******EXECUTION SCHEDULED FOR JANUARY 15, 2020******

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN THE MATTER OF THE FEDERAL BUREAU OF PRISONS' EXECUTION PROTOCOL CASES,	)	
Lead case: ***Roane et al. v. Barr et al.***	)	**Case No. 19-mc-00145-TSC**
THIS DOCUMENT RELATES TO:	)	
Lee v. Barr et al.**, No. 19-cv-2559**	)	

COMPLAINT OF PLAINTIFF-INTERVENOR DUSTIN LEE HONKEN

I.
Nature of Action

1. This is a civil action for declaratory and injunctive relief brought by Plaintiff Dustin Lee Honken for (i) violations and threatened violations of his rights pursuant to the Administrative Procedure Act, 5 U.S.C. § 551 et seq. ("APA"); (ii) violations and threatened violations of his right to due process under the Fifth Amendment to the United States Constitution; (iii) violations and threatened violations of his right to be free from cruel and unusual punishment under the Eighth Amendment to the Constitution; and (iv) violations and threatened violations of his right to access to counsel under the First, Fifth and Sixth Amendments of the Constitution.

2. Plaintiff has been sentenced to death under federal law. Defendants are the

individuals charged by the federal government with carrying out the death sentences of Plaintiff and similarly situated federal prisoners. On July 25, 2019, the United States Department of Justice ("DOJ") announced that Plaintiff's execution will be implemented through the Federal Bureau of Prisons' ("BOP") new lethal injection method, which replaces a three-drug combination with the injection of a single drug: pentobarbital.[1] As alleged in more detail below, the 2019 Protocol violates Plaintiff's constitutional rights and the APA. Plaintiff therefore seeks a preliminary and permanent injunction preventing Defendants from executing him pursuant to their announced procedures, an order declaring that Defendants' lethal injection method and protocol (as well as the procedures through which it was developed) violate the APA and the Constitution, and such other equitable relief as the Court deems just and proper.

3. The 2019 Protocol violates the APA because the DOJ and BOP failed to follow the Act's rule-making requirements, instead secretly adopting and unilaterally announcing the new protocol on the same morning that the Attorney General announced Plaintiff's execution date and four others.

4. The 2019 Protocol is the result of *ultra vires* agency action in violation of the APA and the Constitution. Although Plaintiff was sentenced to death for a violation of the

[1] For the sake of clarity and consistency, the new lethal injection method will be described as the "2019 Protocol," even though Defendants label it as an "addendum" to their previous protocol. *See Roane* ECF 385-1 (Case No. 1:05-cv-02337-TSC).

Anti-Drug Abuse Act of 1988 ("ADAA"), his sentence is governed by the Federal Death Penalty Act ("FDPA") because, *inter alia*, Congress repealed the death penalty portions of the ADAA in 2006. *See United States v. Barrett*, 496 F.3d 1079, 1106 (10th Cir. 2007); "Defendant's Opposition to Plaintiff Daniel Lewis Lee's Motion for a Preliminary Injunction" (ECF Doc. 16), at 5-6 n.1. The FDPA, however, does not authorize the DOJ or BOP to create an execution protocol, set execution dates, or perform the executions of prisoners to whom the Act applies. The DOJ and BOP, therefore, lack the authority to conduct Plaintiff's execution pursuant to the 2019 Protocol unless and until Congress gives the agencies such authority. Moreover, the DOJ's and BOP's attempt to ignore or rewrite the FDPA through the 2019 Protocol is a violation of the Take Care Clause of the Constitution and its underlying principles of separation of powers.

5. The 2019 Protocol additionally violates the APA because, even if the 2019 Protocol were not *ultra vires* as unauthorized by the FDPA, its provisions violate the statute. When, as here, a federal prisoner is sentenced to death in a state that does not have the death penalty, a sentencing court "shall designate another State, the law of which does provide for the implementation of a sentence of death, and the sentence shall be implemented in the latter State in the manner prescribed by such." 18 U.S.C. § 3596(a). The district court at sentencing ordered that Plaintiff be executed within the state of Indiana in the manner prescribed by the state. Nevertheless, the 2019

Protocol differs from Indiana's execution method in several material respects.

6. The 2019 Protocol additionally violates the APA because it contravenes the Controlled Substances Act and the Food, Drug, and Cosmetic Act, which forbid the dispensing of prescription-only drugs – including the Schedule II controlled substance pentobarbital – without the issuance of a valid prescription issued for a legitimate medical purpose, as well as the unprescribed compounding of a drug that is essentially a copy of a commercially available drug that is approved by the Food and Drug Administration ("FDA"). These violations require that the 2019 Protocol be vacated under the APA because it is "not in accordance with law," is "in excess of statutory jurisdiction, authority or limitations," is "short of statutory right" and is "arbitrary, capricious, [and] an abuse of discretion." 5 U.S.C.A. § 706(2).

7. The 2019 Protocol constitutes an "arbitrary and capricious" agency action under the APA because it lacks an adequately reasoned justification for its issuance, and because Defendants have ignored and otherwise violated their duties to comply with federal drug-related statutes aimed at making a regulated drug such as pentobarbital safe and effective for the pain-minimizing purpose that Defendants claim as their motivation for selecting that drug for executions.

8. The Due Process Clause of the Fifth Amendment requires notice and the opportunity to be heard before the deprivation of life, liberty, or property. Defendants, however, refuse to disclose procedures they will use in carrying out

Plaintiff's execution, thereby preventing Plaintiff from specifying all of the aspects in which those procedures constitute cruel and unusual punishment or otherwise violate the laws and Constitution of the United States, and from effectively consulting medical experts concerning those violations or how to remedy them – or even to identify all of the ways in which the Defendants' protocol threatens the infliction of readily avoidable pain and suffering. In addition, Plaintiff was not provided any notice or opportunity to be heard prior to the DOJ's announcement of the 2019 Protocol. Plaintiff therefore did not have the opportunity to raise questions, concerns, or issues about the 2019 Protocol or otherwise participate, through counsel, in the development of the new protocol as part of the rule-making process (which was not followed here).

9. Defendants' unilateral, unsupervised, and standardless determination of which prisoners to schedule for execution reflects an arbitrary administration of the death penalty that violates the Fifth and Eighth Amendments.

10. The 2019 Protocol presents a "substantial risk of serious harm" and therefore violates the Eighth Amendment. *Baze v. Rees*, 553 U.S. 35, 50 (2008); *see also Gregg v. Georgia*, 428 U.S. 153, 173 (1976) (plurality opinion) (holding that the Eighth Amendment prohibits the "unnecessary and wanton infliction of pain"). Plaintiff has alleged below several alternatives to the 2019 Protocol, all of which are feasible, available, and significantly reduce the substantial risk of harm presented by the 2019

Protocol.

11. The Eighth Amendment and principles of substantive due process also forbid "deliberate indifference" to a prisoner's medical needs, which includes mistreatment that is likely to seriously aggravate the prisoner's conditions, as well as the failure to undertake medically appropriate measures to reduce the risk of pain to which Defendants are subjecting Plaintiff.

12. The 2019 Protocol also violates Plaintiff's right, under the First, Fifth and Sixth Amendments, to access to counsel during the execution because there is no provision for such access in the 2019 Protocol (or the earlier protocol), and also no opportunity for counsel to comment on the protocol through the APA or otherwise.

13. The claims in this complaint are cognizable under the constitutional and statutory grounds identified above and described in more detail below. This action is not, and should not be treated as, a successive habeas corpus petition. Plaintiff does not challenge the validity of his conviction or death sentence through this action. Rather, he claims that the 2019 Protocol by which his scheduled execution is to be implemented violates the APA, other applicable laws, and the Constitution.

II.
Parties

14. Plaintiff Dustin Lee Honken is a United States citizen and a death-sentenced prisoner in the custody of Defendants and under the control and supervision of the BOP, which is a department of the DOJ. He is incarcerated at the United States

Penitentiary in Terre Haute, Indiana ("USP Terre Haute"). Unless his capital conviction and/or death sentence are overturned in another judicial proceeding, or unless this Court grants the injunctive relief sought in this action, Plaintiff will face execution at USP Terre Haute on January 15, 2020.

15. Defendant William P. Barr is the Attorney General of the United States. Plaintiff was remanded into the Attorney General's custody upon his conviction and the imposition of his death sentence. To the extent authorized by Congress, the Attorney General prescribes the means for implementing federal judicial death sentences. He is the final executive authority responsible for carrying out sentences of death against federal prisoners. He is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

16. Defendant Uttam Dhillon is the Acting Administrator of the U.S. Drug Enforcement Agency ("DEA"). In his role as Acting Administrator, Defendant Dhillon is responsible for overseeing all controlled substances, which includes pentobarbital (a Schedule II controlled substance). Defendant Dhillon is sued in his official capacity for the purpose of obtaining declaratory and injunctive relief.

17. Defendant Kathleen Hawk Sawyer is the Director of the BOP. As Director of the BOP, Defendant Hawk Sawyer is charged with prescribing and directing the promulgation of rules and regulations for the BOP, including the rules and regulations for the conduct of prison operations and executions. Defendant Hawk

Sawyer is sued here in her official capacity for the purpose of obtaining declaratory and injunctive relief.

18. Defendant Jeffrey E. Krueger is the Regional Director of the North Central Region of the BOP. As Regional Director, Defendant Krueger has responsibility for USP Terre Haute, and plays a critical role in the promulgation of rules and regulations for the BOP, including the rules and regulations for the conduct of prison operations and execution procedures. He is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

19. Defendant Joseph McClain is the United States Marshal for the Southern District of Indiana. In his position as United States Marshal, Defendant McClain directs the personnel who administer the lethal substance(s) during executions. He is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

20. Defendant Nicole C. English is the Assistant Director, Health Services Division, of the BOP. Pursuant to Fed. R. Civ. P. 25(d), she is to be automatically substituted for Defendant Rear Admiral Chris A. Bina as sued in the complaint filed by Plaintiff Daniel Lee on August 23, 2019. In her position, Defendant English is responsible for overseeing the provision of medical care to prisoners at all BOP facilities, and for promulgating and implementing BOP policy with respect to medical care provided by the BOP. Defendant English is sued here in her official capacity for the purpose of obtaining declaratory and injunctive relief.

21. Defendant T.J. Watson is the Complex Warden of USP Terre Haute. In his position as complex warden, Defendant Watson is charged with management of USP Terre Haute and the oversight and implementation of operations there, including the oversight and implementation of executions at the prison. Defendant Watson is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

22. Defendant William E. Wilson, M.D., is the Clinical Director at USP Terre Haute. In his position as Clinical Director, Defendant Wilson is responsible for overseeing the provision of medical care to prisoners at USP Terre Haute. Defendant Wilson is sued here in his official capacity for the purpose of obtaining declaratory and injunctive relief.

23. John Does I - X are employed by the BOP to consult with, prepare for, and/or carry out Plaintiff's execution. Plaintiff does not know, and Defendants have not revealed, their identities. They are sued here in their official capacities for the purpose of obtaining declaratory and injunctive relief.

24. Defendants are acting, and each of them at all times relevant hereto were acting, in their respective official capacities with respect to all acts described herein, and were in each instance acting under the color and authority of federal law. Upon information and belief, unless preliminarily and permanently enjoined, each of the Defendants intends to act in his or her official capacity and under the authority of

federal law in executing Plaintiff, in violation of Plaintiff's constitutional and statutory rights.

III.
Jurisdiction and Venue

25. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 because (i) it arises under the Constitution and the laws of the United States; (ii) it seeks to secure prospective, equitable relief directly under the First, Fifth, Sixth and Eighth Amendments of the Constitution; (iii) one purpose of this action is to secure declaratory relief under 28 U.S.C. § 2201(a); and (iv) one purpose of this action is to secure preliminary and permanent injunctive relief under 28 U.S.C. § 2202. Judicial review of the agency action at issue is also authorized by the APA, 5 U.S.C. §§ 702, 704, 705, and 706.

26. This Court has venue under 28 U.S.C. § 1391(b)(2) because the BOP headquarters is in this District and a substantial part of the events giving rise to the claims made by Plaintiff — including the formulation of the BOP lethal injection procedures that are at issue here — took place and continue to take place in this District.

IV.
Facts

A. Plaintiff's Conviction History and Post-Conviction Motions

27. In 2004, Plaintiff was convicted of five murders and related charges and was sentenced to death in the United States District Court for the Northern District of

Iowa. The District Court conducted formal sentencing on October 11, 2005, and directed:

> Pursuant to 18 U.S.C. § 3596, you are committed to the custody of the Bureau of Prisons until exhaustion of the procedures for appeal of the judgment of conviction and review of sentence. When the sentence is to be implemented, the Attorney General shall release the defendant to the custody of a United States Marshal, who shall supervise implementation of the sentence in the manner prescribed by the law of the State of Indiana.

United States v. Honken, N.D. Iowa Case No. 3:01-cr-3047, Judgment, Doc. No. 702-2 at 3. Plaintiff's convictions and sentence were affirmed on direct appeal. *United States v. Honken*, 541 F.3d 1146 (8th Cir. 2008), *cert. denied*, 558 U.S. 1091 (2009).

28. On December 13, 2010, Plaintiff filed a Motion for Relief Pursuant to 28 U.S.C. § 2255. *Honken v. United States*, N.D. Iowa Case No. 3:10-cv-3074, Doc. No. 1. On October 4, 2013, the District Court granted the motion as to five non-capital convictions but otherwise denied the motion, and denied a certificate of appealability. *Honken v. United States*, 42 F. Supp. 3d 937 (N.D. Iowa 2013). On October 8, 2013, the District Court issued an amended judgment vacating five non-capital convictions but otherwise reinstating the prior judgment and reiterating the requirement that, "a United States Marshal . . . shall supervise implementation of the sentence in the manner prescribed by the law of the State of Indiana." *Honken*, N.D. Iowa Case No. 3:01-cr-3047, Amended Judgment, Doc. No. 804.

29. On April 4, 2014, Plaintiff filed a Motion for Certificate of Appealability with the Eighth Circuit Court of Appeals. The Eighth Circuit denied the motion on May 2,

2014, and the United States Supreme Court denied certiorari. *Honken v. United States*, Case No. 14-1329, Doc. 4150218 (8th Cir. 2014), *cert. denied*, 136 S. Ct. 29 (2015).

B. Previous and Current Protocols

30. The BOP adopted an execution protocol in 2004, to which it added an addendum in 2008. The 2004 protocol and the 2008 addendum called for the use of three drugs: (1) sodium pentothal, (2) pancuronium bromide; and (3) potassium chloride. The 2004 protocol and 2008 addendum are attached to this complaint as Exhibits A and B, respectively.

