenance of the midazolam and hydromorphone, and asked for an explanation of ADC's continuing search for pentobarbital.

22. In his April letter, Mr. Wood's counsel asked for information about the DEA qualifications of the personnel who are expected to participate in Mr. Wood's execution.

23. In his April letter, counsel for Mr. Wood asked Defendant Ryan to explain how ADC decided to use the amounts of midazolam and hydromorphone that ADC selected.

24. In his April letter, counsel for Mr. Wood asked Defendant Ryan to explain why the amounts of midazolam and hydromorphone differ from the amounts required in the State of Ohio's lethal-injection protocol, which apparently served as ADC's model.

25. On May 6, 2014, Defendant Ryan replied to the April letter, and declined to provide information about the drugs, based on ADC's interpretation of Arizona's executioner-confidentiality statute; instead, he avowed that the drugs are "domestically obtained" and "FDA approved."

26. In that same letter, Defendant Ryan noted that ADC continued to look for pentobarbital, and said that ADC would inform counsel for Mr. Wood if ADC succeeded.

27. Defendant Ryan also declined to provide specific information about the DEA qualifications of the personnel expected to participate in Mr. Wood's execution; Defendant Ryan instead stated that the protocol addresses qualifications.

28. Defendant Ryan stated that the development of ADC's two-drug protocol was based on testimony and affidavits in federal district court in an Ohio lethal-injection matter, though he failed to explain why the amounts of the drugs differed.

29. On May 9, counsel for Mr. Wood sent a follow-up letter requesting clarification and more detail, as well as specific Ohio documents referenced in Defendant Ryan's letter.

30. In that same letter, counsel for Mr. Wood asked for qualifications of the medical professional who was expected to participate in Mr. Wood's execution, as well as for evidence demonstrating that ADC verified those qualifications.

31. On May 15, counsel for Mr. Wood sent a second follow-up letter, again asking for DEA and medical qualifications, and for information pertaining to the development of ADC's two-drug protocol.

32. In this second follow-up letter, counsel for Mr. Wood also asked for documents pertaining to correspondence with various state departments of corrections, and with various federal agencies.

33. On May 15, counsel for Mr. Wood also sent Defendant Ryan a "litigation hold" letter.

34. Defendant Ryan sent counsel for Mr. Wood a response on June 6, 2014, and included redacted copies of purchase orders, invoices, and order confirmations for midazolam and hydromorphone, as well as copies of six emails from Director Robert Patton, Director of the Oklahoma Department of Corrections to ADC officials.

35. Information about the manufacturers and suppliers of the midazolam and hydromorphone has been redacted from copies of the purchase orders, invoices, and order confirmations.

36. Defendant Ryan avowed that the Inspector General verified the qualifications of the medical professionals on the IV team.

37. Defendant Ryan declined to provide copies of the Ohio documents; instead, he asserted that "the Federal Public Defender's Office" was involved in the matter, and therefore, Arizona's (separate and distinct) office must have access to those same documents.

38. Defendant Ryan failed to identify the specific documents upon which he relied.

39. To date, Defendant Ryan has refused to provide evidence that the midazolam and hydromorphone are FDA-approved drugs.

40. To date, Defendant Ryan has refused to provide evidence that ADC will only obtain lawful, FDA-approved pentobarbital.

41. To date, Defendant Ryan has refused to provide evidence that ADC execution personnel are authorized by the DEA to handle controlled substances.

42. To date, Defendant Ryan has refused to provide evidence that the medical personnel are qualified.

43. To date, Defendant Ryan has refused to provide evidence elucidating ADC's method of determining why Arizona chose the amounts of midazolam and hydromorphone to use in its lethal-injection protocol.

Relevant Facts

44. Plaintiffs incorporate by reference each and every statement and allegation set forth throughout this Complaint as if fully rewritten here.

Arizona's Execution Statute and Lethal-Injection Protocol

45. Arizona Revised Statutes section 13-757 establishes Arizona's method of execution.

46. Section 13-757(A) establishes that the "penalty of death shall be inflicted by an intravenous injection of a substance or substances in a lethal quantity sufficient to cause death, under the supervision of the state department of corrections."

