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10 **IN THE UNITED STATES DISTRICT COURT**
 11 **FOR THE DISTRICT OF ARIZONA**

12 Joseph Rudolph Wood III, Graham S.
 13 Henry, David Gulbrandson, Todd
 14 Smith, Charles M. Hedlund, Eldon
 Schurz,
 15 Plaintiffs,

16 v.

17 Charles L. Ryan, Director of the
 18 Arizona Department of Corrections;
 19 Ron Credio, Warden, ASPC – Eyman;
 Lance Hetmer, Warden, ASPC –
 20 Florence; and John Does, Unknown
 21 ADC Personnel, in their official
 22 capacities as Employees, Contractors,
 and/or Agents of the Arizona
 23 Department of Corrections,
 Defendants.

Case No. _____

COMPLAINT FOR EQUITABLE,
 INJUNCTIVE, AND DECLARATORY
 RELIEF [42 U.S.C § 1983]

24 **Nature of Action**

25 1. This action is brought pursuant to 42 U.S.C. § 1983 for violations and
 26 threatened violations by the Arizona Department of Corrections (“ADC”) of Plaintiffs’
 27 First Amendment right to petition the government for redress of grievances; their First
 28

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

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

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

10 **Jurisdiction and Venue**

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

16 5. Venue is proper pursuant to 28 U.S.C. § 1391(b). Plaintiffs are currently
17 incarcerated at the Arizona State Prison Complex ("ASPC")–Eyman, Browning Unit,
18 4374 East Butte Avenue, Florence, Arizona, located in this District.

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

22 **The Parties**

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

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

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

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

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

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

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

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

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

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

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

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

13 **Exhaustion of Administrative Remedies**

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

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

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

27
28

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 **Relevant Facts**

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

13 **Arizona's Execution Statute and Lethal-Injection Protocol**

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

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

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

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

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

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

1 on May 12, 2011. The protocol was changed twice more in 2011: on June 10, 2011, and
2 September 12, 2011. ADC then changed the protocol three times in 2012: January 25,
3 2012; June 5, 2012; and September 21, 2012. The current protocol became effective on
4 March 26, 2014.

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

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

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

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

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

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

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

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

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

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

28

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

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

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

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

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

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

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

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

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

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

28

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

4 **Federal Drug Laws**

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

6 73. The FDCA is enforced by the FDA.

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

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

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

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

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

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

18 80. Sodium thiopental is a controlled substance.

19 81. Pentobarbital is a controlled substance.

20 82. Midazolam is a controlled substance.

21 83. Hydromorphone is a controlled substance.

22 **Sodium Thiopental & ADC’s Use of the Drug**

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

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

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

28

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

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

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

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

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

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

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

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

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

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

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

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

3 **Pentobarbital**

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

5 100. Nembutal[®] has an NDC.

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

7 102. ADC has previously provided Nembutal[®] procurement records to counsel
8 with the Office of the Federal Public Defender for the District of Arizona (“FPD”).

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

12 104. According to ADC’s August 2011 procurement records, ADC ordered 75
13 grams of Nembutal[®] on September 27, 2010.

14 105. According to ADC’s August 2011 procurement records, the September
15 2010 purchase was the only supply of Nembutal[®] ADC possessed at the time it produced
16 those records.

17 106. According to ADC’s August 2011 procurement records, ADC’s supply of
18 Nembutal[®] purchased in 2010 expired in March 2013.

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

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

23 109. ADC did not appeal this Court’s order that directed ADC to provide the
24 2013 Release.

25 **Legal Suppliers of Nembutal[®]**

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

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

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

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

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

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

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

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

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

15 **Midazolam and Hydromorphone**

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

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

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

19 **Submission of Clinical-Investigation Protocols to the FDA**

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

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

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

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

7 125. The connection with interstate commerce required for FDCA jurisdiction
8 shall be presumed to exist in actions to enforce the requirements of the FDCA’s drug
9 provisions.⁵

10 126. A “drug” is any substance “intended to affect the structure or any function
11 of the body of man.”⁶

12 127. An “investigational new drug” is defined as a “new drug or biological drug
13 that is used in a clinical investigation.”⁷

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

18
19 ¹ 21 U.S.C. § 355(a).

20 ² 21 U.S.C. § 355(i).

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

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

25 ⁵ 21 U.S.C. § 379a.

26 ⁶ 21 U.S.C. § 321(g)(1).

27 ⁷ 21 C.F.R. § 312.3(a).

28 ⁸ 21 U.S.C. § 321(p)(1).

1 129. The term “new drug” is a statutory term of art, such that even a drug that
2 has already been marketed can be deemed a “new drug” for purposes of the FDCA.⁹

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

6 131. A clinical investigation is “any experiment in which a drug is administered
7 or dispensed to, or used involving, one or more human subjects”.¹¹

8 132. For purposes of the FDCA, “an experiment is any use of a drug except for
9 the use of a marketed drug in the course of medical practice.”¹²

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

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

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

21
22 ⁹ 21 U.S.C. § 321(p)(1) (“Any drug . . . the composition of which is such that
23 such drug is not generally recognized, among experts qualified by scientific training and
24 experience to evaluate the safety and effectiveness of drugs, as safe and effective for use
25 *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).

26 ¹⁰ 21 C.F.R. § 312.20(a).

27 ¹¹ 21 C.F.R. § 312.3(b).

28 ¹² 21 C.F.R. § 312.3(b).

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

4 137. ADC’s use of lethal-injection drugs constitutes the use of an
5 “investigational new drug” because it is a “new drug” used in a clinical investigation.

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

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

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

14 **Claims for Relief**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 159. Defendants' plan to execute Plaintiffs under a lethal-injection protocol that
26 violates the Supremacy Clause violates Plaintiffs' right to be executed in a manner that
27 comports with federal law and the United States Constitution.
28

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:

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- 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.

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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