31. On December 6, 2005, James Roane and other death-sentenced federal prisoners sued the Attorney General and other federal defendants, challenging the three-drug protocol on constitutional and statutory grounds. *See Roane et. al. v. Gonzales et al.*, No. 05-2337 (D.D.C.).

32. On May 24, 2011, while the *Roane* litigation remained pending, the BOP announced that it lacked the drugs necessary to implement the three-drug method, and it was considering revisions. *See Roane* ECF Doc. 286 (Joint motion). The BOP thereafter submitted status reports stating that its revision of the protocol was ongoing. *See*, *e.g.*, *Roane* ECF Docs. 289, 383. The Court effectively stayed the *Roane* litigation pending the BOP's review. *See Roane* Minute Order of July 29, 2011; *Roane* Minute Order of November 3, 2011.

33. The Court entered preliminary injunctions forbidding the scheduling or carrying out

of any executions of the *Roane* plaintiffs. *See Roane* ECF Docs. 5, 27, 67, 68. In the meantime, death-sentenced prisoner Jeffrey Paul moved to intervene into the case, but the Court denied his motion on July 1, 2010. *See Roane* ECF Docs. 259, 260. The Court of Appeals later reversed that ruling, after which this Court allowed Mr. Paul to intervene and enjoined his execution as it had those of the other plaintiffs. *See Roane v. Leonhart*, 741 F.3d 147, 152 (D.C. Cir. 2014); *Roane* ECF Docs. 333, 336.

34. On July 25, 2019, the DOJ issued a press release stating that Plaintiff is currently scheduled to be executed at the USP Terre Haute on January 15, 2020, and that four other federal prisoners are scheduled for execution in December 2019 and January 2020. *See* <<https://www.justice.gov/opa/pr/federal-government-resume-capital-punishment-after-nearly-twodecade-lapse>>.

35. On that same day, the DOJ also announced that, at the direction of Attorney General Barr, the BOP had adopted the 2019 Protocol amending the 2008 Protocol. *See id.* The DOJ and BOP refer to the 2019 Protocol as merely an "addendum," but, in fact, it seeks to effect significant changes to the 2008 Protocol. As described below, the 2019 Protocol replaces the three-drug procedure previously used under the 2008 Protocol with a single drug —pentobarbital. A copy of the 2019 Protocol accompanies this complaint as Exhibit C.

36. By letter dated July 25, 2019, and handed to him by the warden at USP Terre Haute, the BOP advised Plaintiff of his January 15, 2020, execution date. A copy of the July

25, 2019, letter accompanies this complaint as Exhibit D.

37. In the letter notifying Plaintiff of his execution date, the BOP stated that Plaintiff's execution will be carried out pursuant to 28 C.F.R. § 26.3(a)(1) and that the letter constitutes "official notification" of the execution date and method. The letter failed to provide any details about the protocol, other than that the execution will be by lethal injection. As explained above and below, 28 C.F.R. Part 26 does not apply to the implementation of Plaintiff's death sentence.

C. Exhaustion of Administrative Remedies

38. On July 25, 2019, Plaintiff and his counsel were informed that he is scheduled to be executed on January 15, 2020, and counsel learned that DOJ had adopted the 2019 Protocol. Counsel immediately began researching whether and how Plaintiff would challenge the 2019 protocol and/or his selection to be executed thereunder, and sought to schedule confidential client communications about the same.

39. On August 9, 2019, Plaintiff timely submitted a BP-8 form and continuation page at 4:50 p.m. The BP-8 form and continuation page sought informal resolution of the issues raised in this Complaint. True and correct copies of the filed BP-8 form and continuation page are annexed hereto as Exhibit E.

40. On the morning of August 13, 2019, Plaintiff timely submitted a BP-9 form and continuation page, initiating a formal grievance regarding the issues raised in this Complaint. (The BOP did not acknowledge the BP-9 as received until August 19,

2019, after its denial of the BP-8.) True and correct copies of the filed BP-9 form and continuation page are annexed hereto as Exhibit F.

41. On August 15, 2019, the BOP denied Plaintiff's informal BP-8 grievance. *See* Ex. E. On August 22, 2019, the BOP denied Plaintiff's formal BP-9 grievance. *See* Ex. F.

42. On August 29, 2019, Plaintiff timely submitted a BP-10 form and continuation page, appealing the denial of his BP-9. As with his BP-8 and BP-9, the continuation page Plaintiff submitted with the BP-10 was specifically authorized by and compliant with BOP rules for its administrative remedy program, which provide, with respect to the BP-9, BP-10, and BP-11 forms: "If more space is needed, the inmate may use up to one letter-size (8 1/2" by 11") continuation page." U.S. Dep't Justice, Fed. Bureau Prisons, Program Statement, "Administrative Remedy Program," at 6, 7, *available at* <<https://www.bop.gov/ policy/progstat/1330_018.pdf>>. Nonetheless, on September 9, 2019, BOP issued, but did not deliver, a notice rejecting Honken's BP-10 form as non-compliant for not confining his statement of the grounds for his appeal to "the part A section of the BP 10 form." The rejection notice further stated that Plaintiff could resubmit his appeal within 10 days of September 9, 2019. On September 19, 2019, the same date his resubmission was due, BOP first provided the rejection notice to Plaintiff. Plaintiff resubmitted the BP-10 form and continuation page on the same date. True and correct copies of the filed BP-10 form, continuation page, and rejection notice are annexed hereto as Exhibit G.

43. On October 29, 2019, Plaintiff received notice that his resubmitted BP-10 appeal had been denied. *See* Ex. G. at 5-7. Plaintiff timely filed a BP-11 appeal on October 31, 2019, which appeal remains pending.

44. In light of the BOP's delays in processing Plaintiff's grievance forms, its improper rejection of his BP-10 form, its inexplicable delay in delivering its rejection notice, the length of time taken to issue *pro forma* denials of his grievances and appeals, the anticipated duration until the grievance process is complete, and the scheduled execution date of January 15, 2020, waiting until his administrative remedies are completely exhausted could prejudice Plaintiff in pursuing judicial relief on the claims set forth below. Accordingly, Plaintiff is compelled to file this action now, and will exhaust his administrative remedies as they become available.

D. Lack of Notice-and-Comment Rulemaking

45. As alleged above, the DOJ and BOP stated more than eight years ago that the government was revising its lethal injection protocol. Nevertheless, between the time of the 2011 announcement and the recent announcement of the 2019 Protocol, the DOJ and BOP did not provide any public information about the revisions and the development of the 2019 Protocol or an explanation of the new protocol.

46. The DOJ and BOP also did not engage in the requisite rule-making process under the APA, which requires an agency to publish proposed rules in advance of adoption and allows the public an opportunity to comment on such policy changes

before they are put into place. *See*, *e.g.*, 5 U.S.C. § 553. Instead, the revisions to the 2019 Protocol have been shrouded in secrecy.

47. The lack of transparency surrounding the 2019 Protocol prompted the Committee on Oversight and Reform of the U.S. House of Representatives to write to Attorney General Barr and the then-Acting Director of the BOP on August 14, 2019, requesting information and documents regarding the 2019 Protocol. *See* letters from Reps. Jamie Raskin and Ayanna Pressley, copies of which are annexed hereto as Exhibits H and I.

E. <u>The Protocol's Lack of Statutory Authority and its Violations of the FDPA</u>

No statutory authority

48. From 1790 until 1937, Congress provided for hanging as the means by which federal death sentences would be carried out. *See* 1 Stat. 119, sec. 33 (1790); *Andres v. United States*, 333 U.S. 740, 745 n.6 (1948) (discussing subsequent statute to same effect).

49. Beginning in 1937, Congress enacted a more decentralized system for federal executions, providing for them to take place in the state where the sentence was imposed and in accordance with that state's execution method:

> The manner of inflicting the punishment of death shall be the manner prescribed by the laws of the State within which the sentence is imposed. The United States marshal charged with the execution of the sentence may use available State or local facilities and the services of an appropriate State or local official or employ some other person for such purpose, and pay the cost thereof in an amount approved by the Attorney General.

50 Stat. 304 (former 18 U.S.C. § 542; later recodified as 62 Stat. 837 (former 18 U.S.C. § 3566)). The statute also directed that "[i]f the laws of the State within which sentence is imposed make no provision for the infliction of the penalty of death, then the court shall designate some other State in which such sentence shall be executed in the manner prescribed by the laws thereof." *Id.; see also Andres*, 333 U.S. at 745.

50. Congress repealed the capital sentencing scheme that it had enacted in 1937 when it enacted the Sentencing Reform Act of 1984, at which time there was no federal death penalty. *See United States v. Tipton*, 90 F.3d 861, 902 (4th Cir. 1996).

51. Four years later, in 1988, Congress enacted the Anti-Drug Abuse Act and created a narrow set of drug-related crimes that carried a possible death sentence. *See* Anti-Drug-Abuse Act ("ADAA"), Pub. L. 100–690, 102 Stat. 4181. The statute said nothing about how, where, or by whom any such executions should be carried out. *See United States v. Chandler*, 996 F.2d 1073, 1096 (11th Cir. 1993) (stating that ADAA does not "prescrib[e] a method for carrying out federal death sentences"); *Tipton*, 90 F.3d at 902 (same).

52. In 1993, the DOJ promulgated a set of regulations purporting to establish a method of execution for all prisoners "sentenced to death for commission of an offense described in any federal statute." 28 C.F.R. § 26.1. Under the regulations, executions would take place at a federal prison by lethal injection. The location and chemicals would be designated by the Director of the BOP, and BOP personnel selected by the

prison's warden would carry out the executions. *See* 28 C.F.R. §§ 26.2-26.4.

53. The next year, Congress enacted the Federal Death Penalty Act ("FDPA"), 18 U.S.C. § 3591 *et seq.*, which authorizes the imposition of a death sentence in certain circumstances.

54. Although Plaintiff was sentenced to death for violating a provision of the ADAA in 2005, his sentence is governed by the FDPA because Congress repealed the death penalty portions of the ADAA in 2006. *See United States v. Barrett*, 496 F.3d 1079, 1106 (10th Cir. 2007); "Defendant's Opposition to Plaintiff Daniel Lewis Lee's Motion for a Preliminary Injunction" (ECF Doc. 16), at 5-6 n.1. Moreover, the sentencing court invoked the FDPA in its judgment of death, and without objection from the government:

> Pursuant to 18 U.S.C. § 3596, you are committed to the custody of the Bureau of Prisons until exhaustion of the procedures for appeal of the judgment of conviction and review of sentence. When the sentence is to be implemented, the Attorney General shall release the defendant to the custody of a United States Marshal, who shall supervise implementation of the sentence in the manner prescribed by the law of the state of Indiana.

United States v. Honken, N.D. Iowa Case No. 3:01-cr-3047, Judgment, Doc. No. 702-2 at 3. The sentencing court employed the same language in its amended judgment of October 8, 2013, following vacatur of some of Plaintiff's non-capital convictions.

55. The Attorney General had urged Congress to incorporate the DOJ's centralized

approach into the FDPA, but Congress rejected that proposal.[2] As enacted, the FDPA does not specify the means by which an individual sentenced to death under the statute is to be executed, nor does it authorize any agency to make that determination.

56. Rather, section 3596 governs the implementation of death sentences under the FDPA and provides as follows:

> When the [death] sentence is to be implemented, the Attorney General shall release the person sentenced to death to the custody of a United States marshal, who shall supervise implementation of the sentence in the manner prescribed by the law of the State in which the sentence is imposed. If the law of the State does not provide for implementation of a sentence of death, the court shall designate another State, the law of which does provide for the implementation of a sentence of death, and the sentence shall be implemented in the latter State in the manner prescribed by such law.

18 U.S.C. § 3596(a). The FDPA, then, closely resembles the sentencing scheme that Congress had enacted in 1937, and under which numerous prisoners were executed until the statute was repealed in 1984.[3] In both schemes, death sentences were to be

---

[2] *See* Letter of Attorney General Janet Reno to Honorable Joseph R. Biden, Jr., Detailed Comments at 3-4 (June 13, 1994) (recommending amendment "under which the execution of capital sentences in Federal cases" would be "carried out by Federal officials pursuant to uniform regulations issued by the Attorney General"), *quoted in* House Rep. 104-23, 104th Cong, 1st Session, at 22 (1995-96); *see also United States v. Hammer*, 121 F. Supp. 2d 794, 799 (M.D. Pa. 2000).

[3] *See* J. Cunningham, *Death in the Federal Courts: Expectations and Realities of the Federal Death Penalty Act of 1994*, 32 U. Rich. L. Rev. 939, 957-58 (May 1998) (in "requiring the use of state facilities and the hiring of the local state executioner and other 'appropriate' state officials," the FDPA "dramatically" departed from the ADAA regulations for "carrying out a federal death

carried out "in the manner prescribed by the law[]" of the State []in which the sentence is imposed." The U.S. Marshal was to "use . . . State or local facilities" and "the services of an appropriate State or local official." And if the state lacked the death penalty, the sentence should be executed in another state "in the manner prescribed by" that state's laws.

57. The text and history of the FDPA demonstrate that the Act does not authorize the DOJ or BOP to create a protocol for all federal executions under the FDPA. The 2019 Protocol, therefore, contravenes Congressional intent insofar as it prescribes the manner for executing all prisoners, like Plaintiff, whose death sentences are governed by the FDPA.

58. The 2019 Protocol does not refer anywhere to the FDPA or the implementation requirements in Section 3596. Instead, the sole authority cited by the DOJ in the 2019 Protocol is 28 C.F.R. § 26.3(a), which states that death sentences shall be executed (i) at the time and place designated by the Director of the BOP; (ii) at a federal penal or correctional institution; and (iii) by injection of a lethal substance or substances under the direction of the U.S. Marshal. Correspondence from Defendant Watson advising Plaintiff of his execution date likewise lists 28 C.F.R. § 26.3(a) as the

---

sentence"); G. Kannar, *Federalizing Death*, 44 Buffalo L. Rev. 325, 330 (Spring 1996) (FDPA's departures from the ADAA regulations "are actually quite dramatic, and in this very concrete aspect, the 1994 law federalizing the death penalty also de-federalizes the federally-ordered deaths themselves").

authority for Plaintiff's execution. *See* Ex. D.

59. By invoking 28 C.F.R. § 26.3(a), the DOJ and BOP are attempting to establish a protocol covering all executions under federal law, including the FDPA.. This action, however, is directly contrary to the requirements in Section 3596 of the FDPA and, accordingly, it cannot be undertaken without authorization from Congress.

