APPENDIX A

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 20-5329 **September Term, 2020**

FILED ON: NOVEMBER 18, 2020

IN RE: IN THE MATTER OF THE FEDERAL BUREAU OF PRISONS' EXECUTION PROTOCOL CASES,

JAMES H. ROANE, JR., ET AL.,
APPELLANTS

v.

WILLIAM P. BARR, ATTORNEY GENERAL, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:19-mc-00145)

Before: MILLETT, PILLARD and RAO, *Circuit Judges*

JUDGMENT

This cause came on to be heard on the record on appeal from the United States District Court for the District of Columbia and was argued by counsel. Upon consideration thereof and of the emergency motion for stay of execution, the opposition thereto, and the reply, it is, in accordance with the opinion of the court filed herein this date,

ORDERED and **ADJUDGED** that the judgment of the District Court appealed from in this cause be affirmed in part, be reversed in part, and the case be remanded for further proceedings. It is

FURTHER ORDERED that the emergency motion for stay of execution be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/

Daniel J. Reidy
Deputy Clerk

Date: November 18, 2020

Opinion for the court Per Curiam.
Opinion concurring in part and dissenting in part filed by Circuit Judge Pillard.
Opinion concurring in part, concurring in the judgment, and dissenting in part filed by Circuit Judge Rao.

APPENDIX B

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 16, 2020 Decided November 18, 2020

No. 20-5329

IN RE: IN THE MATTER OF THE FEDERAL BUREAU OF PRISONS' EXECUTION PROTOCOL CASES,

JAMES H. ROANE, JR., ET AL.,
APPELLANTS

v.

WILLIAM P. BARR, ATTORNEY GENERAL, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:19-mc-00145)

Alexander C. Drylewski argued the cause for appellants. With him on the briefs were *Jonathan L. Marcus*, *Shawn Nolan*, *Jonathan C. Aminoff*, *Paul F. Enzinna*, *Ginger D. Anders*, *Jonathan S. Meltzer*, *Brendan Gants*, *Amy Lentz*, *Matthew Lawry*, *Gerald W. King, Jr.*, *Jeffrey Lyn Ertel*, and *Evan Miller*.

Melissa N. Patterson, Attorney, U.S. Department of Justice, argued the cause for the appellees. With her on the brief were *Jeffrey Bossert Clark*, Acting Assistant Attorney

General, *Sopan Joshi*, Senior Counsel to the Assistant Attorney General, and *Amanda L. Mundell*, Attorney.

Before: MILLETT, PILLARD and RAO, *Circuit Judges*.

Opinion for the Court filed PER CURIAM.

Opinion concurring in part and dissenting in part by *Circuit Judge* PILLARD.

Opinion concurring in part, concurring in the judgment, and dissenting in part filed by *Circuit Judge* RAO.

PER CURIAM: In July 2019, eight years after federal executions were put on hold due to the government's inability to acquire one of the drugs for its then existing lethal injection protocol, the Department of Justice announced a revised protocol for execution by lethal injection using a single drug, pentobarbital. Plaintiffs, thirteen federal death row inmates, promptly raised statutory and constitutional challenges to the government's revised protocol. In November 2019, the district court preliminarily enjoined the four then-scheduled executions while it (and, in turn, we) considered a pair of baseline legal challenges to the government's lethal injection protocol. When we held that the 2019 Protocol is exempt from notice and comment requirements under the Administrative Procedure Act (APA) and that the Federal Death Penalty Act (FDPA) does not require the federal government to follow execution procedures set forth in state execution protocols that are less formal than state statutes and regulations, we vacated those injunctions and remanded for the district court to consider the balance of plaintiffs' challenges. *See In re Federal Bureau of Prisons' Execution Protocol Cases* (*In re FBOP*), 955 F.3d 106 (D.C. Cir. 2020).

During the pendency of the litigation on those remaining claims, the government scheduled executions to take place within days or weeks of one another through the summer and fall. At the behest of plaintiffs with execution dates and unresolved challenges, the district court issued a series of injunctions barring the federal government from executing inmates whose pending claims it held were likely to succeed. Each of those injunctions was vacated by either this court or the Supreme Court, and the government has since executed seven inmates, six of whom were plaintiffs in this case at the time of their execution. In September, the district court resolved the plaintiffs' remaining claims. On November 3, 2020, the district court denied the Plaintiffs' motion to alter or amend the judgment under Rule 59(e).

The Plaintiffs then sought expedited review in this court of three of the district court's rulings, and two plaintiffs with upcoming execution dates moved for stays of execution pending appeal. We affirm the district court's grant of summary judgment to the defendants based on plaintiffs' new challenges to the FDPA, but we reverse its dismissal of the plaintiffs' Eighth Amendment challenge for failure to state a claim. We also hold that the district court should have ordered the 2019 Protocol to be set aside to the extent that it permits the use of unprescribed pentobarbital in a manner that violates the FDCA. But we affirm the district court's denial of a permanent injunction to remedy the FDCA violation.

I.

A.

In 1988, Congress reinstated the federal death penalty without specifying how executions were to be implemented. Five years later, in 1993, the Attorney General issued regulations to fill that gap. Those regulations provide that the

"method of execution" for a sentence of death is to be "intravenous injection of a lethal substance or substances in a quantity sufficient to cause death." 28 C.F.R. § 26.3(a)(4). The regulations include no details regarding the specific substances to be used or how those substances are to be chosen or administered. In 1994, Congress enacted the Federal Death Penalty Act (FDPA), which states that federal executions are to be implemented "in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a). The FDPA and the Attorney General's regulations remain the federal law governing executions by the United States. *See* Manner of Federal Executions, 854 Fed. Reg. 47,324, 47,325-26 (2020).