47. Section 13-757(C), the executioner-confidentiality statute, protects from public-records requests the identity of "executioners and other persons who participate or perform ancillary functions and any information that would identify those persons…."

48. The Arizona Legislature has given complete authority to the Director to develop the lethal-injection protocol, which includes the procedures for carrying out an execution, as well as the specific drug protocols, without oversight.

49. The Arizona Legislature does not require that ADC's lethal-injection protocol to be reviewed by any authority.

50. Beginning in 2009, ADC changed its written lethal-injection protocol at least eight times. The 2009 version of the written lethal-injection protocol was replaced

on May 12, 2011. The protocol was changed twice more in 2011: on June 10, 2011, and September 12, 2011. ADC then changed the protocol three times in 2012: January 25, 2012; June 5, 2012; and September 21, 2012. The current protocol became effective on March 26, 2014.

51. ADC deviated from its written drug protocol at least once during that time.

52. In September 2009, the protocol called for a three-drug protocol using sodium thiopental, pancuronium bromide, and potassium chloride.

53. In May 2011, ADC made changes to the protocol unrelated to the administration of drugs.

54. On May 24, 2011, the DEA informed ADC that ADC had obtained its sodium thiopental in violation of the CSA.

55. The next day, May 25, 2011, in response to the DEA's notification, ADC executed Donald Beaty using a drug that was not in the protocol.

56. Donald Beaty was executed with pentobarbital instead of the thiopental that was required under the three-drug protocol.

57. Donald Beaty was executed with pentobarbital solely because ADC was unable to use its supply of thiopental.

58. On June 10, 2011, ADC changed the protocol, to allow the use of either sodium thiopental or pentobarbital in the three-drug protocol. Whichever drug was to be administered was to be administered via four separate syringes, each containing 1.25g of the drug.

59. On September 12, 2011, ADC changed the part of the protocol that described the administration method for the pentobarbital, changing administration from four syringes of 1.25g to two syringes of 2.5g of the drug.

60. On January 25, 2012, the protocol was changed to allow a three-drug protocol with either thiopental or pentobarbital, as well as a one-drug protocol with either sodium thiopental or pentobarbital.

61. The January 25, 2012 protocol added a provision that explicitly gave ADC's director the sole discretion as to which drug protocol ADC would use in each execution.

62. On June 5, 2012, ADC made changes to the protocol unrelated to the administration of the drugs.

63. On September 21, 2012, the protocol was changed to remove the three-drug protocol, leaving a one-drug protocol with either sodium thiopental or pentobarbital.

64. The September 21, 2012 protocol added an explicit statement giving the Director the ability to use drugs other than the protocol-specified drugs.

65. The September 21, 2012 protocol also *removed* the requirement that the condemned prisoner be constantly monitored while lethal drugs were administered to him.

66. The current protocol, which became effective March 26, 2014, added a two-drug protocol with midazolam and hydromorphone.

67. All the written protocols contain a provision that requires the written protocol to be followed—unless the Director determines that deviation or adjustment is required.

68. The Director is not constrained or guided in any decision to deviate or adjust the lethal-injection protocol.

69. According to Defendant Ryan, ADC's current two-drug protocol was developed after ADC personnel reviewed and modified the amounts of drugs required in the State of Ohio's lethal-injection protocol.

70. ADC's current protocol provides that ADC can carry out lethal-injection executions with a single-drug protocol using sodium pentothal ("sodium thiopental"); in with a single-drug protocol using pentobarbital; or with a two-drug protocol using midazolam and hydromorphone.

71. On information and belief, ADC has not submitted any version of its lethal-injection protocol to the Food and Drug Administration ("FDA") for review under the federal Food, Drug, and Cosmetics Act ("FDCA"), and related regulations.