60. The legislative history of proposed amendments to the FDPA confirms that the DOJ and BOP cannot rewrite the statute by seeking to implement a protocol in contravention of the FDPA's mandates. Indeed, soon after the FDPA was passed in 1994, the DOJ apparently realized that the implementation provisions in Section 3596 are at odds with 28 C.F.R. § 26.3. The DOJ complained to Congress about the burdens imposed on the states by the FDPA's de-federalized execution scheme:

> It is our position that States should not be burdened with the difficult duties of carrying out Federal executions. State governments and correctional systems are currently busy enough with their own cases. When this issue has come up during informal discussions with State officials, the view of those officials had been that they are not interested in having any involvement with Federal executions . . . . [I]t makes little sense for the Federal government to spend extra funds to reimburse States for carrying out this duty, thereby unnecessarily shifting the practical burdens of this Federal responsibility to the States.

Appendix to Hearing on Minor and Miscellaneous Bills, Subcommittee on Crime, Committee on the Judicial, U.S. House of Representatives, 104 Cong., 1st Sess., at 149-51 (Sept. 28, 1995), Letter from Assistant Attorney General Andrew Fois to

Honorable Bill McCollum, Chairman (Oct. 18, 1995) (available on Lexis-Nexis).

61. In the legislative session immediately following the FDPA's enactment – 1995 – Rep. William McCollum introduced H.R. 2359, which sought to amend Section 3596(a) so that it would read as follows:

> A person who is sentenced to death shall be committed to the custody of the Attorney General. At the time the sentence is to be carried out, it shall be implemented pursuant to the regulations prescribed by the Attorney General.

Thus, the amended Section 3596(a) would have explicitly given the DOJ authority to do what it is attempting to do here: create an execution protocol and carry out executions of federal prisoners by removing the requirement that such federal executions follow the procedures of the state where the sentence was imposed or a designated state.

62. Rep. McCollum specifically referred to this issue in introducing the bill. He observed that, under the existing version of the FDPA, the implementation of the death sentence must be in the manner prescribed by the state where the sentence was imposed. *See* Hearing Before the Subcommittee on Crime of the House Committee on the Judiciary (104th Congress), Sept. 28, 1995 at 2. Rep. McCollum also stated that, under the proposed amendment, the Attorney General would prescribe the manner for all federal executions. *Id.*

63. Various DOJ officials provided written and oral testimony to the same effect. *See id.* at 33-34, 37-38, 46, 149-50. Defendant Hawk Sawyer (then Kathleen M. Hawk),

who was the BOP director in 1995 and was recently reappointed as the Director of the BOP, provided a written statement in support of the amendment that largely tracked the statement of her DOJ colleagues.[4]

64. After the hearing before the Subcommittee on Crime, Congress took no further action on the proposed amendment to the FDPA in H.R. 2359.

65. Since 1995, there have been eight other attempts to amend Section 3596, all in an apparent effort to allow the BOP to carry out executions under its own procedures as opposed to those of the state where the sentence was imposed. Congress declined to pass any of those amendments.[5]

Failure to comply with DOJ regulations

66. In the July 25, 2019 Letter, the BOP states that Plaintiff's execution will be carried out pursuant to 28 C.F.R. § 26.3(a)(1) and that the letter constitutes "official notification" of the execution date and method. Ex. D. Nevertheless, the regulations invoked by

[4] Defendant Hawk Sawyer opined that, under the existing law, the only executions under the FDPA that could occur at USP Terre Haute "are those for which lethal injection was permissible in the State in which the inmate was convicted" and in the manner prescribed by the law of such state. *See* Congressional Testimony of Kathleen M. Hawk, Subcommittee on Crime of the House Committee on the Judiciary, June 8, 1995, 1995 WL 352705. However, it is not clear the FDPA would allow for such executions to take place at USP Terre Haute, because section 3596 requires, *inter alia*, that condemned prisoners be released to the custody of a U.S. Marshal for execution.

[5] There are other conflicts between Section 3596 of the FDPA and the 2019 Protocol. For example, the latter states that the director of the BOP will appoint a senior-level BOP employee to "supervise the activities of personnel preparing and administering the lethal substances." Ex. C ¶ E. Section 3596(a), however, provides that the U.S. Marshal "shall supervise implementation of the sentences."

the BOP also state that, when a criminal defendant is sentenced to death, the Government "*shall* promptly file with the sentencing court a proposed Judgment and Order" setting forth certain details regarding the execution. 28 C.F.R. § 26.2(a) (emphasis added). Those details are as follows:

> (1) The sentence shall be executed by a United States Marshal designated by the Director of the United States Marshals Service;
> (2) The sentence shall be executed by intravenous injection of a lethal substance or substances in a quantity sufficient to cause death;
> (3) The sentence shall be executed on a date and at a place designated by the Director of the Federal Bureau of Prisons; and
> (4) The prisoner under sentence of death shall be committed to the custody of the Attorney General or his authorized representative for appropriate detention pending execution of the sentence

Id.

67. Plaintiff was sentenced to death in October 2005, but the Government did not file a proposed "Judgment and Order" regarding Plaintiff's execution with the Iowa District Court, as mandated by 28 C.F.R. § 26.2(a). The judgment sentencing Plaintiff to death therefore lacks the specifications set forth in Section 26.2(a). It provides instead that Plaintiff's sentence is to be administered "[p]ursuant to 18 U.S.C. § 3596," at which time "the Attorney General shall release the defendant to the custody of a United States Marshal, who shall supervise implementation of the sentence in the manner prescribed by the law of the state of Indiana." *United States v. Honken*, N.D. Iowa Case No. 3:01-cr-3047, Judgment, Doc. No. 702-2 at 3.

68. The July 25, 2019 Letter from the BOP does not cure the deficiency stemming from

the Government's failure to file a proposed order with the sentencing court in conformity with 28 C.F.R. § 26.2(a). The letter is not timely and was not filed with the sentencing court in Iowa.

The 2019 protocol differs from the protocol of Indiana, which governs Plaintiff's execution.

69. As explained above, the FDPA requires that a defendant who is sentenced to death under the statute must be executed "in the manner prescribed by the law of the State in which the sentence is imposed" unless that state's law does not provide for the death penalty. 18 U.S.C. § 3596(a). Plaintiff was sentenced to death within the state of Iowa, whose law does not provide for the death penalty. Citing 18 U.S.C. § 3596, the sentencing court therefore ordered Plaintiff to be sentenced "in the manner prescribed by the law of the State of Indiana." Indiana law, in turn, requires the prisoner to be executed by lethal injection in the manner formulated by that state's Department of Correction. *See* Ind. Code § 35-38-6-1.

70. A copy of Indiana's lethal injection protocol is attached to this Complaint as Exhibit J.

71. Defendants' plan to execute Plaintiff through the 2019 Protocol violates the FDPA – as well as the sentencing judgment of the United States District Court for the Northern District of Iowa – because, among other reasons, the 2019 Protocol differs from the Indiana's method in numerous material respects, including:

a. *IV insertion* - The Indiana procedure provides for the IV Team to

make at most four separate attempts at venous access in each of the prisoner's arms. Ex. J. at 10. The lethal drugs are injected into only one arm, and the other arm is a "backup in case of a failure to administer the drugs." *Id.* at 15. If attempts to insert the line into the prisoner's arms fail, a physician performs a "cut-down" procedure. *Id.* at 5, 10. The "cut-down" procedure itself has several specific steps for the physician to follow, including the use of a local anesthetic. *Id.* at 16-17. The federal protocol, by contrast, offers no guidance whatsoever. It provides for the method of venous access to be chosen based on the training, experience, or recommendation of execution personnel, or to comply with a court order. *See* Ex. C ¶ H. The federal method creates no presumption in favor of the prisoner's arm, no discouragement of central line access, and no prohibition against a "cut-down." *Id.* It effectively allows execution personnel – who may have no greater medical credentials or skills than those of phlebotomist – to "freelance" at the prisoner's peril.

b. *Presence of a physician* - The Indiana procedure requires a physician to be present in order to observe the process of IV insertion, to monitor the IV lines through the procedure, to perform a "cut-down" procedure if that becomes necessary, and to monitor the process by which the drugs are prepared and drawn into the syringes. *See* Ex. J at 5, 10-11, 18-19. The federal protocol carries no such requirement. Instead, it provides that medically "qualified personnel" may include "currently licensed physicians, nurses, EMTs, Paramedics, Phlebotomists, other medically trained personnel, including those trained in the United States Military having at least one year professional experience and other personnel with necessary training and experience in a specific execution related function." Ex. C ¶ D.

c. *Different drugs* – The Indiana procedure is a three-drug protocol. For the first drug, the execution team uses a choice of 5 grams of sodium pentothal, pentobarbital, or brevital – a choice that gives the executioners a greater opportunity to avoid the use of compounded drugs. For the second drug, the team administers either of two paralytic agents: pancuronium or vecuronium. And for the third drug, the team administers potassium chloride to stop the prisoner's heart. Ex. J. at 15. The federal protocol, of course,

consists of only a single drug – 5 grams of pentobarbital, and it will be administered in compounded form because that is what the Defendants obtained. Ex. C § H; AR 5.

d. *Storage and expiration of drugs* – The Indiana protocol specifies that the records must be kept of the drugs' refrigeration, and that expired drugs will be used only in practice executions. *See* Ex. J. at 18. The federal protocol, by contrast, does not describe how the compounded drugs will be stored, when they will be compounded in relation to their use in an execution, and indeed, whether the compounded drug may be administered past its USP-designated "beyond use date" in light of the means of storage – a shortcoming described in fuller length by pharmacologist Michaela Almgren below.

F. Violations of Federal Drug Laws

Lack of a valid medical prescription under the CSA and FDCA

72. Defendants intend to execute Plaintiff and other prisoners through the administration of pentobarbital, which is a Schedule II controlled substance. *See* 21 C.F.R. § 1308.12.

73. Documents disclosed by defense counsel show that Defendants do not intend to administer FDA-approved pentobarbital, but instead a compounded version of the drug. Defendants have enlisted the aid of an unnamed "compounding pharmacy" to process the drug's active pharmaceutical ingredient ("API") into an injectable form of the drug. The API, in turn, has been and/or will be obtained from a separate source that the Defendants describe as a "domestic bulk manufacturer." *See* AR 4-5, 859, 932-33; "Defendant's Opposition to Plaintiff Daniel Lewis Lee's Motion for a Preliminary Injunction," (ECF Doc. 16), at 8.

74. The Controlled Substances Act ("CSA") requires the written prescription of a medical practitioner in order for a Schedule II controlled substance to be dispensed and administered. *See* 21 U.S.C. § 829(a).

75. The Food, Drug and Cosmetic Act ("FDCA") similarly conditions the dispensing of FDA-approved drugs such as pentobarbital upon either (a) "a written prescription of a practitioner licensed by law to administer such drug," or (b) "an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist[.]" 21 U.S.C. § 353(b)(1).

76. In order to be legally effective, a medical prescription requires "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). A prescription must be a "bona fide order" reflecting a genuine practitioner-patient relationship. *United States v. Nazir*, 211 F. Supp. 2d 1372, 1375 (S.D. Fla. 2002). It directs "the preparation and administration of a medicine, remedy, or drug for a real patient who actually needs it after some sort of examination or consultation by a licensed doctor – and does not include pieces of paper by which physicians are directing the issuance of a medicine, remedy, or drug to patients who do not need it, persons they have never met, or individuals who do not exist." *Id.*

77. Among the Defendants' chief reasons for crafting the 2019 Protocol as they have, and for selecting an execution method based on the single-drug administration of

pentobarbital, is the Defendants' professed belief that such executions will result in a "humane death." Defendants formed that belief in consultation with at least two medical experts. *See* AR 3, 931. Among the Defendants' stated objectives, then, is to select an execution drug for the medical purpose of diminishing the pain and risk of pain that the prisoner may suffer during an execution.

78. On information and belief, Defendants do not intend to obtain a medical prescription for the dispensing and administration of pentobarbital for purposes of Plaintiff's execution or those of similarly situated prisoners. The 2019 Protocol, as well as the Administrative Record that documents aspects of the protocol's issuance, do not reflect any intent to obtain such a prescription.

79. Even if Defendants were to obtain a purported prescription for the use of pentobarbital in Plaintiff's execution, they have not, and do not intend, to arrange for a medical practitioner to examine Plaintiff and to determine whether pentobarbital is the appropriate drug to administer in order to meet the objective of a "humane" or otherwise minimally painful death – as would be necessary for any such prescription to be legally effective under the CSA and FDCA.

80. The Defendants are not exempt from otherwise applicable drug laws simply because their intended use of federally-regulated drugs involves the execution of death-sentenced prisoners. There is no express or implied "lethal injection" exception to the federal drug laws. Indeed, this Court issued a permanent injunction requiring

FDA to block the importation of sodium thiopental for use in executions because the drug was unapproved and misbranded under the FDCA. *See Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012); *see also* Civil Case No. 11-189 (RJL), ECF Doc. 24. The Court of Appeals affirmed in relevant part. *See Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013).

81. The D.C. Circuit's ruling in *Cook* is binding on this Court, notwithstanding the Department of Justice's more recent attempt to exempt itself from the FDCA when executing prisoners. *See* Office of Legal Counsel, DOJ, "Whether the Food and Drug Administration has Jurisdiction over Articles Intended for Use in Lawful Executions," May 3, 2019, available at 2019 WL 2235666; AR 938-63. Congress has the ability to exempt federal executions from otherwise applicable drug laws. *See*, *e.g.*, Ind. Code § 35-38-6-1(e) (providing that the issuance or compounding of execution drugs does not constitute "the practice of pharmacy" and is not subject to the jurisdiction of the state's medical or pharmacy board). But it has never done so.

Illicit compounding of pentobarbital

82. According to the FDA, the term "compounding" means a practice in which a licensed pharmacist "combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." *Human Drug Compounding*, available at <<https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-

compounding?source=govdelivery&utm_medium=email&utm_source=govdelivery >>.

83. The Defendants similarly define a "compounding" pharmacy as one 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 patient*." AR 857 (emphasis added).

84. Unless the Defendants' chosen compounding pharmacy is registered as an "outsourcing facility" under 21 U.S.C. § 353b – a status neither claimed nor documented in the 2019 Protocol or the materials that purportedly detail its issuance – the Defendants' proposed dispensing and administration of compounded pentobarbital requires a valid medical prescription reflecting a medical practitioner's order that "a compounded product is necessary for the identified patient." 21 U.S.C. § 353a(a). Without such a prescription, the compounded drug is subject to the FDCA's onerous drug-approval process under 21 U.S.C. § 355, and thus, the Defendants' compounded drug is an illicit, misbranded, and unapproved "new drug" under the FDCA. 21 U.S.C. § 353a(a).

85. In addition to the prescription requirement, Section 353a generally prohibits the compounding of drug products that are "essentially copies of a commercially available drug product." 21 U.S.C. § 353a(b)(1)(D). The statute distinguishes such a "copied" drug from a traditionally understood compounding drug "in which there

is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product." 21 U.S.C. § 353a(b)(2).