Between 2001 and 2003, the federal government carried out its first three executions since the death penalty was reinstated. *See In re Federal Bureau of Prisons' Execution Protocol Cases* (*In re FBOP*), 955 F.3d 106, 110 (D.C. Cir. 2020). The method of execution for each was lethal injection using a combination of three substances—sodium thiopental, pancuronium bromide, and potassium chloride. *Id.* In 2005, three death row inmates filed suit in the District Court for the District of Columbia alleging they were to be executed under a protocol that violated the Constitution and the APA. *See* Complaint at 30-36, *Roane v. Gonzales*, 05-cv-2337 (D.D.C. Dec. 6, 2005); *see also* Amended Complaint at 28-32, *Roane*, 05-cv-2337 (July 10, 2006) The court granted motions by the three original plaintiffs and several plaintiffs who intervened for preliminary injunctions barring their executions. *See, e.g.*, Order at 1, *Roane*, 05-cv-2337 (D.D.C. June 30, 2006); Minute Order, *Roane*, 05-cv-2337 (D.D.C. Feb. 14, 2007); Order at 1, *Roane*, 05-cv-2337 (D.D.C. Feb. 21, 2007). During the litigation, the government produced a 50-page protocol, first adopted in 2004, detailing the procedures for carrying out executions, including admitting witnesses to the execution,

providing for the prisoner's final meal, and permitting statements, among many other things. *In re FBOP*, 955 F.3d at 110. In 2008, the government produced an addendum to the 2004 Protocol specifying that the method of execution would be by lethal injection using the same three-drug protocol the government used in the executions between 2001 and 2003. *See In re FBOP*, 955 F.3d at 110. That same year, the Supreme Court rejected an Eighth Amendment challenge to Kentucky's use of the same three substances for execution by lethal injection. *See Baze v. Rees*, 553 U.S. 35, 53-54 (2008). In 2011, however, the government announced it was unable to procure sodium thiopental, one of the drugs required to carry out an execution under its existing protocol. At that point, at least two cases involving method-of-execution challenges were pending in the district court and two more were filed shortly thereafter. *See Roane*, 05-cv-2337; *Robinson v. Mukasey*, 05-cv-2145 (D.D.C.); *Bourgeois v. Dep't of Justice*, 12-cv-782 (D.D.C.); *Fulks v. Dep't of Justice*, 13-cv-938 (D.D.C.). All four were put on hold pending the government's issuance of a revised protocol.

On July 25, 2019, eight years after announcing the unavailability of sodium thiopental, the Department of Justice announced its revised protocol, referred to in this litigation as the 2019 Protocol. A two-page addendum to the 2019 Protocol makes pentobarbital, a barbiturate, the sole drug to be used in federal executions. *See In re FBOP*, 955 F.3d at 110. On the same day that it announced the 2019 Protocol, the government also announced scheduled execution dates in December 2019 and January 2020 for five inmates on death row.

In response to the government's notification of its revised protocol, the district court scheduled a status conference in the four pending cases for August 15 of last year and consolidated the cases five days later. *See* Minute Order, *Roane*, 05-cv-2337

(Aug. 5, 2019). Because the execution date of one of the plaintiffs before the court, Alfred Bourgeois, had been scheduled for January 13, 2020, the district court asked the government at the scheduling conference if it was willing to stay Bourgeois's execution pending the resolution of his case. *See* Status Hr'g Tr. 6, *supra*. The government stated that it did not intend to stay the execution date, so the district court proceeded to set an expedited schedule, requiring an amended complaint by the end of March. *Id.* at 19; *see* Fed. R. Civ. P. 30(b)(6). On March 18, the parties jointly requested that the court extend by 60 days the deadline for plaintiffs' amended complaint because of the disruptions the COVID-19 outbreak had caused in plaintiffs' efforts to complete pre-amendment discovery. The court granted that request the next day and set a briefing schedule for dispositive motions extending from July to December. *See* Minute Order, *In re FBOP*, No. 19-mc-145 (D.D.C. Mar. 18, 2020).

In the meantime, plaintiffs with execution dates in December and January sought to enjoin their executions until their pending claims could be resolved. Three of the inmates with scheduled execution dates—Daniel Lee, Wesley Purkey, and Dustin Honken—had intervened in the master case in the months after the protocol was announced. Those three plaintiffs and Bourgeois all moved for preliminary injunctions, which the district court granted in November 2019. *See* Memorandum Opinion, *In re FBOP*, No. 19-mc-145 (D.D.C. Nov. 20, 2019), ECF No. 50. The court found that plaintiffs had shown a likelihood of success on their claim that the 2019 Protocol exceeded the government's statutory authority under the FDPA but it did not reach any of the plaintiffs' other claims. *Id.* at 13, 15. Both this court and the Supreme Court denied the government's motion to stay the district court's preliminary injunction. *See* Order, *In re FBOP*, No. 19-5322 (D.C. Cir. Dec. 2, 2019); *Barr v. Roane*, 140 S. Ct. 353 (2019) (mem.).

On April 6, 2020, in a divided opinion, this court vacated the district court's injunction and reversed its FDPA ruling on the merits. *See In re FBOP*, 955 F.3d 106. We denied plaintiffs' petition for rehearing *en banc* on May 15, and the Supreme Court denied their petition for writ of certiorari on June 29. *See Bourgeois v. Barr*, No. 19A1050, 2020 WL 3492763 (U.S. June 29, 2020) (mem.).