Federal Drug Laws

72. Drugs are regulated by, *inter alia*, the FDCA.

73. The FDCA is enforced by the FDA.

74. The FDA requires registered drug establishments to provide the agency with current lists of all drugs the establishments produce for commercial distribution.

75. Each drug produced by registered drug establishments is identified by a unique number called the National Drug Code ("NDC").

76. Each FDA-approved drug has an expiration date.

77. Each FDA-approved drug has a lot number.

78. If a drug is classified as a controlled substance under the federal Controlled Substances Act ("CSA"), the drug is also regulated by the federal Drug Enforcement Agency ("DEA").

79. If a drug is a controlled substance, individuals who wish to handle it must have appropriate registration from the DEA.

80. Sodium thiopental is a controlled substance.

81. Pentobarbital is a controlled substance.

82. Midazolam is a controlled substance.

83. Hydromorphone is a controlled substance.

Sodium Thiopental & ADC's Use of the Drug

84. Beginning in 2010, ADC developed a history of using illegitimately obtained controlled-substance drugs in executions.

85. In 2010, ADC's protocol called for lethal injections to be carried out via a three-drug procedure, the first drug of which was sodium thiopental.

86. Sodium thiopental is a Schedule III drug under the CSA.

87. In September 2010, the State of Arizona scheduled the execution of Jeffrey Landrigan.

88. In 2010, ADC was unable to obtain a domestic source of sodium thiopental, owing to a nationwide shortage of that drug.

89. On October 20, 2010, the State admitted during a hearing before the Arizona Supreme Court that ADC had obtained sodium thiopental that was not manufactured by a domestic source.

90. In 2010 and 2011, various prisoners on Arizona's death row informed ADC and the courts that ADC had likely violated the CSA and the FDCA when it acquired non-domestic sodium thiopental.

91. In 2010 and 2011, Defendant Ryan repeatedly avowed in state and federal courts that ADC had complied with applicable laws when it obtained the non-domestic sodium thiopental.

92. In May 2011, the DEA informed the State that ADC had violated the CSA when ADC imported sodium thiopental.

93. ADC used illegitimately obtained sodium thiopental in the execution of Jeffrey Landrigan on October 26, 2010.

94. ADC used illegitimately obtained sodium thiopental in the execution of Eric King on March 29, 2011.

95. In October 2011, ADC's then-Deputy Director provided documents during his deposition in a civil-rights lawsuit that indicated that he ignored counterfeiting and efficacy concerns about imported sodium thiopental.

96. In March 2012, in a case filed against the FDA that challenged the legality of the importation of sodium thiopental for purposes of lethal injection, the United States District Court for the District of Columbia found that the importation of that drug was a violation of the FDCA.

97. In July 2013, the United States Court of Appeals for the D.C. Circuit affirmed the decision of the D.C. district court.

98. Sodium thiopental is not legally available to departments of corrections in the United States.

Pentobarbital

99. FDA-approved pentobarbital is sold under the brand name Nembutal®.

100. Nembutal® has an NDC.

101. Pentobarbital is a Schedule II drug under the CSA.

102. ADC has previously provided Nembutal® procurement records to counsel with the Office of the Federal Public Defender for the District of Arizona ("FPD").

103. In August 2011, during litigation unrelated to the current matter, ADC provided the FPD with photographs and other documentation about its supply of Nembutal.®

104. According to ADC's August 2011 procurement records, ADC ordered 75 grams of Nembutal® on September 27, 2010.

105. According to ADC's August 2011 procurement records, the September 2010 purchase was the only supply of Nembutal® ADC possessed at the time it produced those records.

106. According to ADC's August 2011 procurement records, ADC's supply of Nembutal® purchased in 2010 expired in March 2013.

107. In October 2013, in response to an order of this Court, ADC turned over information about its supply of Nembutal® to two death-row prisoners ("2013 Release").

108. In the 2013 Release, ADC revealed the manufacturer, NDC, lot number, and expiration date of its supply of Nembutal.®

109. ADC did not appeal this Court's order that directed ADC to provide the 2013 Release.

Legal Suppliers of Nembutal®

110. From 2010 (when ADC purchased its supply of Nembutal®) through approximately January 2012, Lundbeck was the only FDA-approved source of pentobarbital, which was marketed as Nembutal®.