86. Nembutal is the FDA-approved and non-compounded version of the drug pentobarbital. That drug is a "commercially available drug product" under the FDCA, even if the Defendants are unable to obtain the drug for the purpose of executing prisoners. The question is not whether the drug is available to a particular dispenser for a particular purpose. Rather, an FDA-approved drug is "commercially available" under the statute "if it is a marketed drug product" that has not been as discontinued and is not the subject of an established "drug shortage" as designated by the FDA. *See* FDA, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry* (Jan. 2018), at 5, available at <<https://www.fda.gov/media/98973/download>>. Nembutal has not been discontinued, nor is there a designated shortage of the drug.

87. The Defendants do not plan to change the compounded pentobarbital to some version of the drug that may be more medically appropriate for an individual patient such as Plaintiff. To the contrary, they plan to administer a compounded drug that is "essentially a copy" of the FDA-approved version. A compounded drug

is "essentially a copy" of the approved drug when it is "identical or nearly identical to an approved drug" (unless it appears on the FDA's list of drug shortages), or a drug that contains a "bulk drug substance" contained in the approved drug (unless the drug has been changed in order to make a "clinical difference" for an individual patient). 21 U.S.C. §§ 353b(d)(2)(A)-(B). In this instance, laboratory tests obtained by Defendants show that their objective is to simulate the FDA-approved drug. *See* AR 4-5, 932-33, 970-1015.

88. The Defendants plan to administer compounded pentobarbital because they have (purportedly) been unable to obtain the commercially available and FDA-approved version of the drug for use in executions, and *not* because (a) a medical practitioner has determined that the compounded drug is more suitable for Plaintiff as a unique patient, or (b) a licensed pharmacist has adjusted the drug to make it more suitable for an individual patient.

89. In the unlikely event that that Defendants' chosen compounded pharmacy is a registered "outsourcing facility" under 21 U.S.C. § 353b, their compounded drug remains illegal. In order to exempt the "outsourcing facility" from the FDCA's "new drug" approval process, the statute erects several conditions, one of which is that "[t]he drug is not essentially a copy of one or more approved drugs." 21 U.S.C. § 353b(a)(5). As explained above, Defendants are making "essentially a copy" of FDA-approved pentobarbital.

G. Lack of Notice of Execution Method

Unclear Which Protocol Applies

90. The 2019 Protocol is styled as an "addendum" to the 2008 Protocol, which implies a consistency between the two documents. As alleged below, however, there are several material inconsistences between the 2008 Protocol and the 2019 Protocol.

91. For example, the 2019 Protocol provides that the final selection of the execution team members (not less than 14 days before the execution) will be made by the director of the BOP (or his/her designee), in conjunction with U.S. Marshal. *See* Ex. C ¶ D. The 2008 Protocol, however, repeatedly states that the Warden has responsibility for selecting the execution team and related matters. *See* Ex. A, Chapter 1, §§ III (F), IV (B) and IV (E).

92. Similarly, the 2019 Protocol states that the BOP director shall appoint a senior-level BOP employee to "supervise the activities of personnel preparing and administering the lethal substances." Ex. C ¶ E. The 2008 Protocol, by contrast, gives extensive supervisory responsibility to the Warden. *See* Ex. A, Chapter 1, §§ III-VII.

93. Under the circumstances, Plaintiff has no notice (or inadequate notice) as to which of the various provisions controls and how he is to be executed. These complaints are not merely academic. For a prisoner, like Plaintiff, who has been notified to anticipate an execution date in a few short months, knowing who will select execution team members and supervise the administration of lethal substances takes

on immediate and substantial significance, in part due to the drug administration and related concerns detailed below.

Lack of Transparency and Specificity Regarding Personnel and Procedures under the 2019 Protocol

94. The 2019 Protocol states that the BOP Director (or his/her designee) will determine the method of IV access for an execution based on the training and experience of the personnel establishing the IV access, based on a recommendation from qualified personnel, or to comply with specific orders of federal courts. *See* Ex. C, § H. No information is provided relating to the qualifications of the BOP Director to make this determination, the identity of these "qualified personnel," or the circumstances under which they would be present. Moreover, the protocol clearly contemplates that the experience of the execution team member placing the IVs can change from one execution to the next. There is no indication whether the prisoner's veins will be assessed as part of the determination of appropriate IV placement.

95. Thus, the 2019 Protocol gives total discretion to the personnel involved in the execution, and it provides no guidelines with regard to the options and limitations for the IV placement. Can the execution team establish central line access? Can they perform a cut-down? Is there an order of preferred access sites? Is there a time limit for establishing IV access? Is there a limit on the number of times the team can attempt IV access? These critical questions are left unanswered in the 2019 Protocol.

96. The same lack of transparency and lack of standards that plague the 2019 Protocol's

approach to IV placement characterize the Protocol's treatment of personnel and procedures more generally, as explained below.

97. The preparation of drugs, particularly for IV use, is a technical task requiring significant training in pharmaceutical concepts and calculations. There are many risks associated with drug preparation that, if not properly addressed by credentialed and trained personnel, further elevate the risk that a person will experience excruciating pain during lethal injection. The correct and safe management of IV drug and fluid administration requires a high level of professional acumen, and cannot be performed adequately by personnel lacking the requisite training and experience.

98. As alleged elsewhere in this complaint, many of the problems relating to pentobarbital arise because of improper procedures, which illustrates the importance of well-trained and qualified personnel as well as the use of accepted, verifiable procedures. *See, e.g.*, Exs. H & I, at 2 ("We are extremely concerned about the types of facilities from which the [BOP] will obtain its pentobarbital, whether the [BOP] will be able to guarantee that its intended method of execution is as painless as possible, and whether the [BOP] will be subject to rigorous protocols to prevent the problems that have occurred at the state level.").

99. Rather than complying with the APA by supplying adequate information to Plaintiff and the public about the 2019 Protocol or, for example, the provenance and qualities

of the pentobarbital they intend to use, the DOJ and BOP have taken steps to block access to information about the personnel, procedures, and the lethal substance (including testing of the substance). The 2019 Protocol, for example, states that "any documentation establishing [the] qualifications" of the personnel involved in the executions "shall be protected from disclosure to the fullest extent permitted by law." Ex. C ¶ B. There is no legal basis cited nor any justification for refusing to disclose proof that such personnel are qualified to perform the complex medical tasks assigned to them.

100. Moreover, the 2019 Protocol gives the BOP director overly broad discretion to change the procedures for implementing death sentences:

> The procedures utilized by the BOP to implement federal death sentences shall be as follows unless modified at the discretion of the Director or his/her designee, as necessary to (1) comply with specific judicial orders; (2) based on the recommendation of on-site medical personnel utilizing their clinical judgment; or (3) as may be required by other circumstances.

Id. ¶ A. In particular, the ability of the BOP director to make modifications "as may be required by other circumstances" is so broad as to constitute nearly unfettered discretion to change the procedures by which pentobarbital is administered.

101. Although the 2019 Protocol provides some vague and high-level information, it lacks sufficient detail regarding the planned implementation of executions. Specifically, it fails to address numerous factors that are necessary to ensure compliance with constitutional and statutory requirements, including, but not

limited to, the following:

a) the methods for obtaining, storing, mixing, and appropriately labeling the pentobarbital, the chain of custody for the pentobarbital, the minimum qualifications and expertise required for the person who will be determining the concentration and dosage to give, and the criteria that shall be used in exercising this discretion;

b) the form and provenance of the pentobarbital to be used (manufactured, FDA-approved, compounded, imported, etc.);

c) testing of the pentobarbital at regular intervals to ensure, at a minimum, identity, purity and potency, and conveyance of test results to condemned prisoners facing execution prior to their execution;

d) the consideration of individualized factors, including health circumstances and medical history;

e) the manner in which the IV tubing, three-way valve, saline solution or other apparatus shall be modified or repaired in the event it malfunctions during the execution process, the minimum qualifications and expertise required of the person who shall have the discretion to decide to attempt such action, and the criteria that shall be used in exercising this discretion;

f) the manner in which a monitoring system shall be installed and utilized to ensure that the prisoner is deeply sedated while dying; and the qualifications and expertise required for the person who operates this equipment;

g) the manner in which the IV catheters shall be inserted into the condemned prisoner, the minimum qualifications and expertise required for the person who is given the responsibility and discretion to decide when efforts at inserting the IV catheters should be abandoned in favor of some other constitutionally acceptable procedure; and the manner in which the condition of the condemned prisoner will be monitored to confirm that the protocol is not inflicting severe and unnecessary pain;

h) the minimum qualifications and expertise required of the person who is given the responsibility and discretion to order the staff to divert from the established protocols if necessary to avoid inflicting severe and unnecessary pain and suffering, and the criteria to be used in exercising this discretion; and

i) the minimum qualifications and expertise required of the person who is given the responsibility and discretion to ensure that appropriate procedures are followed in response to unanticipated problems or events arising during the execution, and the criteria that shall be used in exercising this discretion.

102. On August 30, 2019, more than a month after the announcement of the 2019 Protocol, counsel from the DOJ provided counsel for Plaintiff with what was described as the "Administrative Record" relating to the 2019 Protocol.

103. The Administrative Record is sparse, and it includes only a handful of documents (most of which are formal memoranda) discussing the process for the adoption of the 2019 Protocol. A large portion of its 1067 pages – some 88 percent of it – is from public sources; for example, it includes over 300 pages of case law and law review articles. There are no notes or communications (such as e-mails or any correspondence) reflecting the internal processes by which the DOJ and BOP reached their conclusions and developed the 2019 Protocol. For example, the BOP states in the Administrative Record that it consulted with a number of agencies, including the U.S. Marshal Service, U.S. Food and Drug Administration, and U.S. Drug Enforcement Agency. *See* AR 858-59, 872. Such communications are not included in the Administrative Record, even though they likely shed light on why certain decisions were made. In addition, there are several references in the Administrative Record to licenses, trainings, and discussions with USP Terre Haute (*see*, *e.g.*, AR 859, 872), none of which are disclosed in any detail.

104. The Administrative Record elsewhere states that two medical experts opined that the 2019 Protocol will result in "humane" executions. *See* AR 3, 931. The Administrative Record contains only a single expert's cursory analysis (*see* AR 525-26), even though the Defendants claim to have relied on multiple assessments in developing the protocol. *See* AR 1, 929 (stating that BOP has "consulted with medical professionals" and others, and "[a]s a result of this review" has determined to use a single-drug protocol using pentobarbital). Neither does the Administrative Record inform Plaintiff or counsel of (a) the form, source, and quality of the execution drug; (b) the procedures for storing, mixing, compounding, and otherwise preparing the drug; or (c) the procedures for administering the drug intravenously. It is evident, then, that the Administrative Record is an attempt to "paper the file" rather than a true record of a rule-making process.

105. The Administrative Record also does not contain any evidence of participation by the general public in the development of the 2019 Protocol or any opportunity for the public to comment on it.

106. The Administrative Record includes a more general execution protocol that describes procedures beyond the preparation and administration of lethal chemicals. AR 1016-67. Just as the 2019 "addendum" allows the BOP Director to amend the procedure as he sees fit, so too does the more general protocol: "These procedures should be observed and followed as written unless deviation or adjustment is

required, as determined by the Director of the BOP or the Warden." AR 1019.

107. Just as the 2019 Protocol does not specify the procedures by which it will execute Plaintiff and other prisoners, neither the protocol nor the later-issued Administrative Record provides any guidance on how the Attorney General and other Defendants select which federally death-sentenced prisoners should be scheduled for execution, even as among those prisoners who have completed trial, direct appeal, and initial post-conviction proceedings under 28 U.S.C. § 2255.

108. The Department of Justice regulations that purport to implement federal death sentences do not provide any standards on how to select prisoners for execution dates. *See* 28 C.F.R. §§ 26.1-26.4.

109. The Attorney General exercises unilateral authority to schedule federal prisoners for execution, needing no advance authorization from the President, no approval by any court, no adversarial proceedings, and no determination that legal remedies have run their course or that the prisoner is otherwise better-suited for execution than his fellow death-sentenced prisoners.

Pentobarbital and the Risk of Severe Pain and Suffering during an Execution

110. Pentobarbital is a barbiturate that affects the activity of the brain and nervous system. It is clinically indicated for use as a pre-anesthetic, a sedative, and for treatment of brain-swelling, seizures and insomnia.

111. Pathologist Mark Edgar, M.D., has evaluated the 2019 Protocol and the

Administrative Record in consultation with Plaintiff's counsel. Dr. Edgar's expert declaration and CV accompany this complaint as Exhibits K and L, respectively. Dr. Edgar explains that pentobarbital has a highly alkaline pH of 9.5, compared to normal blood's pH of 7.4. Defendants' supplies of pentobarbital, to the extent they have been analyzed and disclosed, show even higher pH readings, specifically, 9.91, 10.0, 10.03, 10.3, and 10.12. *See* Ex. K at 19.

112. Injection of pentobarbital at high doses – including the five grams contemplated in Defendants' protocol – carries an "injurious, caustic effect on blood vessels." *Id.* Once injected into a peripheral vein, a "high volume of alkaline solution" travels to the right side of the heart, and then directly to the lungs, where it induces non-pulmonary "edema as a direct toxic effect of alkaline pentobarbital solution on the lung capillaries." *Id.* at 19-20

113. Pulmonary edema is "the movement of fluid from small blood vessels in the lung (alveolar capillaries) into the air spaces." *Id.* at 5. Dr. Edgar distinguishes between cardiogenic and non-cardiogenic pulmonary edema; the former occurs when fluid backs up in the lungs as the result of heart failure, while the latter can result from "a variety of chemical, infectious, or physical insults to the lung." *Id.* at 3. Sudden non-cardiogenic pulmonary edema – also referred to as "fulminant" pulmonary edema – "produces sensations similar to drowning or asphyxiation as fluid occupies a greater volume of the air spaces." *Id.* Such severe edema "is an intolerable state that

produces panic and terror." *Id.*

114. Fulminant pulmonary edema is known to produce "the presence of foam or froth in the small/lower or large/upper airways (bronchi and trachea) resulting from the mixture of air, edema fluid, and pulmonary surfactant (a detergent-like secretion normally present in the airspaces)." *Id.* at 4.

115. Dr. Edgar has reviewed autopsy reports following 15 Georgia executions that were carried out with a single-drug pentobarbital method similar to the Defendants' 2019 Protocol. Two-thirds of the reports revealed evidence consistent with acute pulmonary edema, with eight of them showing foam or froth in the airways. *Id.* at 18, 20. The autopsy reports may even understate the incidence of fulminant edema, both because the autopsies did not involve a microscopic examination of lung tissue and also because some of the reports note the presence of airway froth but without specifically noting the presence of fluid in the lungs. *Id.* at 18.