On June 15, with the preliminary injunction on the FDPA claim vacated, but prior to briefing on the merits of plaintiffs' other claims, the government set new execution dates in July and August for four of the plaintiffs in this case—Lee, Purkey, Honken, and Keith Nelson. Four days later, those same plaintiffs moved for a preliminary injunction. *See* Plaintiffs' Motion for a Preliminary Injunction, *In re FBOP*, No. 19-mc-145 (D.D.C. June 19, 2020), ECF No. 102. On July 13, the day the first of these four plaintiffs, Lee, was scheduled to be executed, the district court preliminary enjoined the executions, concluding that plaintiffs were likely to succeed on the merits of their Eighth Amendment challenge to the 2019 Protocol. *See* Memorandum and Opinion, *In re FBOP*, No. 19-mc-145, 2020 WL 3960928 (D.D.C. July 13, 2020). Later that day, this court denied the government's motion for a stay of the injunction, concluding it had not demonstrated a likelihood of success on its claim that the district court abused its discretion. *See* Order, No. 20-5199 (D.C. Cir. July 13, 2020). We ordered that the appeal be expedited and set a briefing schedule with a final deadline of July 24. In the early morning hours of July 14, however, the Supreme Court vacated the district court's preliminary injunction, holding that the plaintiffs had failed to establish a likelihood of success on the merits of their Eighth Amendment claim. *Barr v. Lee*, 140 S. Ct. 2590 (2020). The government executed Lee that same day.

The second of the four plaintiffs with a scheduled execution date, Purkey, was scheduled to be executed the next day, July 15, and the third of the four plaintiffs, Honken, was scheduled to be executed on July 17. Plaintiffs thus requested on July 15 that the district court issue a preliminary injunction on the remaining grounds they had asserted in their June 19 motion. *See* Plaintiffs' Emergency Notice Requesting Ruling on Pending Motion, *In re FBOP*, No. 19-mc-145 (D.D.C. July 15, 2020), ECF No. 144. On July 15, prior to Purkey's execution, the district court issued another preliminary injunction, finding that plaintiffs were likely to succeed on the merits of their claim that the 2019 Protocol violates the FDCA. *See* Order, *In re FBOP*, No. 19-mc-145 (D.D.C. July 15, 2020), ECF Nos. 145, 146. Late on July 15, this court denied the government's motion for a stay pending appeal, holding that the government had not demonstrated a likelihood of success on the merits of its claim that the 2019 Protocol comports with the FDCA. *See* Order, *In re FBOP*, No. 20-5210 (D.C. Cir. July 15, 2020). In the early morning hours of July 16, however, the Supreme Court vacated the district court's injunction without addressing the merits of the FDCA claim or this court's order. *See Barr v. Purkey*, No. 20A10, 2020 WL 4006821 (U.S. July 16, 2020) (mem.). Purkey was executed later that day. Honken was executed on July 17, after this court denied his motion for a stay of execution pending appeal of the district court's denial of a preliminary injunction on several other claims. *See* Order, *In re FBOP*, No. 19-mc-145 (D.D.C. July 16, 2020), ECF No. 166; *In re FBOP*, No. 5206 (D.C. Cir. July 17, 2020).

Alongside the litigation over the stays of the executions that summer, proceedings on the merits continued. In accordance with the district court's briefing schedule, the plaintiffs filed an amended complaint on June 1, and the government filed its dispositive motions on July 31. But

Nelson—then the only plaintiff left with a scheduled execution date (August 28)—filed an emergency motion to expedite a trial on the Eighth Amendment claim (on July 31) and for summary judgment on the FDCA claim (on August 4). The district court then changed course from its prior briefing schedule, which did not require plaintiffs to file any opposition and cross motions until the end of September, and instead required that by August 10 plaintiffs respond to the government's dispositive motions and the government respond to Nelson's emergency motion for summary judgment on the FDCA claim. On August 15, the district court granted the government's motion to dismiss the Eighth Amendment claim in light of the Supreme Court's July 15 decision, *Barr v. Lee*, vacating the preliminary injunction the district court had earlier issued on the Eighth Amendment claim. Order, *In re FBOP*, No. 19-mc-145 (D.D.C. Aug. 15, 2020), ECF No. 193.

On August 25, this court denied Nelson's motion for a stay of execution pending appeal of the district court's dismissal, concluding that the record before the court contained no findings of fact that could distinguish Nelson's request for equitable relief from the request the Supreme Court rejected in *Lee*. *See* Order, *In re FBOP*, No. 20-5210 (D.C. Cir. July 15, 2020). On August 27, a day before Nelson's execution, the district court granted summary judgment to Nelson on the FDCA claim, enjoining the government from executing him. *See* Memorandum Opinion, *In re FBOP*, No. 19-mc-145 (D.D.C. Aug. 27, 2020), ECF No. 213. Later that same day this court granted the government's motion to vacate the district court's injunction, noting the court failed to include findings that irreparable injury would result from the FDCA violation. *See* Order, *In re FBOP*, No. 20-5260 (D.C. Cir. Aug. 27, 2020). On August 28, the district court denied Nelson's motion to clarify or amend its prior order. The government executed Nelson later that same day.

The district court's August decision granting judgment on the FDCA claim was limited to Nelson; on September 9 the remaining plaintiffs moved for summary judgment on the same ground. Included among the plaintiffs were Christopher Andrew Vialva and William LeCroy, who the government had announced on July 31 would be executed on September 22 and 24, respectively. In their September 9 motion, the plaintiffs argued that violations of the FDCA would subject them to irreparable harm, noting that the rush of litigation before Nelson's execution had prevented him from making the same showing. *See* Plaintiffs' Motion for Partial Summary Judgment and Permanent Injunction, *In re FBOP*, No. 19-mc-145 (D.D.C. Sept. 9, 2020), ECF No. 236. The district court held an evidentiary hearing on September 18 and 19 on the FDCA claim.