111. In July 2011, Lundbeck instituted distribution controls on Nembutal®.

112. Lundbeck's distribution controls established a limited set of distributors authorized to sell Nembutal®.

113. Lundbeck instituted its distribution controls to prevent the legitimate sale of Nembutal® to departments of corrections in states that use lethal injection for capital punishment.

114. In December 2011, Lundbeck announced the sale of its interest in Nembutal® to Akorn.

115. When Akorn purchased Lundbeck's interest in Nembutal®, Akorn kept Lundbeck's distribution controls in place.

116. Currently, Akorn is the only FDA-approved source of pentobarbital.

117. As of July 2011, ADC had no legitimate source from which to purchase Nembutal®.

118. ADC has applied to the DEA to obtain a license to import pentobarbital.

Midazolam and Hydromorphone

119. FDA-approved sources of midazolam and hydromorphone have NDCs.

120. Midazolam is a Schedule IV drug under the CSA.

121. Hydromorphone is a Schedule II drug under the CSA.

Submission of Clinical-Investigation Protocols to the FDA

122. The authority of the FDA aims at maintaining a high standard of human health protection. This objective has been made clear in the FDCA. The "[m]ission" of the FDA is described in 21 U.S.C. § 393(b) as to "promote the public health by promptly and efficiently reviewing clinical research" and "with respect to such [regulated] products, protect the public health by ensuring that … human … drugs are safe and effective." Accordingly the FDA is in charge of safeguarding the public health and the protection of the health of every drug user.

123. Congress has established only two legal routes to move a new drug into interstate commerce: The drug must either be the subject of an approved new drug

application (NDA),[1] or it must be the subject of an Investigational New Drug ("IND") application filed with FDA.[2]

124. Under FDA regulations, "'Interstate commerce' applies to all steps in a product's manufacture, packaging, and distribution."[3] Therefore, it is sufficient that "at least some of [the] ingredients or packaging […] originate from out of state, or even out of the country."[4]

125. The connection with interstate commerce required for FDCA jurisdiction shall be presumed to exist in actions to enforce the requirements of the FDCA's drug provisions.[5]

126. A "drug" is any substance "intended to affect the structure or any function of the body of man."[6]

127. An "investigational new drug" is defined as a "new drug or biological drug that is used in a clinical investigation."[7]

128. A drug is a "new" drug if its "composition . . . is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof."[8]

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[1] 21 U.S.C. § 355(a).

[2] 21 U.S.C. § 355(i).

[3] FDA, Key Legal Concepts: Interstate Commerce, Adulterated, and Misbranded, online at: http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074248.htm.

[4] FDA, Key Legal Concepts: Interstate Commerce, Adulterated, and Misbranded, online at: http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074248.htm.

[5] 21 U.S.C. § 379a.

[6] 21 U.S.C. § 321(g)(1).

[7] 21 C.F.R. § 312.3(a).

[8] 21 U.S.C. § 321(p)(1).

129. The term "new drug" is a statutory term of art, such that even a drug that has already been marketed can be deemed a "new drug" for purposes of the FDCA.[9]

130. A person intending to conduct a clinical investigation with an investigational new drug does not need an approved NDA, but instead must submit an Investigational New Drug ("IND") application to the FDA.[10]

131. A clinical investigation is "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects".[11]

132. For purposes of the FDCA, "an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice."[12]

133. Because a "drug" is any substance "intended to affect" the structure or any function in the human body, ADC's use of midazolam, hydromorphone, pentobarbital, thiopental, or other substances, constitutes the use of "drugs" in its lethal-injection protocol.

134. Because ADC is using drugs in combinations and doses that are not "recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed," ADC's use of these drugs constitutes the use of "new drugs."