116. The presence of froth in the airways indicates not only the onset of acute pulmonary edema from the toxic alkaline pentobarbital, but also that the prisoner continued to breathe after the onset of the edema – as demonstrated by the mixing of edema-fluid and air. *Id.* at 20. "[T]he presence of froth in the airways indicates that there was continued breathing for a significant period of time after pulmonary edema had commenced, and witness reports of respiratory distress in some of the inmates before loss of consciousness suggest this can occur soon after administration

of the drug." *Id.* at 20-21. The finding of fulminant pulmonary edema, then, is inconsistent with the possibility that the prisoner simply experienced sudden cardiogenic pulmonary arrest. *Id.* at 21.

117. Beyond the 15 Georgia autopsies, witness reports from another 29 pentobarbital executions reveal signs of heavy breathing and respiratory distress, including signs of such distress before the prisoner lost consciousness. *Id.* Eleven prisoners complained of a burning sensation, which is "additional evidence of pentobarbital's injurious, caustic effect on blood vessels when injected in high doses, possibly the result of highly alkaline pH." *Id.* at 18-19. More generally, the witness observations of labored breathing, gasping, and other signs of respiratory distress support Dr. Edgar's explanation that the highly alkaline pentobarbital solution travels to the lungs and causes acute edema. *Id.* at 19-20. In seven of the cases, witnesses describe the onset of respiratory distress before loss of consciousness, "making it extremely unlikely that the respiratory distress was due to cardiogenic pulmonary edema, as the drug had not yet acted on the brain to produce deep sedation (and therefore would not be expected to produce respiratory depression through an effect on the brain)." *Id.* at 20.

118. The experience of acute pulmonary edema prior to the loss of consciousness "produces sensations of drowning and asphyxia," and therefore, "the experience of this condition in an inmate who was still sensate would result in extreme pain,

terror and panic." *Id.* at 21. That feeling of terror and panic is made "more frightening by being positioned lying flat in restraints," which aggravates the "noxious sensations" of pulmonary edema. *Id.* at 22.

119. Anesthesiologist Gail A. Van Norman, M.D., has evaluated the 2019 Protocol, the Administrative Record, and additional materials in consultation with counsel for federally death-sentenced prisoner Daniel Lewis Lee, who is scheduled to be executed December 9, 2019. Dr. Van Norman's report accompanies this complaint as Exhibit M.

120. Dr. Van Norman concludes that "flash" or "acute" pulmonary edema occurs in the "vast majority, if not all" of pentobarbital executions. Ex. M at 31 She describes the experience as "excruciating" because the prisoner drowns to death:

> Not being able to breathe during drowning or asphyxiation is one of the most powerful, excruciating feelings known to man. It is nearly impossible for most untrained human beings to hold their breath voluntarily for more than 1 minute. In under 60 seconds, sensations of asphyxia and compulsion to breathe appear and rapidly overwhelm the brain. Panic and terror, and the attempt to fight take over. Even human beings who are underwater will reach such a level of agony that they will be compelled to take a "breath" within about 1 minute. This is the sensation that is deliberately elicited in "the enhanced interrogation technique" called waterboarding, which is defined by the European Court of Human Rights as a form of torture.

Id. at 34 (footnotes omitted).

121. Dr. Van Norman agrees with Dr. Edgar that, in the lethal injection context, flash edema results from "direct toxic/caustic damage to the lung capillaries as extremely high concentrations of barbiturates (which are highly alkaline and caustic) make

physical contact with the lung and capillary surfaces, causing immediate leakage of fluid through the damaged capillaries into the lungs," which describes the phenomenon of "non-cardiogenic pulmonary edema." *Id.* at 32. Another mechanism of such edema occurs through "obstruction or partial obstruction of the upper airway due to effects of barbiturates on respiratory centers in the brain, or due to laryngospasm (a spasmodic, involuntary closure of the larynx) while respiratory efforts continue against the obstruction or partial obstruction, 'sucking' fluids from the capillaries into the lung air spaces" – a mechanism known as "negative pressure pulmonary edema." *Id.* Edema may also result from "acute left heart failure due to direct toxic effects of barbiturates on the heart, leading to 'backing up' of blood into the lungs." *Id.*

122. Dr. Van Norman studied autopsy findings from 27 executions in which pentobarbital was used alone or in combination with other drugs. In the 20 of those cases in which the autopsy report included relevant commentary on the lungs, 100 percent demonstrated pulmonary congestion and pulmonary edema, which are not normal autopsy findings. *Id.* at 35. Moderate to severe edema was present in 18 of of the 20, "many with fluid filling their major airways." *Id.*

123. The flash pulmonary edema from the autopsy reports that Dr. Van Norman reviewed was found "in a woman as well as men, across a wide age range, and in individuals who had no signs of heart disease on autopsy." *Id.* Therefore, the flash

edema "was not due to heart failure," but instead resulted from "immediate toxic damage to the pulmonary capillaries by the barbiturate," which may combine with "negative pressure pulmonary edema" described above. *Id.*

124. It is a "virtual medical certainty" that the prisoners whose autopsies were reviewed by Dr. Van Norman experienced "immediate, flash pulmonary edema." *Id.* at 36.

125. Flash pulmonary edema occurs "virtually immediately during and after high-dose barbiturate injection," and well within the time frame for the drug to carry out its peak effects on the brain. *Id.* It is therefore "extremely likely" that the prisoners "were aware and experienced sensations of drowning and suffocation when they died." *Id.* It is likewise "extremely likely" that prisoners who are injected with five grams of pentobarbital under the 2019 Protocol will remain "capable of feeling pain, terror, and suffocation." *Id.* at 7. And it is a "virtual medical certainty that most, if not all, prisoners will experience excruciating suffering, including sensations of drowning and suffocation, as a result of its effect of IV injection of 5 grams of pentobarbital." *Id.* All told, "the Federal Protocol will subject executed prisoners to severe pain and suffering, when they remain conscious and aware prior to their deaths." *Id.* at 6-7. The 2019 Protocol carries "an extremely high risk of causing prisoners severe pain, and is virtually certain to cause prisoners excruciating suffering through their awareness of the sensations of suffocation and drowning

caused by pulmonary edema." *Id.* at 8.

Problems Arising from Compounded Pentobarbital

126. The Administrative Record, together with the Defendants' recent pleadings, demonstrate that Defendants plan to administer a compounded version of pentobarbital for the executions of Plaintiff and similarly situated prisoners. As Defendants recognize, a "compounding" pharmacy is one 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 patient*." AR 857 (emphasis added).

127. Compounding facilities have had well-documented problems. Texas, for example, purchased its supply of pentobarbital from a compounding pharmacy (Greenpark) whose license was on probation for providing dangerous mixtures to children. *See* "Inmates Said the Drug Burned as They Died. This is How Texas Gets its Execution Drugs, Buzzfeed News (Nov. 28, 2018), available at <<www.buzzfeednews.com/article/chrismcdaniel/inmates-said-the-drug-burnedas-they-died-this-is-how-texas>>. Five people who were executed in Texas through the use of pentobarbital complained that they felt as if they were burning before they finally died. *Id.* In addition, the FDA has warned Greenpark about "serious deficiencies in [its] practices for producing sterile drug products." *See* FDA, Warning Letter: Greenpark Compounding Pharmacy (Oct. 26, 2018), available at <<www.fda.gov/inspections-complianceenforcement-and-criminal-

investigations/warning-letters/greenpark-compounding-pharmacy-566233-10262018>>. Similarly, Missouri purchased pentobarbital for executions from a company (Foundation Care) that has been repeatedly found to engage in hazardous pharmaceutical procedures. *See* "Missouri Fought For Years To Hide Where It Got Its Execution Drugs. Now We Know What They Were Hiding," Buzzfeed News (Feb. 20, 2018), available at <<www.buzzfeednews.com/article/chrismcdaniel/missouri-executed-17-men-withdrugs-from-a-high-risk>>.

128. Dr. Van Norman explains that, because compounded drugs are not regulated by the FDA, they are exempt from Good Manufacturing Practice regulations that govern "the facilities and equipment used in manufacturing a drug, training of personnel, calibration and cleaning of processing equipment, and ensuring that validated analytical test procedures are used to guarantee potency, purity, sterility and other characteristics." Ex. M at 44. GMPs require "that all ingredients and components coming in to the manufacturer be tested upon receipt; that an independent quality control unit oversee the manufacturing, packaging, and testing process; that substandard batches be rejected; and that stability studies are done to support expiration dates." *Id.*

129. Compounding pharmacies are not required to report adverse events to the FDA, and, as a result, "[t]he compounding industry often uses the low reported rate of

adverse events as evidence of safety of compounded pharmaceuticals, which is a stark misrepresentation." *Id.*

130. Dr. Van Norman observes that "[p]harmaceutical preparation errors are much more common among compounding pharmacies than commercial manufacturers," as documented by testing performed by the FDA as well as state agencies. *Id.* Such testing shows that "compounded drugs fail to meet specifications at a much higher rate than FDA-approved drugs." *Id.* In the FDA's 2001 survey of 29 compounded drugs, for example, the FDA found that 10 of the 29 (or 34 percent) failed quality testing – mostly for sub-potency. *Id.* at 46. That rate of failure substantially exceeds the less than 2 percent failure rate among FDA-approved drugs from the same time period. *Id.*

131. The "most common compounding error" is sub-potency, which Dr. Van Norman describes as a "potentially critical error[]" in the execution context. *Id.* at 50. Compounded drugs are "*likely* to be less potent than the label indicates, and *very likely* to *not* be within 30% of their labeled potency, compared to less than 2% of FDA-regulated compounds." *Id.* (emphases in original). Dr. Van Norman finds it "extremely likely that prisoners will be subjected to injection of an inferior, subpotent drug that vastly increases the risk that execution will be prolonged and the prisoner will suffer prolonged feelings of pain and suffocation." *Id.* at 8.

132. Pharmacologist Michaela Almgren, Pharm.D., explains that the compounding of

pentobarbital is a complex and highly specialized process. Dr. Almgren's sworn declaration accompanies this complaint as Exhibit N, and her CV appears as Exhibit O. According to Dr. Almgren, the compounding process requires specialized equipment, numerous pharmaceutical-grade ingredients, chemical adjustments during the process, and of course the appropriate experience and credentials in aseptic compounding technique. Ex. N at 2-3.

133. Deviations from the complex procedures for compounding pentobarbital can result in a sub-potent drug. For example, a small shift in the concentration of one ingredient might result from its improper storage, which in turn could lead the pentobarbital solution to precipitate. That possibility is "extremely concerning" not only because the precipitate could injure tissues or obstruct blood vessels during or after injection (and be "extremely painful" in the process), but also because a sub-potent drug may bring about a "slow and excruciatingly painful death" in which the prisoner experiences the feeling of drowning or suffocation for an extended period of time. *Id.* at 4.

134. Among Dr. Almgren's concerns is the lack of information describing how Defendants' pentobarbital has been compounded or will be compounded. Neither Plaintiff nor the public know the formulation recipe, the procedures by which the drug has been or will be compounded, the ingredients and their concentrations, the equipment that was used and how that equipment has been maintained and

calibrated, or the contents of "compounding logs" that include "the criteria used to determine the beyond use date, a master work sheet containing storage requirements, and documentation of performance of quality control procedures." *Id.* Without that information, it is impossible to verify that the pentobarbital has been properly prepared and is "safe to be used without causing unnecessary suffering to the prisoner." *Id.* Dr. Van Norman shares these concerns. *See* Ex. M at 8, 41.

135. Dr. Almgren is additionally concerned that the Defendants plan to administer expired drugs. United States Pharmacopeia ("USP") standards establish a "beyond use date" of 24 hours from time of compounding if the pentobarbital solution is kept at room temperature, 72 hours if it is refrigerated, and 45 days if it is frozen. Ex. N at 5. If administered after the "beyond use date," the drug may be unstable or unsterile and may thus lose potency. *Id.*

136. Documents from the Administrative Record show that Defendants have been testing compounded pentobarbital since April 2019, but it is not clear whether Defendants intend to administer at execution the drugs that they have already compounded, or instead whether they plan to compound additional batches of the drug for each execution or series of executions. A memorandum to the Attorney General, dated November 27, 2017, states that compounded pentobarbital has a "shelf-life" of "approximately two years" (AR 859), which radically departs from the USP-dictated beyond-use dating explained above.

137. Defendants have been carrying out a "stability study" of their compounded drug, which Dr. Almgren believes is an attempt to extend the beyond-use date. *See* Ex. N at 6. Nevertheless, Dr. Almgren observed that, "[O]ne of the stability test points in the accelerated study has failed and is outside of the range as specified per testing protocol." *Id.* (citing AR 1013). That failure seems to have gone unnoticed or unacknowledged by the Defendants, who claim that the compounded drug has passed all "quality assurance testing." AR 5.

138. What is more, the 2019 Protocol and the Administrative Record do not explain how the drug is stored, and especially the temperature, humidity, and sterile conditions of the storage. Ex. N at 6. Storage conditions must be documented and continually monitored. *Id.* Improper storage, such as excessive temperature or humidity, may cause the drug – whether the API powder or the compounded solution – to be degraded, contaminated, or damaged. *Id.* at 7. Because the details of storage have not been identified or shared by Defendants, "there is a risk that the drugs could lose potency and thus the drugs would not have the pharmacological effect as expected, potentially leading to the prisoner's prolonged suffering as a result." *Id.* at 7-8.

139. Dr. Almgren also observed, as explained elsewhere in this Complaint, that the Defendants' compounding pharmacy is violating the FDCA. The pharmacy is dispensing a compounded version of pentobarbital without a medical prescription

justifying that drug for a particular patient, and it is making "essentially a copy" of the commercially-available drug Nembutal rather than modifying the drug so that it suits a patient's specific needs. *Id.* at 8-9. The compounding pharmacy's apparent indifference to the law does not inspire confidence in its product: "The pharmacy is not following the proper regulations as outlined by the FDA," Dr. Almgren explains, "and its good standing with state board of pharmacy in which this pharmacy is registered and permitted should be questioned." *Id.* at 8.

140. Similarly deficient is the pentobarbital API powder. Dr. Almgren observes that one specific lot of API was tested in November 2018 and failed one of the specifications. *Id.* at 9 (citing AR 977). Unfortunately, the documents provided by Defendants do not disclose which lot of API failed the specification standards, whether that lot was ultimately compounded into solution, or indeed, whether Defendants intend to administer that solution to execute Plaintiff and others. *Id.* at 9-10. Dr. Almgren also noticed a disturbing "number of impurities" in the API that are "certainly concerning" and could impair the compounded drug's potency. *Id.* at 9-10.