On September 20, the district court issued an order entering final judgment on the remaining claims in the case. *See* Memorandum Opinion, *In re FBOP*, No. 19-mc-145 (D.D.C. Sept. 20, 2020), ECF No. 261. The court granted summary judgment to the plaintiffs on the FDCA claim, as it had to Holder in August, but denied a preliminary injunction, holding that plaintiffs failed to establish irreparable harm. The court ruled in favor of the government on all other claims, including a claim that the 2019 Protocol violated the FDPA. It also vacated preliminary injunctions that it had issued between 2005 and 2007, during challenges to the prior three-drug protocol, that continued to bar the executions of several plaintiffs in this case. LeCroy was executed on September 22 and Vialva was executed on September 24.

Four days later, on September 30, the government set November 19 as the execution date for Orlando Hall, one of the plaintiffs whose execution the court had previously enjoined. On October 16, it set December 10 as the execution date for

Brandon Bernard. On November 4, the day after the district court denied their motions to alter or amend its judgment on their Eighth Amendment, FDCA, and FDPA claims, plaintiffs filed this appeal. They moved to expedite briefing and oral argument two days later, noting the upcoming executions of Hall and Bernard. On November 10, Hall and Bernard filed an emergency motion for stay of execution pending appeal. We expedited briefing on both the merits appeal and the stay motion and heard oral argument on November 16.

B.

The Bureau of Prisons developed its 2019 Protocol through review of state practices and in consultation with medical professionals. *See* Administrative Record at PDF 6, *In re FBOP*, No. 19-mc-145 (D.D.C. Nov. 13, 2019), ECF No. 39-1**.** Like the federal government, at least 30 states previously had lethal injection protocols in place that used three drugs: sodium thiopental, "a fast-acting barbiturate sedative that induces a deep, comalike unconsciousness when given in the amounts used for lethal injection," pancuronium bromide, "a paralytic agent that inhibits all muscular-skeletal movements and, by paralyzing the diaphragm, stops respiration," and potassium chloride, which "interferes with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest." *See Baze v. Rees*, 553 U.S. 35, 44 (2008). When sodium thiopental became unavailable, states began using pentobarbital, another barbiturate, instead. *See Glossip v. Gross*, 576 U.S. 863, 871 (2015). Some states use pentobarbital as part of a three-drug protocol, but others use it as a single-drug protocol. Administrative Record at PDF 6.

The Bureau of Prisons also decided to use pentobarbital after locating "a viable source" for the drug. *Id.* at PDF 9. It elected a single-drug protocol because of the "complications

inherent in obtaining multiple drugs," the superior "effien[cy]" of acquiring and storing a single drug, and the "reduce[d] . . . risk of errors" in administration of a single drug. *Id.* at PDF 7. The protocol provides for three injections—two containing 2.5 grams of pentobarbital in 50 milliliters of diluent and the third containing 60 milliliters of a saline flush. *Id.* at PDF 1075. According to the Bureau, two medical experts whom it asked to review its protocol concluded that it "would produce a humane death." *Id.* at PDF 8. The Supreme Court rejected an as-applied challenge to Missouri's one-drug pentobarbital protocol last year. *See Bucklew v. Precythe*, 139 S. Ct. 1112 (2019). The Court held that the inmate at issue, who had a medical condition he argued would prevent the drug from working properly, failed to present a viable alternative to the protocol, as required by its precedent. *Id.* at 1129-33; *see also id.* at 1135-36 (Kavanaugh, J., concurring).

Plaintiffs in this case have presented evidence indicating that use of pentobarbital in executions causes inmates to experience "flash pulmonary edema," a medical condition in which fluid rapidly accumulates in the lungs, causing respiratory distress and "sensations of drowning and asphyxiation," which in turn induce "extreme pain, terror and panic" comparable to death by drowning. J.A. 346. Medical experts cited by the plaintiffs have concluded based on autopsy reports that it is very likely inmates will experience such pain and distress before they are rendered insensate. Plaintiffs also point to many autopsies revealing froth or foam trapped in the airways, which they say demonstrates that edema began while the deceased was still attempting to draw breath. J.A. 346-48. And one of the plaintiffs' experts found it is a "virtual medical certainty that most, if not all, prisoners executed with a single dose of pentobarbital . . . experienced 'immediate, flash pulmonary edema.'" J.A. 347.

Plaintiffs have bolstered their claims with witness reports from executions, J.A. 348, including those of Lee, Honken, and Purkey, J.A. 122, as well as the results of an autopsy of Purkey, concluding that all suggest those plaintiffs experienced symptoms of pulmonary edema. The government has not contested that most individuals who are executed through the lethal injection of pentobarbital experience flash pulmonary edema but they have submitted competing expert testimony suggesting that the condition occurs only after the inmate has been rendered insensate. One of its experts has stated that "[t]here is no way to determine based on autopsy findings how quickly the pulmonary edema occurred." J.A. 121. Allegations regarding flash pulmonary edema were not, we note, before the Supreme Court in *Bucklew*.

II.

A.

The Plaintiffs challenge the district court's dismissal under Federal Rule of Civil Procedure 12(b)(6) of their Eighth Amendment claims. Order at 5 n.1, *In re FBOP*, No. 19-mc-145-TSC (D.D.C. Aug. 15, 2020), ECF No. 193; Order at 14–15, *In re FBOP*, No. 19-mc-145-TSC (D.D.C. Sept. 20, 2020), ECF No. 261. To survive a motion to dismiss under Rule 12(b)(6), the complaint must allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). That standard is met if the complaint's factual allegations support a "reasonable inference" that the defendant is liable for the challenged conduct. *Id.* In evaluating the complaint, the court must take as true all plausible factual allegations and reasonable inferences drawn from them. *Banneker Ventures, LLC v. Graham*, 798 F.3d 1119, 1129 (D.C. Cir. 2015).