135. Because an "experiment" is defined as "any use of a drug except for the use of a marketed drug in the course of medical practice[,]" ADC's lethal-injection procedures constitute an experiment on death-row prisoners, including Plaintiffs.

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[9] 21 U.S.C. § 321(p)(1) ("Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use *under the conditions prescribed*, recommended, or suggested in the labeling thereof . . . .") (emphasis added); *see also United States v. 50 Boxes More or Less*, 909 F.2d 24 (1st Cir. 1990) (holding that a drug that had been sold for thirty-five years was nevertheless deemed a "new drug" because it was not generally recognized among experts as safe and effective).

[10] 21 C.F.R. § 312.20(a).

[11] 21 C.F.R. § 312.3(b).

[12] 21 C.F.R. § 312.3(b).

136. Because a clinical investigation is defined as "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects[,]" ADC's lethal-injection protocol constitutes a clinical investigation.

137. ADC's use of lethal-injection drugs constitutes the use of an "investigational new drug" because it is a "new drug" used in a clinical investigation.

138. The FDCA and its related regulations do not provide for exceptions to the IND requirement for drugs used in executions.

139. Although Arizona's lethal-injection statute does not specify that ADC comply with the FDCA, ADC must nevertheless do so, under the Supremacy Clause of Article VI of the United States Constitution.

140. Because ADC's lethal-injection protocol constitutes a clinical investigation with an investigational new drug, ADC must submit its protocol(s) to the FDA for review in an IND application.

Claims for Relief

Claim One: By deliberately concealing necessary information from Plaintiffs, Defendants have violated Plaintiffs' First Amendment right to petition the government for redress of grievances.

141. Plaintiffs incorporate by reference each and every statement and allegation set forth throughout this Complaint as if fully rewritten here.

142. Defendants' refusal to provide Plaintiffs with information that would enable them to determine how the State intends to execute them denies Plaintiffs' First Amendment right to petition the government for redress of grievances.

143. The First Amendment right to petition the government for redress of grievances includes the right of access to the courts.

144. The right of access to the courts is especially critical for prisoners, because their access to other remedies is limited.

145. State action that denies a plaintiff the opportunity to litigate gives rise to a claim that the State is violating the plaintiff's right of access to the courts.

146. The right of access to the courts is an ancillary claim, which is necessary for the vindication of underlying rights.

147. By deliberately concealing information about the specific drugs the State intends to use to execute Plaintiffs, Defendants have erected a condition that frustrates Plaintiffs' ability to litigate their claims relating to the constitutionality of their executions. This frustrating condition deprives Plaintiffs of their First Amendment right to petition the government for redress of grievances. This frustrating condition also deprives Plaintiffs of their due-process right of access to the courts.

148. Defendants' deliberate concealment of information that would enable Plaintiffs to determine how the State intends to carry out their death sentences, including information relating to lethal-injection drugs, the authority of Defendants to handle controlled substances, and the qualifications of the execution personnel, deprives Plaintiffs of their right not to be deprived of their lives without due process of law.

149. Defendants' deliberate concealment of information that would enable Plaintiffs to determine how the State intends to carry out their death sentences, including information relating to lethal-injection drugs, the authority of Defendants to handle controlled substances, and the qualifications of the execution personnel, deprives Plaintiffs of their ability to determine whether the State is capable of carrying out their executions in a lawful, constitutional manner.

Claim Two: By deliberately concealing necessary information from Plaintiffs, Defendants have violated Plaintiffs' First Amendment right to be informed about the manner in which the State implements the most serious penalty available in the criminal-justice system.

150. Plaintiffs incorporate by reference each and every statement and allegation set forth throughout this Complaint as if fully rewritten here.

151. Defendants' deliberate concealment of information that would enable Plaintiffs to determine how the State intends to carry out their death sentences, including information relating to lethal-injection drugs and the authority of Defendants to handle

controlled substances, deprives Plaintiffs of their First Amendment right of access to governmental proceedings.