141. Dr. Almgren points to numerous "knowledge gaps" concerning the compounded drug that Defendants plan to administer. The potency of the drug depends on numerous factors, including the quality of the API; the identity, regulatory record, and practices of the compounding pharmacy; the manner of storing the

compounded drug; and the length of time between compounding and administration – all factors that the 2019 Protocol and Administrative Record either fail to document or which are objective defects in Defendants' product and procedures. *Id.* at 10.

142. Defendants' compounding practices put Plaintiff at substantial risk, according to Dr. Almgren. "Poor pharmacy practices and a lack of transparency create the substantial risk that the drugs that the Board of Prisons intends to use in execution will not be of the appropriate quality and potency to cause death without significant suffering." *Id.* at 10.

Issues with IV insertion

143. Lethal injection executions have also been plagued by difficulties with setting IVs. The 2012 complaint of prisoner-plaintiff Alfred Bourgeois (Case No. 1:12-cv-00782-TSC) detailed the following examples:

a. March 13, 1985, Texas. Because of Stephen Peter Morin's history of drug abuse, the execution technicians were forced to probe both of Morin's arms and one of his legs with needles for nearly 45 minutes before they found a suitable vein.

b. August 20, 1986, Texas. Randy Woolls, a drug addict, was required to help the execution technicians find a usable vein for the execution.

c. June 24, 1987, Texas. Because of collapsed veins, it took nearly an hour to complete the execution of Elliot Rod Johnson.

d. January 24, 1992, Arkansas. It took medical staff more than 50 minutes to find a suitable vein in Rickey Ray Rector's arm. Witnesses were kept behind a

drawn curtain and not permitted to view this scene, but reported hearing Rector's eight loud moans throughout the process. During the ordeal, Rector (who suffered from serious brain damage) helped the medical personnel find a vein.

e. April 23, 1992, Texas. Billy Wayne White was not pronounced dead until 47 minutes after being strapped to the execution gurney. The delay was caused by difficulty finding a vein. White had a long history of heroin abuse. During the execution, White attempted to assist the authorities in finding a suitable vein.

f. January 23, 1996, Virginia. The execution of Richard Townes, Jr. was delayed for 22 minutes while medical personnel struggled to find a vein large enough for the needle. After unsuccessful attempts to insert the needle through the arms, the needle was finally inserted through the top of Mr. Townes' right foot.

g. July 18, 1996, Indiana. Because of unusually small veins, it took one hour and nine minutes for Tommie J. Smith to be pronounced dead after the execution team began sticking needles into his body. For sixteen minutes, the execution team failed to find adequate veins, and then a physician was called. Smith was given a local anesthetic, and the physician twice attempted to insert the tube in Smith's neck. When that failed, an angiocatheter was inserted in Smith's foot. Only then were witnesses permitted to view the process. The lethal drugs were finally injected into Smith 49 minutes after the first attempts, and it took another 20 minutes before death was pronounced.

h. June 13, 1997, South Carolina. Because Michael Eugene Elkins's body had become swollen from liver and spleen problems, it took nearly an hour to find a suitable vein for the insertion of the catheter. Elkins tried to assist the executioners, asking, "Should I lean my head down a little bit?" as they probed for a vein. After numerous failures, a usable vein was finally found in Elkins's neck.

i. August 26, 1998, Texas. The execution of Genaro Ruiz Camacho was delayed approximately two hours due, in part, to problems finding suitable veins in Camacho's arms.

j. October 5, 1998, Nevada. It took 25 minutes for the execution team to find a vein suitable for the lethal injection of Roderick Abeyta.

k. May 3, 2000, Arkansas. Christina Marie Riggs' execution was delayed for 18 minutes when prison staff could not find a suitable vein in her elbows. Finally, Riggs agreed to the executioners' requests to have the needles in her wrists.

l. June 8, 2000, Florida. It took execution technicians 33 minutes to find suitable veins for the execution of Bennie Demps. "They butchered me back there," said Demps in his final statement. "I was in a lot of pain. They cut me in the groin; they cut me in the leg. I was bleeding profusely. This is not an execution, it is murder." The executioners had no unusual problems finding one vein, but because Florida protocol requires a second alternate intravenous drip, they continued to work to insert another needle, finally abandoning the effort after their prolonged failures.

m. December 7, 2000, Texas. The execution of Claude Jones, a former intravenous drug abuser, was delayed 30 minutes while the executioners struggled to insert an IV into a vein. One member of the execution team commented, "They had to stick him about five times. They finally put it in his leg."

n. November 7, 2001, Georgia. Jose High was pronounced dead more than one hour after his execution began. After attempting to find a usable vein for 39 minutes, the emergency medical technicians under contract to do the execution abandoned their efforts. Eventually, one needle was stuck in High's hand, and a physician was called in to insert a second needle between his shoulder and neck.

o. May 24, 2007, Ohio. Christopher Newton. According to the Associated Press, "prison medical staff" at the Southern Ohio Correctional Facility struggled to find veins on each of Newton's arms during the execution. Newton, who [weighed] 265 pounds, was not declared dead until almost two hours after the execution process began. The execution team stuck Newton at least ten times with needles before getting the shunts in place where the needles are injected.

p. June 26, 2007, Georgia. John Hightower took approximately 40 minutes for the nurses to find a suitable vein to administer the lethal chemicals, and death was not pronounced until almost an hour after the execution process began.

q. September 15, 2009, Ohio. Romell Broom. After two hours of searching for

> suitable veins to insert the needles for lethal injection, the execution team was unable to complete the process and the execution was called off. Since then, stays have been granted by courts considering whether it would be constitutional to attempt Broom's execution a second time.

144. Since the filing of the *Bourgeois* action in 2012, there have been several other instances of IV problems in lethal injections. For example, at the well-publicized Clayton Lockett execution in 2014, the femoral line was not placed correctly and he regained consciousness before dying. *See* <<https://www.nytimes.com/2014/04/30/us/oklahomaexecutions.html>>. In addition, in Ohio (2017) and Alabama (2018), personnel tried unsuccessfully for an extended period of time to set IVs in two very ill prisoners, Alva Campbell and Doyle Lee Hamm. *See* <<https://www.nbcnews.com/news/us-news/alva-campbell-inmatewho-survived-execution-try-dies-ohio-prison-n852961>>; <<https://www.nbcnews.com/storyline/lethal-injection/doyle-lee-hamm-wished-death-during-botched-execution-report-says-n853706>>. Those two executions were called off as a result.

The protocol's lack of guidance

145. The 2019 Protocol enhances the risk of pain, agony, and prolonged executions from unskilled, inept, and unsuccessful IV insertions. For one thing, the protocol provides no guidance on the preferred method of venous access, whether peripheral (arm), a central line, or an invasive cut-down surgery. *See* Ex. C ¶ H. For another, the protocol does not assure that medical personnel will be qualified to make that

decision and carry it out. Purportedly "qualified" personnel may have as little professional training and expertise as a phlebotomist, or even less. *Id.* ¶ D.

146. By failing to specify critical details of the execution process, the 2019 Protocol "poses a significant impediment to expert review," Dr. Van Norman observes. Ex M. at 39. It specifies essentially nothing other than the lethal drug and its amount. *Id.*

147. The 2019 Protocol's lack of specificity places Plaintiff at risk. Improper IV insertion may lead to infiltration (in which the drug is injected or bursts into the surrounding tissue instead of the prisoner's vein) or extravasation (leakage of the drug into the surrounding tissue). *See id.* at 36-37. Extravasation and infiltration are "common" as the result of IV-based executions, and they often cause "significant, excruciating pain for prisoners." *Id.* at 8. Pentobarbital has a strongly alkaline pH, and as a result, infiltration or extravasation causes "instant, excruciating pain that patients liken to being set on fire." *Id.* at 36. Another hazard is the injection of the drug into an artery instead of a vein, the result of which is "instant arterial spasm, pain, excruciating local tissue destruction, and also immediate ischemia (i.e. lack of oxygen, tissue damage and necrosis) in the area of the body supplied by the artery." *Id.* at 36. For example, an IV at the elbow "can cause the entire arm from the IV site down to the hand to turn white and generate excruciating pain." *Id.*

148. Improper injection also diminishes the drug's potency: line infiltration and arterial injection "can result in slow suffocation, a lingering and extremely painful

death, and/or failure of the execution altogether." *Id.* at 41. The 2019 Protocol provides no rescue measures or backup plan in such an event: "Will the prisoner be given treatment or simply allowed to suffocate as the execution proceeds?" *Id.* at 42.

149. Failed IV insertions, featuring "repeat attempts to establish peripheral or central venous access" are yet another occasion of severe pain and an "excruciating event." *Id.* at 41. The 2019 Protocol does not say how long that suffering will last:

> [T]he Addendum does not specify the number of lines, if a backup line is necessary, how many attempts are allowed, how much time will be permitted, nor specific access sites that will be used, and the order in which they will be attempted. Will more than an hour of attempts, or hundreds of punctures be permissible? What will be the procedure if extravasation or infiltration is recognized? Will pain be treated while another IV site is sought?

Id. at 42. The problem is not theoretical. Indeed, "It is likely that adherence to the Federal Protocol will lead to protracted efforts and multiple attempts to establish IF access and to faulty IVs." *Id.* at 8. The consequences are troubling: "It is therefore likely that a prisoner will experience either significant pain from protracted IV access attempts, severe or excruciating pain from injection of barbiturate into tissues other than veins, and/or prolongation of the execution process due to incomplete delivery of the drug." *Id.*

150. The 2019 Protocol also fails to specify the rate at which the pentobarbital will be administered. An excessively fast rate creates the risk of suffering, according to Dr. Van Norman: "Fast redistribution of the drug can cause significant awareness to

linger while the prisoner experiences suffocation, . . . and rapid administration can cause pulmonary edema within seconds, with associated sensations of drowning." *Id.* at 42-43. Rapid administration also increases the probability of extravasation and infiltration." *Id.* at 43.

151. Similarly ambiguous is the protocol's description of "qualified" personnel, the expertise needed to perform a particular task, or indeed, the assignment of specific tasks to specific personnel. *Id.* at 39 "For example, a 'phlebotomist' (a person who draws blood at a laboratory) is listed as a 'qualified person,' but the task assigned to the phlebotomist is not defined," Dr. Van Norman explains. *Id.* at 39-40. "Phlebotomists are not professionally trained, nor necessarily expert in, medication management, intravenous line placement, or administration of medications." *Id.* at 40. A phlebotomist "might not be qualified to carry out *any* of the tasks associated with executions." *Id.* (emphasis added).

152. The protocol likewise fails to specify "what skills and experience are required of each 'qualified' person." *Id.* at 40. For example, the 2019 Protocol contemplates the possibility of central line access, but without assuring that the person setting the access has the necessary experience and skill. "Success of central IV access is significantly affected by the number of such lines and frequency with which the provider places them," Dr. Van Norman observes. *Id.* "The incidence of line infiltration and inadvertent placement into an artery instead of a vein are high in

personnel without significant, ongoing and routine placement of those lines, even if they have the technical expertise to do them." *Id.* at 40-41.

Alternatives Relating to Eighth Amendment Issues

153. There are numerous alternatives regarding the Eighth Amendment issues raised by the 2019 Protocol. Plaintiff has identified the alternatives below based on available information, but Defendants have sole possession of the information regarding other potential alternatives and they should be ordered to provide it in discovery in this case.

Safeguards

154. *First*, the implementation of the safeguards alleged in Paragraph 101 above presents a straightforward and available alternative to the defective 2019 Protocol. The DOJ and BOP should incorporate these safeguards in order to ensure (1) the selection of qualified, competent and vetted team members, whose qualifications are disclosed; (2) establishment of two patent, functioning peripheral IV lines and (a) that no central line will be placed unless it is determined to be necessary following a vein assessment by a qualified medical professional and (b) central lines will be set only by qualified and competent medical professionals; (3) use of compounded pentobarbital that (a) complies with all state and federal compounding requirements, (b) has been tested(as shown with the records of this testing and chain of custody documentation) and (c) the compounding formula disclosed to prisoners

and their counsel. Upon information and belief, these safeguards are available, are feasible, and would significantly reduce the substantial risks of harm posed by the 2019 Protocol.

Bedside administration

155. *Second*, the bedside administration of pentobarbital could reduce or eliminate several of the deficiencies in the 2019 Protocol. Eliminating the need for extension sets of IV tubing can significantly reduce the risks of leakage or pinching of the tubing. Bedside administration would also ensure adequate surveillance and monitoring of the IV, the catheter site, and the prisoner. And, by eliminating the need for lengthy IV tubing, bedside administration would greatly reduce the variation and risk introduced by the increased contact, and subsequent resistance, between the drug and the walls of the tubing. Upon information and belief, bedside administration is available, is feasible, and would significantly reduce the substantial risks of harm posed by the 2019 Protocol.

Pre-treatment

156. *Third*, along with incorporating safeguards and transparency into the pentobarbital protocol, the DOJ and BOP could add a pre-dose of either an opioid or an anti-anxiety medication in a large clinical dose. This pre-treatment of the prisoner would substantially reduce the risk that the prisoner would remain sensate to experience pain, including the pain of pulmonary edema. Upon information and

belief, a pentobarbital protocol with transparency, safeguards, and pre-treatment constitutes an alternative procedure that is available and feasible, and it would significantly reduce the substantial risks of harm posed by the 2019 Protocol.

FDA-approved, non-compounded pentobarbital

157. *Fourth*, Defendants could execute Plaintiff by a lethal injection of FDA-approved, manufactured pentobarbital (Nembutal). At least one state, Missouri, has obtained FDA-approved pentobarbital in the recent past. *See* Chris McDaniel, *Missouri Execution Drug Purchases Revealed*, Buzzfeed News (January 8, 2017) (available at <<https://www.buzzfeednews.com/article/chrismcdaniel/missouri-execution-drug-purchases-revealed#.qtdQQ75pX>>. The use of FDA-approved pentobarbital, and the accompanying guarantee of potent, non-contaminated drugs, would eliminate significant risks presented by Defendants' protocol and its administration. Defendants could, therefore, at minimal cost, significantly reduce Plaintiff's risk of pain by acquiring substantially-safer, FDA-approved pentobarbital.

Firing squad

158. *Fifth*, Defendants could execute Plaintiff by use of a firing squad. Execution by use of a firing squad is plainly a "known and available" alternative method under *Baze v. Rees*, 553 U.S. 35 (2008), and *Glossip v. Gross*, 135 S. Ct. 2726 (2015). The Supreme Court has held that the firing squad is a constitutionally permissible form of execution. *See Wilkerson v. Utah*, 99 U.S. 130, 134-35 (1878) (upholding sentence of

death by firing squad); *see also Arthur v. Dunn*, 137 S. Ct. 725 (2017) (Sotomayor, J., dissenting from denial of certiorari) (recognizing that condemned inmates may "find more dignity in an instantaneous death [by firing squad]"). Since 1976, Utah has carried out three executions by firing squad – most recently on July 18, 2010. *See Kirk Johnson, Double Murderer Executed by Firing Squad in Utah*, N.Y. TIMES, June 19, 2010, at A12.