The Eighth Amendment sets a "high bar" for challenges to the government's mode of implementing the death penalty. *Barr v. Lee*, 140 S. Ct. 2590, 2591 (2020) (per curiam). So to properly make out an Eighth Amendment claim that the government's chosen method of execution is "cruel and unusual," U.S. CONST. AMEND. VIII, plaintiffs first must allege that the execution method is "*sure or very likely* to cause serious illness and needless suffering," and "give rise to sufficiently *imminent* dangers." *Glossip v. Gross*, 576 U.S. 863, 877 (2015) (formatting modified; quoting *Baze v. Rees*, 553 U.S. 35, 50 (2008) (opinion of Roberts, C.J.)). Specifically, the complaint must allege either a "substantial risk of serious harm" that is "objectively intolerable," or a "demonstrated risk of severe pain." *Id.* at 877–878 (internal quotation marks omitted).

In addition, the complaint must show that the risk of this harm is "substantial when compared to the known and available alternatives." *Glossip*, 576 U.S. at 878 (quoting *Baze*, 553 U.S. at 61 (opinion of Roberts, C.J.)). The Supreme Court has described this inquiry as comparative—it is necessary to identify when pain caused by a method of execution is "gratuitous" given other methods available to the government. *Bucklew v. Precythe*, 139 S. Ct. 1112, 1126 (2019).

Finally, the complaint must "identify an alternative" method that "is feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain." *Glossip*, 576 U.S. at 877 (internal quotation marks omitted) (quoting *Baze*, 553 U.S. at 52 (opinion of Roberts, C.J.)). If the complaint makes each of those showings, the government cannot refuse to implement the plaintiffs' suggested alternative without a legitimate penological reason. *Bucklew*, 139 S. Ct. at 1125.

Taking the factual allegations as true, the Plaintiffs' amended complaint meets that strict test. The complaint and incorporated declarations allege that, in the "vast majority, if not all" executions using only pentobarbital, the large dosage injected will cause flash pulmonary edema—the rapid accumulation of fluid in the lungs. J.A. 345 ¶ 76, 347 ¶ 79. More specifically, because of its high pH, pentobarbital is corrosive. J.A. 345–346 ¶ 76. So when it makes physical contact with the lungs, it dissolves natural barriers in the body, causing bodily fluid to course into the airways. J.A. 346 ¶ 76. As these fluids flood into the lungs, and as the individual struggles to breathe, the edema creates a foam that fills and blocks the airways. J.A. 346 ¶ 77. The body's efforts to dislodge the painful obstruction only compounds the problem—the lungs' effort to dislodge the foam merely causes them to suck in even more fluid. J.A. 346 ¶ 77.

The complaint further alleges that the pulmonary edema will occur "virtually instantaneously" upon administration of the pentobarbital, J.A. 345 ¶ 76 (formatting modified), at a time when the inmate is still "capable of feeling pain, terror, and suffocation," J.A. 347 ¶ 80. As a result, it is "extremely likely," to the point of "virtual medical certainty," that "most, if not all, prisoners will experience excruciating suffering, including sensations of drowning and suffocation" during the lethal injection process. J.A. 347 ¶ 80. That is so, the complaint alleges, because barbiturates like pentobarbital "'do not guarantee lack of consciousness," but instead can "produce[] only unresponsiveness, not unconsciousness or lack of awareness." J.A. 345 ¶ 74. In that way, the lethal injection procedure causes "extreme pain, terror and panic," because "[n]ot being able to breathe during drowning or asphyxiation is one of the most powerful, excruciating feelings known" to humans. J.A. 346 ¶ 78. While not necessary at the pleading stage, the amended complaint plausibly substantiates its

allegations with the declarations of multiple expert witnesses and eyewitness testimony from executions that employed the pentobarbital-only execution method. *See, e.g.*, J.A. 345–350, 360–361.

The complaint adds that this extreme suffering could easily be avoided by providing the inmate a pre-pentobarbital dose of a pain-relieving anesthetic drug, such as, for example, fentanyl, which is alleged to be readily available to the government. J.A. 360–361 ¶ 114. According to the complaint, the Bureau of Prisons itself has acknowledged that many companies manufacture fentanyl in the United States and could provide the drug for executions. J.A. 361 ¶ 114(a). In fact, Plaintiffs allege that the Bureau of Prisons has located a lawfully licensed compounding pharmacy that is both "able and willing" to compound fentanyl for the Bureau as needed. J.A. 361 ¶ 114(a).

Equally importantly, the complaint does not invoke a novel or "untried and untested" mode of execution. *Bucklew*, 139 S. Ct. at 1130 (internal citations omitted). The combination of drugs as part of lethal injection protocols has been used by both states and the federal government, and is still used in a number of jurisdictions. *See, e.g.*, J.A. 384–388; *Glossip*, 576 U.S. at 869. The two-drug protocol also fits squarely within the plain text of the federal execution protocol, which provides that the method of execution is the "intravenous injection of a lethal substance or substances[.]" 28 C.F.R. § 26.3(a)(4). To be sure, Plaintiffs propose using two drugs rather than the three drugs used in many capital-punishment jurisdictions. But that change *eases* the logistics of known protocols, and does so by adding a commonly used and available pain reliever.

By pleading that the federal government's execution protocol involves a "virtual medical certainty" of severe and torturous pain that is unnecessary to the death process and could readily be avoided by administering a widely available analgesic first, the Plaintiffs' complaint properly and plausibly states an Eighth Amendment claim. *See Glossip*, 576 U.S. at 877–878.

Whether Plaintiffs will ultimately be able to climb the Eighth Amendment's high constitutional mountain of proof is not the question for today. *See Bucklew*, 139 S. Ct. at 1124 (noting that the Supreme Court "has yet to hold that a State's method of execution qualifies as cruel and unusual"). The only issue before us it whether the Plaintiffs have plausibly alleged the critical elements of a successful Eighth Amendment claim. Plaintiffs' complaint hurdles that bar.