152. Defendants' deliberate concealment of information that would enable Plaintiffs to determine how the State intends to carry out their death sentences, including information relating to lethal-injection drugs and the authority of Defendants to handle controlled substances, deprives Plaintiffs of their First Amendment right to be informed about how the State intends to implement the most serious punishment possible: the penalty of death.

Claim Three: Defendants' use of a lethal-injection protocol that they developed without complying with the federal Food, Drug, and Cosmetics Act, violates the Supremacy Clause of Article VI of the Constitution, and deprives Plaintiffs of their right to be executed in a manner that comports with the Supremacy Clause of the Constitution.

153. Plaintiffs incorporate by reference each and every statement and allegation set forth throughout this Complaint as if fully rewritten here.

154. Defendants' lethal-injection protocol qualifies as a "clinical investigation" under the FDCA and related regulations.

155. Protocols for clinical investigations must be submitted to the FDA for review, absent an exception that would exempt the protocol.

156. The FDCA does not contain an exception for drugs used in executions.

157. Defendants' failure to submit their lethal-injection protocol to the FDA for review violates the FDCA.

158. Defendants' failure to comply with the FDCA violates the Supremacy Clause of the United States Constitution.

159. Defendants' plan to execute Plaintiffs under a lethal-injection protocol that violates the Supremacy Clause violates Plaintiffs' right to be executed in a manner that comports with federal law and the United States Constitution.

Prayer for Relief

Wherefore, Plaintiffs pray for:

1. Temporary, preliminary, and permanent injunctive relief to enjoin the Defendants, their officers, agents, servants, employees, and all persons acting in concert with them from concealing information that is not related to the identification of persons participating in executions, that is necessary to ensuring Plaintiffs' First Amendment right to petition the government for redress of grievances, including but not limited to:
    i. The FDA-approved manufacturer(s) and other suppliers of the lethal-injection drugs that ADC will or may use in Plaintiffs' executions;
    ii. The lot numbers of the lethal-injection drugs that ADC will or may use in Plaintiffs' executions;
    iii. The NDCs of the lethal-injection drugs that ADC will or may use in Plaintiffs' executions;
    iv. The expiration dates of the lethal-injection drugs that ADC will or may use in Plaintiffs' executions;
    v. Documentation (not including personally identifying information) indicating that those who will handle controlled substances in the executions have the appropriate DEA authorization to do so;
    vi. Documentation (not including personally identifying information) indicating that those who will be responsible for inserting any IVs are qualified to do so.
2. Temporary, preliminary, and permanent injunctive relief to enjoin the Defendants, their officers, agents, servants, employees, and all persons acting in concert with them from concealing execution-related, non-personally-identifying information that Plaintiffs require in order to ensure their First Amendment right of access to governmental proceedings, including but not limited to:

i. The FDA-approved manufacturer(s) and other suppliers of the lethal-injection drugs that ADC will or may use in Plaintiffs' executions;

ii. The lot numbers of the lethal-injection drugs that ADC will or may use in Plaintiffs' executions;

iii. The NDCs of the lethal-injection drugs that ADC will or may use in Plaintiffs' executions;

iv. The expiration dates of the lethal-injection drugs that ADC will or may use in Plaintiffs' executions;

v. Documentation (not including personally identifying information) indicating that those who will handle controlled substances in the executions have the appropriate DEA authorization to do so;

vi. Documentation (not including personally identifying information) indicating that those who will be responsible for inserting any IVs are qualified to do so.

3. Temporary, preliminary, and permanent injunctive relief to enjoin the Defendants, their officers, agents, servants, employees, and all persons acting in concert with them from executing Plaintiffs unless and until Defendants comply with the FDCA (and therefore with the Supremacy Clause of the Constitution).

4. Appropriate and necessary discovery and an evidentiary hearing to permit Plaintiffs to prove their constitutional claims; and

5. Any such other relief as the Court deems just and proper.

Respectfully submitted this 26th day of June, 2014.

Jon M. Sands
Federal Public Defender
District of Arizona
Dale A. Baich
Robin C. Konrad

s/ Dale A. Baich
Counsel for Plaintiffs