159. Protocols for execution by firing squad are known and available. Utah's technical manual, specifying the state's execution protocol in great detail, is publicly accessible. *See* Technical Manual of Utah Department of Corrections (Ex. H), available at << https://cdn.muckrock.com/foia_files/2017/03/22/3-13-17_MR34278_RES.pdf>>. For example, in Utah's most recent execution by firing squad, the inmate was seated in a chair set up between stacked sandbags to prevent the bullets from ricocheting. A target was pinned over the inmate's heart. Five shooters set up at a distance of 21 feet from the inmate, armed with .30-caliber Winchester rifles. One rifle was loaded with blanks so that no one knew which officers killed the inmate. The inmate was pronounced dead two minutes after he was shot. *Id.* at ¶ 12; *see also Utah Brings Back the Firing Squad, So How Does It Work?*, ASSOCIATED PRESS, Mar. 24, 2015.

160. Upon information and belief, Defendants could easily identify qualified personnel to carry out an execution by firing squad. Furthermore, the federal

government already has a sufficient stockpile of both the weapons and ammunition necessary to carry out an execution.

161. Execution by firing squad is both swift and virtually painless. If performed properly, the use of a firing squad eliminates the substantial risk of severe pain presented by Defendants' current execution protocol, and its likely maladministration. Evidence and recent experience strongly suggest that "the firing squad is significantly more reliable" than lethal injection. *Glossip*, 135 S. Ct. at 2796 (Sotomayor, J., dissenting). Historically, the firing squad has resulted in significantly fewer "botched" executions. "Botched executions are those involving unanticipated problems or delays that caused, at least arguably, unnecessary agony for the prisoner or that reflect gross incompetence of the executioner." Austin Sarat, *Gruesome Spectacles: Botched Executions and America's Death Penalty*, p. 5 (2014) (quotations omitted). A recent study, which analyzed the contemporaneous news reports of all executions in the United States from 1900 to 2010, found that 7.12% of the 1,054 executions by lethal injection had been "botched," but none of the 34 executions by firing squad had been botched. *Id.* at App. A, p. 177. Accordingly, execution by firing squad is a known and available alternative method that presents a substantially lower risk of pain and suffering than Defendants' flawed protocol.

V.
Claims for Relief

Count I: Violation of the APA – Absence of Notice-and-Comment Rulemaking

162. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

163. The APA requires a reviewing court to set aside any agency action taken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). The APA imposes a number of non-discretionary duties regarding rule-making procedures. *See* 5 U.S.C. § 553. Pursuant to the APA, the DOJ and BOP were required to provide advance notice of the 2019 Protocol, an opportunity for public comment, and an explanation of the rule ultimately adopted. *See* 5 U.S.C. §§ 553(b) and (c).

164. The DOJ and BOP failed to provide advance notice or opportunity for the public to comment on the 2019 Protocol prior to its promulgation. The DOJ and BOP also failed to provide an adequate explanation of why the 2019 Protocol was adopted. In issuing the 2019 Protocol in contravention of such procedural requirements, the DOJ and BOP violated the APA.

165. This violation of the APA will cause an injury to Plaintiff's rights and interests because, if the DOJ and BOP had complied with the procedural requirements described above, Plaintiff could have addressed the multiple issues with the 2019 Protocol including, but not limited to, Defendants' failure to provide adequate notice of the procedures to which Plaintiff would be subjected; the protocol's failure

to protect Plaintiff's right of access to counsel and the courts; and the risk that the execution will result in an avoidably painful execution – including the risk of cruel and unusual punishment under the Eighth Amendment – on account of the properties of the pentobarbital, the undefined and unrestricted procedures to be used in the execution, and/or the absence of sufficient safeguards as described above.

166. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2).

Count II: Violation of the APA – *Ultra Vires* Agency Action Contrary to U.S. Constitution and the Federal Death Penalty Act

167. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

168. Under the APA, a reviewing court must set aside any agency action that is "not in accordance with the law," "in excess of statutory jurisdiction, authority or limitations," or "contrary to constitutional right, power, privilege or immunity." 5 U.S.C. §§ 706(2)(A), 2(C).

169. As alleged above, the 2019 Protocol violates the mandates of the FDPA, which governs the implementation of Plaintiff's death sentence. *See United States v. Barrett*, 496 F.3d 1079, 1106 (10th Cir. 2007); *United States v. Honken*, N.D. Iowa Case No. 3:01-cr-3047, Judgment, Doc. No. 702-2 at 3. The 2019 Protocol sets forth the manner for implementing all federal executions (including those under the FDPA), but the

FDPA does not authorize the DOJ or BOP to create an execution procedure for prisoners whose sentences are governed by its provisions, to set execution dates, or to carry out their executions.

170. The DOJ and BOP have acknowledged in public testimony that the FDPA does not allow for the manner of execution set forth in the 2019 Protocol.

171. The 2019 Protocol, therefore, constitutes *ultra vires* agency action because the DOJ and BOP lacked the authority under the FDPA to issue the 2019 Protocol.

172. The Take Care Clause of the Constitution imposes a duty on the Executive Branch to "take care that the laws be faithfully executed." U.S. Const., art. II, § 3. The Take Care Clause forbids the Executive Branch from making acts of Congress unlawful by refusing to enforce them as written. The Take Care Clause preserves the principles of separation of powers inherent in the Constitution by preventing the Executive Branch from arrogating to itself the legislative power to revoke or rewrite laws.

173. As alleged above, the DOJ and BOP seek to rewrite the FDPA by ignoring its express requirements regarding the implementation of death sentences. Through the 2019 Protocol, therefore, the DOJ and BOP are violating the Take Care Clause of the Constitution and the principles of separation of powers.

174. In addition, Plaintiff's death sentence must be carried out in accordance with Indiana's execution method, as specified by the sentencing court when it invoked

and followed the FDPA. As alleged above, the 2019 Protocol differs from Indiana's method of execution in numerous and material respects.

175. Defendants' violations of the APA, based on their violations of the FDPA and the actions they have taken without statutory authorization, will cause an injury to Plaintiff's rights and interests because an execution under the 2019 Protocol would fail to provide adequate notice of the procedures to which Plaintiff would be subjected; would unconstitutionally infringe on his right of access to counsel and the courts; and would carry the risk of an avoidably painful execution – including, but not limited to, a risk that the execution will result in cruel and unusual punishment under the Eighth Amendment – on account of the properties of the pentobarbital, the undefined and unrestricted procedures to be used in the execution, and/or the absence of sufficient safeguards as described above.

176. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2).

Count III: Violation of the APA – Agency Action Contrary to the Controlled Substances Act and the Food, Drug and Cosmetic Act

177. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

178. Under the APA, a reviewing court must set aside any agency action that is "not in accordance with the law," or is "in excess of statutory jurisdiction, authority or limitations." 5 U.S.C. §§ 706(2)(A), 2(C).

179. As alleged above, the 2019 Protocol violates the CSA because it requires the dispensing and administration of a Schedule II controlled substance without any medical prescription, let alone a valid prescription reflecting a medical practitioner's clinical judgment concerning how treat a specific patient. *See* 21 U.S.C. §§ 802(21), 829(a), 829(e)(2).

180. As alleged above, the 2019 Protocol violates the FDCA because it requires the dispensing and administration of an FDA-approved drug without any medical prescription, valid or otherwise. *See* 21 U.S.C. § 353(b)(1).

181. As alleged above, the 2019 Protocol violates the FDCA because it involves the dispensing and administration of compounded pentobarbital without a medical prescription – valid or otherwise – ordering that a particular patient receive a compounded version of the drug because of that patient's specific needs. *See* 21 U.S.C. § 353a(a).

182. As alleged above, the 2019 Protocol violates the FDCA because it involves the compounding, dispensing, and administration of pentobarbital that is "essentially a copy" of the FDA-approved and commercially available version of pentobarbital. *See* 21 U.S.C. §§ 353a(b)(1)(D), 353a(b)(2), 353b(a)(5), and 353b(d)(2).

183. Defendants' violations of the federal drug laws will cause an injury to Plaintiff's interest because those violations enable Defendants to carry out an execution with a drug that was chosen by Defendants for the stated medical purpose of diminishing

the risk of pain, yet without observance of the federal statutes that govern the dispensing and administration of those drugs. The "core" legislative purpose of the FDCA is to ensure that a "drug" is "safe and effective for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). The FDCA and CSA embody safeguards that govern the very drug that Defendants plan to compound, dispense, and administer. "[I]gnoring those safeguards, as Plaintiffs allege Defendants intend to do, places Plaintiffs at risk." *Ringo v. Lombardi*, 706 F. Supp. 2d 952, 958 (W.D. Mo. 2010) (holding that prisoner-plaintiffs had standing to seek a declaratory judgment that the state's former protocol violated the FDCA). Those safeguards apply even to drugs that are used in executions. *Id.* at 962 ("Where the Eighth Amendment requires protocols that include adequate safeguards against unnecessary pain . . . and superior courts have indicated that the involvement of medical professionals and rules for administration enhances such safeguards, the safeguards provided by the CSA and FDCA are not irrelevant."). This Court has held unequivocally that the FDCA's text and purposes apply to lethal injection drugs, the DOJ's recent and unilateral declaration to the contrary notwithstanding. *Compare* AR 938-39 (arguing that the statutory aim drug safety "markedly conflicts with the purpose of an execution"), *with Beaty v. FDA*, 853 F. Supp. 2d 30, 42-43 (D.D.C. 2012) (explaining that importation of a misbranded execution drug implicates the FDCA's statutory purposes, including the need to ensure that a drug

is safe and effective: "Even when in the correct hands, prisoners on death row have an unnecessary risk that they will not be anesthetized properly prior to execution.").

184. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2).

Count IV: Violation of the APA – Agency Action that is Arbitrary, Capricious, an Abuse of Discretion, and Otherwise Not in Accordance with Law in Promulgating the 2019 Protocol

185. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

186. Under the APA, a reviewing court must set aside any agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

187. Agency action that is not the product of reasoned decision-making is arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). To satisfy the requirement of reasoned decision-making, an agency must "cogently explain why it has exercised its discretion in a given manner." *Id.* at 48

188. Despite the substantial changes to the 2008 Protocol that the 2019 Protocol seeks to effect, the DOJ and BOP offered no explanation for these changes in the 2019 Protocol and scant justification in the Administrative Record. The DOJ and BOP have utterly failed to explain the basis and reason(s) for their decision to adopt the

2019 Protocol or the specific procedures therein. Such an explanation is particularly important in this case given that, as alleged above, the 2019 Protocol is inconsistent with the 2008 Protocol in material ways (in addition to being contrary to the requirements of the FDPA), and risks the unnecessary infliction of pain during execution in numerous respects as described above.

189. An agency's rule is also arbitrary and capricious when, among other circumstances, the agency has "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. The 2019 Protocol and the Administrative Record demonstrate that DOJ and BOP have "entirely failed" to consider the 2019 Protocol's compliance with federal laws governing the safety and effectiveness of drugs – in particular, the FDCA and the CSA – even as Defendants purport to have chosen a particular execution drug for the medical purpose of offering a "humane" death. Other than Defendants' unilateral and counter-precedential announcement that the FDCA does not apply *at all* to drugs that are used in executions – *see* AR 938-63 – the DOJ and BOP have ignored the need to comply with statutes that they are facially violating.

190. Thus, the adoption of the 2019 Protocol is arbitrary and capricious, in violation of the APA, because it was not the product of reasoned decision-making and because Defendants entirely failed to consider whether and how to conform the 2019 Protocol to relevant federal drug statutes.

191. This violation of the APA will cause an injury to Plaintiff's interest because, if the DOJ and BOP had provided the required explanation of their decision-making, and had they adequately considered whether and how to comply with federal statutes that govern the dispensing, administration, and compounding of pentobarbital, it is likely that Defendants would have chosen a different execution method that would diminish the risks of harm described in this complaint.

192. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2).

Count V: Violation of the APA — Arbitrary and Capricious Failure to Exercise Enforcement Authority under the FDCA

193. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

194. As described above, the 2019 Protocol violates the FDCA in numerous respects, including the dispensing and administration of pentobarbital without a valid medical prescription, the compounding of that drug without such a prescription, and compounding what is essentially a copy of the commercially-available form of pentobarbital. *See* 21 U.S.C. §§ 353(b)(1), 353a(a), 353a(b)(1)(D), 353a(b)(2), 353b(a)(5), and 353b(d)(2). Because of these violations, the Defendants' compounded drug is an unapproved "new drug" and is misbranded under 21 U.S.C. §§ 352 and 355.

195. Defendants have consulted with the FDA with respect to the development and

implementation of the 2019 Protocol. *See* AR 859, 938-63.

196. On May 3, 2019, the DOJ's Office of Legal Counsel issued a memorandum declaring that the FDA lacks the authority and jurisdiction to regulate execution drugs and effectively ordering the FDA to decline such regulation categorically. *See* Office of Legal Counsel, Department of Justice, "Whether the Food and Drug Administration Has Jurisdiction Over Articles Intended for Use in Lawful Executions," May 3, 2019 (AR 938-63; also available at 2019 WL 2235666). Some two months later, the Defendants announced the method and date for Plaintiff's execution and four others.

197. As explained above, the FDCA's "core" legislative purpose is to ensure that a drug is "safe and effective for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Defendants chose pentobarbital as an execution drug because they believe it will serve the medical purpose of achieving a "humane" death. AR 3, 525-26, 931.

198. The Court of Appeals in *Cook* held that the FDA violated the FDCA by refusing to exercise its jurisdiction to interdict a misbranded execution drug. *See Cook*, 733 F.3d at 10-11. Defendants defend their non-acquiescence to *Cook* by arguing that the D.C. Circuit in that case did not "squarely address[] whether FDA has administrative jurisdiction" over lethal injection drugs – AR 938, 958 – even though the court in fact ordered the FDA to exercise such jurisdiction. *Cook*, 733 F.3d at 10-

11; *accord Beaty v. FDA*, 853 F. Supp. 2d 30, 41-43 (D.D.C. 2012).

199. As a result of the DOJ's legal memorandum as well as other actions of Defendants, the FDA now exercises a broad policy of refusing to enforce the FDCA's requirements with respect to otherwise regulated drugs that are intended for use in human executions. Consistent with that policy, and on information and belief, the FDA has taken no action to require the Defendants to comply with the FDCA's requirements concerning the need for a medical prescription for pentobarbital, the need for a prescription justifying the compounded form of that drug, or the prohibition against compounding a copy of a commercially-available drug.