B.

The district court's dismissal of the complaint rested on two critical legal errors.

First, the district court misread the Supreme Court's per curiam decision in *Lee*, 140 S. Ct. 2590, as holding that, "absent particular medical circumstances, the use of pentobarbital will withstand Eighth Amendment scrutiny, no matter the evidence of excruciating pain." Order at 5, *Fed. Bureau. of Prisons' Execution Protocol Cases*, No. 19-mc-145-TSC (D.D.C. Aug. 15, 2020), ECF No. 193; *see also* Order at 2, *Fed. Bureau of Prisons' Execution Protocol Cases*, No. 19-mc-145-TSC (D.D.C. Nov. 3, 2020), ECF No. 305. The district court, in other words, ruled that whatever pain is caused by pulmonary edema arising from pentobarbital injections is a type of pain that is categorically permissible under the Eighth Amendment. The court added that, under its reading of *Lee*, "no amount of new evidence will suffice to prove that the pain

pentobarbital causes reaches unconstitutional levels." Order at 4, *In re FBOP*, No. 19-mc-145-TSC (D.D.C. Aug. 15, 2020), ECF No. 193; Order at 14, *In re FBOP*, No. 19-mc-145-TSC (D.D.C. Sept. 20, 2020), ECF No. 261.

Lee did not hold that the Eighth Amendment turns its back on needless and extreme suffering as long as it is caused by flash pulmonary edema. For starters, *Lee* involved an entirely different legal question. The Supreme Court's decision there arose not out of a motion to dismiss, but Lee's motion for a preliminary injunction, which is "an extraordinary remedy that may only be awarded upon a clear showing that plaintiffs are entitled to such relief." *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 22 (2008). To obtain a preliminary injunction, Lee had to show that he was "likely to succeed on the merits, that he [was] likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tip[ped] in his favor, and that an injunction [was] in the public interest." *Id*. at 20.

That is a decidedly far more searching inquiry than the question of whether a complaint properly alleges a claim for relief. There is nothing "extraordinary" about surviving a Rule 12(b)(6) motion to dismiss. Quite the opposite, the plaintiff enjoys the benefit of having all plausible allegations and reasonable inferences from those facts taken in favor of sustaining the complaint. *See Warth v. Seldin*, 422 U.S. 490, 501 (1975); *see Iqbal*, 556 U.S. at 678. Nor must plaintiffs show a likelihood of success at this stage. They simply must show that their claim is plausible. *Iqbal*, 556 U.S. at 678.

That means that all we are deciding at this stage is whether the complaint contains the necessary factual allegations to state a legal claim for relief, and so to open the courthouse doors to the Plaintiffs. That is a far distant inquiry from Lee's request

that a court take the extraordinary step of affirmatively proscribing a party's behavior before adjudicating its rights.

Second, and relatedly, the court erred in concluding that *Lee* forevermore categorically exempted the federal government's execution protocol from Eighth Amendment scrutiny even if it were found to unnecessarily and unreasonably inflict an "excruciating" death. Order at 5, *Fed. Bureau of Prisons' Execution Protocol Cases*, No. 19-mc-145-TSC (D.D.C. Aug. 15, 2020), ECF No. 193. Indeed, the district court went so far as to say that the Supreme Court in *Lee* "found no viable Eighth Amendment challenge." Order at 3, *Fed. Bureau of Prisons' Execution Protocol Cases*, No. 19-mc-145-TSC (D.D.C. Nov. 3, 2020), ECF No. 305.

Not so. Nothing in the Supreme Court's decision purported to vastly overshoot the question of whether a stay of execution should issue and entered a final ruling on the merits of the case. Rather, all that the Supreme Court said in *Lee* was that, under the demanding preliminary-injunction standard and before any conclusive factual findings could be made in the case, "competing expert testimony" over whether pulmonary edema occurs before or after the inmate is rendered insensate would not by itself support a "last-minute" stay of execution. *Lee*, 140 S. Ct. at 2591. Nothing in that ruling addressed the ability of a well-pleaded complaint to go forward for discovery and fact finding in the normal course, and it certainly did not *sua sponte* enter final judgment in the case. More to the point, if the government's pentobarbital protocol were constitutional as a matter of law no matter what facts and science might show and regardless of whether every element of an Eighth Amendment violation were proven, there would have been no need for the Court to even mention the government's competing evidence.

The government points to *Baze*, *Glossip*, and *Bucklew* as establishing the constitutionality of its protocol as a matter of law. But none of these cases involved the federal government's execution scheme *see Baze*, 553 U.S. at 40–41 (opinion of Roberts, C.J.) (Kentucky death-penalty protocol); *Glossip*, 576 U.S. at 872–873 (Oklahoma death-penalty protocol), and therefore those cases do not predetermine the outcome here. *Bucklew* was an as-applied challenge to Missouri's death-penalty protocol arguing that the inmate's unique medical condition rendered the use of pentobarbital cruel and unusual even in the absence of a viable alternative form of execution. 139 S. Ct. at 1121.

To be sure, those cases collectively mark out the difficult task ahead for Plaintiffs on the merits. And the government is correct (Br. 21) that, if all that Plaintiffs can produce at summary judgment is a "scientific controvers[y]" between credible experts battling between "marginally safer alternative[s]," their claim is likely to fail on the merits. *See Baze*, 553 U.S. at 51 (opinion of Roberts, C.J.). But not one of those cases altered the rules governing a motion to dismiss and, in fact, each one allowed the complaints to proceed past the pleading stage. *See Bucklew*, 139 S. Ct. at 1129 (granting summary judgment for the government after discovery); *Glossip*, 576 U.S. at 874 (rejecting claim after discovery and evidentiary hearing); *Baze*, 553 U.S. at 46 (opinion of Roberts, C.J.) (rejecting claim after a "7-day bench trial"). Applying settled law, we do the same.

Contrary to the district court's suggestion, at this early procedural stage of litigation, the Plaintiffs do not need to prove entirely uniform scientific consensus or that every execution carried out using pentobarbital in the past was unconstitutional. *See* Order at 7, *Fed. Bureau of Prisons' Execution Protocol Cases*, No. 19-mc-145-TSC (D.D.C. Nov.

3, 2020), ECF No. 305. Nor do they need to show a likelihood of success on the merits. They only need to plausibly allege that the government's execution protocol will, without relevant penological justification, impose a substantial risk of severe pain and suffering that is needless given a readily available, administrable, and known alternative. This complaint does that. The Supreme Court has not said otherwise. The order of dismissal is reversed.

C.

Plaintiffs Hall and Bernard also request that their stay be granted on the grounds that they are likely to succeed on the merits of their Eighth Amendment claim. Plaintiffs argue that the holding in *Lee* was limited only to last-minute stays of execution. This Court declined to enjoin a previous execution based on the exact same Eighth Amendment claim Plaintiffs put forward here. Order, *In the Matter of the Fed. Bureau of Prisons' Execution Protocol Case*, No. 20-5252 (D.C. Cir. Aug. 25, 2020). Because Plaintiffs are unable to distinguish that precedent, their request for a stay of execution based on the Eighth Amendment claim is denied.

III.

A.

The district court granted the Plaintiffs partial summary judgment on their claim that the government's execution protocol is contrary to law in violation of the Administrative Procedure Act to the extent that it allows the dispensing and injection of pentobarbital without the prescription required by the FDCA, 21 U.S.C. § 353(b)(1)(B); *see also* Memorandum Opinion at 32-33, *In re FBOP*, No. 19-mc-145 (D.D.C. Sept. 20, 2020), ECF No. 261; Memorandum Opinion at 6-10, *In re FBOP*, No. 19-mc-145 (D.D.C. Aug. 27, 2020), ECF No. 213.

At the same time, the district court denied Plaintiffs' motion to enjoin their executions pending the government's compliance with the FDCA on the ground that they had not shown a likelihood of suffering irreparable harm due to the absence of a prescription. On appeal, the Plaintiffs argue that the court erred in failing both to set aside the Protocol and to enjoin the government from conducting plaintiffs' executions without first complying with the FDCA. The government, for its part, argues that the FDCA does not apply to the dispensing and administration of drugs for lethal injection and that the Plaintiffs lack a cause of action to enforce the FDCA. We agree that the district court should have ordered the protocol set aside only to the extent that it permits the dispensing and administration of pentobarbital without a prescription. But we deny the Plaintiffs' request for an injunction and the government's arguments, without having filed a cross-appeal, that the district court's FDCA holding should be reversed.

There is no dispute that pentobarbital is a drug regulated under the FDCA. *See* 21 U.S.C. § 321(g)(1). Nor is there any dispute that pentobarbital is the type of drug that the FDCA requires to be dispensed only through a prescription issued by a licensed medical professional. 21 U.S.C. § 353(b)(1)(B); *see* 21 C.F.R. Part 1306.[1] There likewise is no question that prisoners are generally entitled to the protections of the FDCA's prescription requirement. *See* 21 C.F.R. § 1301.23 (exempting Bureau of Prisons officials from registration requirement, while recognizing their obligations to comply

[1] A number of state laws protect their medical professionals who write prescriptions for FDCA-covered drugs to be used as part of an execution protocol. *See, e.g.*, GA. CODE ANN. § 42-5-36(d)(2); TENN. CODE ANN. § 10-7-504(h)(1); TEX. CRIM. PRO. CODE § 43.14(b).

with regulations governing the issuance and filling of prescriptions under 21 C.F.R. Part 1306).

The government nevertheless argues that when pentobarbital is dispensed and administered to a prisoner as part of a lethal injection, the FDCA falls away, invoking the Supreme Court's decision in *Gonzales v. Oregon*, 546 U.S. 243 (2006), and *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 133 (2000). The Supreme Court has never resolved "the thorny question of the FDA's jurisdiction" over the drugs used in lethal injections. *Heckler v. Chaney*, 470 U.S. 821, 828 (1985). But binding precedent in this circuit has. *See Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) (applying the FDCA's regulation of drug imports to a lethal injection drug); *Chaney v. Heckler*, 718 F.2d 1174, 1179-1182 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985); *Beaty v. FDA*, 853 F. Supp. 2d 30, 42-43 (D.D.C. 2012) (holding that the Food and Drug Administration's failure to apply the FDCA to lethal injection drugs "undermined the purpose of the [statute] and acted in a manner contrary to the public health," with the consequence that "prisoners on death row have an unnecessary risk that they will not be anesthetized properly prior to execution"), *aff'd in relevant part*, 733 F.3d 1 (D.C. Cir. 2013). That precedent binds this panel. *See LaShawn A. v. Barry*, 87 F.3d 1389, 1395 (D.C. Cir. 1996) (en banc).

The government also argues that the FDCA does not provide the inmates a right of action. That may well be true. But the Plaintiffs have sued under the APA, which entitles any person "suffering legal wrong because of agency action" to judicial review. 5 U.S.C. § 702. And binding circuit precedent recognizes that the APA provides a cause of action to review agency action in violation of the FDCA. *See Cook*, 733 F.3d at 10-11; *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 884–885 (D.C. Cir. 2004) (quoting *Purepac Pharm. Co. v.*

Thompson, 238 F. Supp. 2d 191, 212 (D.D.C. 2002)). The government also argues that 21 U.S.C. § 337 allows only the government to bring an enforcement proceeding. An APA suit to review agency action unlawfully taken against an individual is not a civil enforcement action, and that provision does not provide the type of comprehensive review scheme for those adversely affected by agency action that would displace the APA. *See Cook*, 733 F.3d at 10-11. *See generally Guerrero-Lasprilla v. Barr*, 140 S. Ct. 1062, 1069 (2020) ("Consider first a familiar principle of statutory construction: the presumption favoring judicial review of administrative action.") (citation and internal quotation marks omitted).