200. The Defendants' actions are arbitrary and capricious, and they are not in accordance with law under the APA. *See* 5 U.S.C. § 706(2).

201. This violation of the APA will cause an injury to Plaintiff's interest because, as alleged above, an execution under the 2019 Protocol — with the use of pentobarbital in violation of the FDCA — carries a likelihood that Plaintiff will suffer an avoidably painful execution, including but not limited to a substantial possibility of suffering cruel and unusual punishment due to the properties of pentobarbital.

202. Accordingly, the 2019 Protocol should be set aside pursuant to 5 U.S.C. § 706(2).

Count VI: Violation of the APA — Arbitrary and Capricious Failure to Exercise Enforcement Authority under the CSA

203. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

204. The CSA makes it unlawful to "dispense" any "controlled substance," 21 U.S.C. § 841(a)(1), except pursuant to a valid prescription "issued for a legitimate medical purpose" by a practitioner who is "acting in the usual course of professional practice" and registered pursuant to the statute. 21 U.S.C. §§ 802(21), 829(a), and 829(e)(2).

205. Pentobarbital is a Schedule II controlled substance.

206. Regulations promulgated by the DEA provide that every person who "dispenses" a "controlled substance" is required to obtain a registration. 21 C.F.R. § 1301.11. The regulations also provide that the DEA Administrator "shall deny" an application for registration unless the issuance of a registration is "required" under the CSA. 21 C.F.R. § 1301.35.

207. Upon information and belief, the 2019 Protocol calls for the dispensing of pentobarbital absent a valid prescription and by persons who lack a valid registration. Moreover, Defendant Dhillon has arbitrarily and capriciously failed to exercise his authority to enforce the CSA by not requiring the persons who will dispense the pentobarbital to apply for a registration, and will continue to act arbitrarily and capriciously by permitting them to dispense the pentobarbital without doing so or obtaining a valid medical prescription.

208. Such arbitrary and capricious action violates the APA.

209. This violation of the APA will cause an injury to Plaintiff's interest because, as

alleged above, an execution under the 2019 Protocol — with the use of pentobarbital in violation of the CSA — carries a likelihood that Plaintiff will suffer an avoidably painful execution, including but not limited to a substantial possibility of suffering cruel and unusual punishment due to the properties of pentobarbital.

210. Accordingly, the 2019 Protocol should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2).

Count VII: Fifth Amendment Violation – Denial of Due Process

211. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

212. The Due Process Clause of the Fifth Amendment requires notice and the opportunity to be heard before the deprivation of life, liberty, or property.

213. Defendants, acting under color of federal law, have not disclosed sufficient details regarding the procedures that will be used in carrying out Plaintiff's execution. Plaintiff is thereby prevented from determining all the aspects of the 2019 Protocol that violate provisions of federal law and constitute cruel and unusual punishment, and from consulting medical experts concerning those aspects. More broadly, Plaintiff is prevented from determining and seeking to remedy all of the ways in which the 2019 Protocol presents an avoidable risk of pain and suffering during an execution.

Count VIII: Fifth and Eighth Amendment Violation – Denial of Due Process – Arbitrary Selection of Prisoners for Execution

214. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

215. As explained above, the Due Process Clause in the Fifth Amendment requires notice and the opportunity to be heard before the deprivation of life, liberty, or property.

216. The Eighth Amendment forbids the arbitrary imposition and implementation of capital punishment. "[I]f a State wishes to authorize capital punishment it has a constitutional responsibility to tailor and apply its law in a manner that avoids the arbitrary and capricious infliction of the death penalty." *Godfrey v. Georgia*, 446 U.S. 420, 428 (1980).

217. Defendants, including the Attorney General, have not published or disclosed any standards or criteria by which the government chooses which prisoners it will schedule for execution.

218. The Death Penalty Information Center lists 63 prisoners as federally death-sentenced. *See* <<https://deathpenaltyinfo.org/state-and-federal-info/federal-death-penalty/list-of-federal-death-row-prisoners>>. From among those 63 prisoners, the Attorney General chose five to execute in December 2019 and January 2020.

219. The Administrative Record lists ten separate prisoners as having "exhausted their appeals." AR 859 (memorandum dated Nov. 27, 2017). Of those ten, only three

were set for execution this December and January (Dustin Honken, Daniel Lee, and Wesley Purkey). Two others who were absent from that list – Alfred Bourgeois and Lezmond Mitchell – were nevertheless also scheduled for execution this winter.

220. In a recent filing urging the Court to deny equitable relief, the Defendants invoked the interest of crime victims in "timely" enforcement of a death sentence. *See* "Defendants' Opposition to Plaintiff Daniel Lewis Lee's Motion for a Preliminary Injunction" (ECF Doc. 16), at 45. Nevertheless, Defendants have not followed a practice of scheduling executions according to the length of time that has passed since a sentence was imposed, the length of time since a crime was committed, or even the length of time since the prisoner finished an initial round of post-conviction remedies.

221. The absence of discernible criteria creates a legal vacuum for deciding which prisoners will suffer the ultimate punishment, leading to arbitrary decisionmaking on the weightiest question a government can address. The mere fact that a prisoner has been convicted and sentenced to death, and that the sentence has survived appellate and post-conviction review, does not cure the arbitrariness with which the sentence is carried out. "Arbitrariness in execution is still arbitrary, regardless of when in the process the arbitrariness arises." *Jones v. Chappell*, 31 F. Supp. 3d 1050, 1063 (C.D. Cal. 2014), *rev'd on other grounds sub nom. Jones v. Davis*, 806 F.3d 538 (9th Cir. 2015).

222. In addition to lacking standards, the Attorney General's exercise of discretion is unilateral and lacks any judicial or executive oversight. At no point does a warrant issue from a federal court or the President, and at no point does the prisoner have the opportunity to argue against the issuance of a warrant in light of current legal proceedings, prospective litigation, or other circumstances that militate against scheduling an execution.

223. The Defendants claim to have modeled their execution method after those in Georgia, Missouri, and Texas. *See Roane v. Gonzales*, No. 1:05-cv-02337-TSC, ECF 389-1, at 1 (press release). Nevertheless, all of those states provide for an execution warrant to be issued by a court, and even then, only on a showing by the prosecutor or attorney general that a death warrant is justified. *See* Mo. Sup. Ct. R. 30.30(d); Tex. Code Crim. Proc. Art. 43.141; Ga. St. § 17-10-40(a).

224. Other than the federal government, there is not a *single* death penalty jurisdiction within the entire United States that gives law enforcement the unilateral discretion to select prisoners for execution and to schedule their deaths. Even federal military executions must be approved by the President. *See* Department of the Army, Army Reg. 190-55 (§ 1-4(a)(3)).

225. Granting the Attorney General unfettered discretion has, in practice, led to a completely arbitrary process for determining who lives and who dies. There are no limits to cabin executive discretion, there are no guidelines for the selection process,

and the entire process is cloaked in secrecy. *Cf. Furman v. Georgia*, 408 U.S. 238, 309-10 (1972) (Stewart, J., concurring) ("These death sentences are cruel and unusual in the same way that being struck by lightning is cruel and unusual. For, of all the people convicted of rapes and murders . . . many just as reprehensible as these, the petitioners are among a capriciously selected random handful upon whom the sentence of death has in fact been imposed.").

226. The foregoing is a violation of the Due Process Clause and the Eighth Amendment.

Count IX: Eighth Amendment Violation – Cruel and Unusual Punishment

227. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

228. The Eighth Amendment forbids the Government, in carrying out a death sentence, from inflicting pain beyond that necessary to end the prisoner's life. *In re Kemmler*, 136 U.S. 436, 447 (1890). "Punishments are cruel when they involve torture or a lingering death . . . something more than the mere extinguishment of life." *Id.* *See also Baze v. Rees*, 553 U.S. 35, 50 (2008) (execution violates the Eighth Amendment if it presents a "substantial risk of serious harm").

229. Defendants, acting under color of federal law, intend to execute Plaintiff in a manner that is arbitrary, cruel and/or unreliable, and which will inflict excruciating pain on Plaintiff, or has a foreseeable and significant but completely avoidable and

unnecessary risk of causing such pain, and where one or more substantially less painful methods of execution are feasible and available. Because the 2019 Protocol poses a substantial risk of serious harm to Plaintiff, it violates Plaintiff's constitutional right to be free from arbitrary, capricious, cruel, and unusual punishment.

230. Defendants' refusal to disclose all material aspects of their protocol leaves Plaintiff unaware of how he will be executed, and it thereby creates "an immense mental anxiety amounting to a great increase of the offender's punishment" and independently violates the Eighth Amendment. *In re Medley*, 134 U.S. 160, 172 (1890) (Colorado statute enacted after prisoner's crime and allowing him to be executed, at any date chosen by and known only to the warden, increased the prisoner's punishment and was an *ex post facto* law).

231. The right to be free from arbitrary, capricious, cruel, and unusual punishment is secured and guaranteed to Plaintiff by the Eighth Amendment to the Constitution.

Count X: Fifth and Eighth Amendment Violation – Deliberate Indifference

232. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

233. The Eighth Amendment forbids "deliberate indifference" to "serious medical needs of prisoners," *Estelle v. Gamble*, 429 U.S. 97, 104 (1976), and to a substantial risk of serious harm to a prisoner. *See Farmer v. Brennan*, 511 U.S. 825, 834 (1994).

234. Substantive due process affords similar protections: "[A] physician who acts on behalf of the State to provide needed medical attention to a person involuntarily in state custody (in prison or elsewhere) and prevented from otherwise obtaining it, and who causes physical harm to such a person by deliberate indifference, violates the Fourteenth Amendment's protection against the deprivation of liberty without due process." *West v. Atkins*, 487 U.S. 42, 58 (1988) (Scalia, J., concurring).

235. The BOP undertakes to provide inmates with medical care that is "presently medically necessary," which is defined as treatment "without which an inmate could not be maintained . . . without significant pain or discomfort." (Fed. Bureau of Prisons, U.S. Dep't of Justice, Program Statement, No. 6000.4 (Dec. 15, 1994), Ch. 1, § 1.)

236. The Attorney General and the BOP Defendants are required to provide Plaintiff with appropriate medical care until the moment of his death. Thus, the constitutional proscription against "deliberate indifference" requires that they administer the death penalty without the "unnecessary and wanton infliction of pain." *Gregg v. Georgia*, 428 U.S. 153, 173 (1976).

237. Defendants purport to have chosen the 2019 Protocol as their preferred means of execution because it advances their claimed medical objective of bringing about a "humane death." *See* AR 3, 525, 931.

238. The means chosen by Defendants to execute Plaintiff under the 2019 Protocol

constitute deliberate indifference to substantial harms to Plaintiff as described in this complaint. Plaintiff has alleged above several alternatives to the 2019 Protocol, all of which would substantially reduce the identified harms.

239. The 2019 Protocol violates rights secured and guaranteed to Plaintiff by the Fifth and Eighth Amendments to the Constitution.

Count XI: First, Fifth, and Sixth Amendment Violations – Access to Counsel

240. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs of this complaint as if set forth in full below.

241. Prisoners have a right under the First and Fifth Amendment of the Constitution to access to the courts. *See*, *e.g.*, *Lewis v. Casey*, 518 U.S. 343, 350-51 (1996); *Wolff v. McDonnell*, 418 U.S. 539, 579 (1974). They are also entitled, under the Sixth Amendment, to have access to counsel at all "critical" stages of criminal proceedings. *United States v. Wade*, 388 U.S. 218, 227-28 (1967).

242. Prisoners have the right to appointed counsel throughout the execution procedure. *Harbison v. Bell*, 556 U.S. 180, 194 (2009). Moreover, prisoners are entitled to have access to such counsel in every proceeding subsequent to appointment, including during an execution. *See*, *e.g., In re Ohio Execution Protocol Litig.*, No. 2:11-CV-1016, 2018 WL 6529145, at *4-*5 (S.D. Ohio Dec. 12, 2018); *Cooey v. Strickland*, No. 2:4-CV-1156, 2011 WL 320166, at *5-*12 (S.D. Ohio Jan. 28, 2011).

243. The 2019 Protocol does not provide prisoners with access to counsel during the

execution. Nor does the 2008 Protocol. Therefore, under the 2019 Protocol, Plaintiff could be deprived of access to counsel immediately preceding and during the execution and would not be able to communicate with counsel regarding any problems, including constitutional violations.

244. In addition, the protocols do not permit witnesses (including attorneys) to view the setting of IVs, so those witnesses have no way of knowing if there are issues with the IV-setting process.

245. This deprivation of access to counsel violates the First, Fifth and Sixth Amendments of the U.S. Constitution.

VI.
Prayer for Relief

WHEREFORE, in order to prevent the violations of the First, Fifth, Sixth and Eighth Amendments of the U.S. Constitution and the federal statutes as alleged above, Plaintiff requests that the Court enter a judgment:

a. declaring that the Defendants' actions, practices, customs, and policies with regard to their means, methods, procedures, and customs regarding executions, and specifically the 2019 Protocol, are illegal and violate the First, Fifth, Sixth and Eighth Amendments of the U.S. Constitution and the APA;

b. vacating the 2019 Protocol and enjoining Defendants and all persons acting on their behalf from using the 2019 Protocol, or any revised

protocol that violates Plaintiff's rights and the law, for the same reasons challenged above;

c. granting such further relief as the Court deems just and proper.

Dated: 11/1/2019

Respectfully Submitted,

/s/ Jon Jeffress

Jon Jeffress
KaiserDillon PLLC
1099 14th Street NW
8th Floor West
Washington, DC 20005
Telephone - 202-640-2850
Email - jjeffress@kaiserdillon.com

Timothy Kane, Assistant Federal Defender
Shawn Nolan, Chief, Capital Habeas Unit
Federal Community Defender Office, E.D. Pa.
601 Walnut Street, Suite 545 West
Philadelphia, PA 19106
Telephone - 215-928-0520
Email – timothy_kane@fd.org
Email – shawn_nolan@fd.org

Counsel for Plaintiff Dustin Lee Honken

CERTIFICATE OF SERVICE

I certify that on November 1, 2019, a copy of the foregoing complaint and the exhibits thereto were filed using the CM/ECF system, which will then send notification of such filing to all counsel of record.

/s/ Jon Jeffress
Jon Jeffress
KaiserDillon PLLC
1099 14th Street NW
8th Floor West
Washington, DC 20005
Telephone - 202-640-2850
Email - jjeffress@kaiserdillon.com

Counsel for Plaintiff Dustin Lee Honken