The Bureau of Prisons does not dispute that it fails to obtain prescriptions for the pentobarbital used in executions, nor does it deny that it does not intend to obtain prescriptions for the upcoming executions. Because, under binding circuit precedent, the FDCA applies when already-covered drugs like pentobarbital are used for lethal injections, the execution protocol as administered by the Federal Bureau of Prisons is "not in accordance with law" to the extent that it allows the dispensation and administration of pentobarbital without a prescription and must be "set aside" in that respect. 5 U.S.C. § 706(2).

B.

The district court, however, was correct to deny the entry of a permanent injunction. Success on an APA claim does not automatically entitle the prevailing party to a permanent injunction. Instead, the party must demonstrate that (i) "it has suffered an irreparable injury," (ii) "remedies available at law * * * are inadequate to compensate for that injury," (iii) the balance of hardships weighs in favor of an injunction, and (iv) "the public interest would not be disserved by a permanent

injunction." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 156-157 (2010) (quoting *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006)). To obtain an injunction, then, the prevailing party must demonstrate that it actually "has suffered," *id*., or is "likely to suffer irreparable harm," *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). The district court specifically found, however, that "the evidence in the record does not support Plaintiffs' contention that they are likely to suffer flash pulmonary edema while still conscious," Order at 39, *In re FBOP*, 1:19-mc-145-TSC (D.D.C. Sept. 20, 2020), ECF No. 261. The Plaintiffs have not identified before the district court or this court any other type of irreparable harm that would likely be suffered due to the unprescribed use of pentobarbital.

IV.

We hold that the district court did not err in granting summary judgment for the government on Plaintiffs' Federal Death Penalty Act ("FDPA") claim.[2] Plaintiffs had pointed to several alleged discrepancies between the 2019 Protocol and state statutes dictating different methods of execution or aspects of the execution process. Memorandum Opinion at 27-28, *In re FBOP*, 19-mc-145 (D.D.C. Sept. 20, 2020). The district court concluded that there was no conflict in this case,

[2] The government maintains that this court lacks jurisdiction to review the district court's order granting summary judgment because the district court had not, at the time of the notice of appeal, entered final judgment on its FDPA ruling. The district court has since entered partial final judgment on Plaintiffs' FDPA claim. Order, *In re FBOP*, No. 19-mc-145-TSC (D.D.C. Nov. 16, 2020), ECF No. 315. A Rule 54(b) judgment rendered after notice of appeal is filed is jurisdictionally permissible under our precedents. *See, e.g.*, *Outlaw v. Airtech Air Conditioning & Heating Inc.*, 412 F.3d 156 (D.C. Cir. 2005).

either because the government had committed to complying with the state statutes at issue or because no plaintiff had requested to be executed in accordance with them. *Id.* at 30-31. Upon a motion for reconsideration, the district court affirmed that decision, pointing out that Hall's request to be executed after 6 p.m. in accordance with Texas law had been granted so "Plaintiffs [had] failed to identify a statutory violation." Order at 9, *In re FBOP*, 19-mc-145 (D.D.C. Nov. 11, 2020). We agree.

In this expedited process, we are particularly mindful to decide no more than what is necessary to resolve the appeal. The government here argues that the district court erred in concluding that the Texas time-of-day provision is incorporated under the FDPA because this provision is not a "procedure[] that effectuate[s] the death." Appellee Br. 48 (quoting *In re FBOP*, 955 F.3d 106, 151 (D.C. Cir. 2020) (Tatel, J., dissenting)). As we agree with the district court that there is no live controversy, we find it unnecessary here to engage in a line-drawing exercise about whether a statute setting the time of execution is a procedure that implements "the sentence in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a).

Plaintiffs are correct that non-binding statements by a defendant are generally insufficient to moot an otherwise active controversy. *See United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953) ("Such a profession does not suffice to make a case moot although it is one of the factors to be considered in determining the appropriateness of granting an injunction against the now-discontinued acts."). But here we have not only a governmental agreement to comply, but also the absence of any concretely aggrieved plaintiff. Nonetheless, the government has affirmed it will comply with the Texas statute at issue and so Hall's request to be executed after 6 p.m. has

been granted. J.A. 135. It does not appear that Bernard has made the same request, but the government has indicated it will consider the request if made. In a case where no plaintiff has asserted a present denial of a desired state procedure, the mere possibility that the government may not comply with state procedures, without more, is insufficient to establish a statutory violation of the FDPA. *Cf. United States v. Mitchell*, 971 F.3d 993, 999 (9th Cir. 2020) ("It is not enough to show a 'mere possibility' that the Bureau of Prisons might use protocols inconsistent with [state] procedures." (citation omitted)).

* * *

For the foregoing reasons, the judgment of the district court is affirmed in part, reversed in part, and remanded for further proceedings consistent with this opinion.

So ordered.

PILLARD, *Circuit Judge*, concurring in part and dissenting in part: The court correctly holds that, because the 2019 Protocol calls for the use of pentobarbital unaccompanied by an FDCA-mandated prescription, it must be set aside as contrary to law under the APA. That conclusion alone requires a stay of the pending executions until the government complies. It is the government's prerogative to execute the plaintiffs by a method of its choosing. But if it elects a method subject to statutory requirements, the government must then abide by those requirements. The government could choose to execute plaintiffs by firing squad, for instance, assuming the method remained permissible under the Eighth Amendment. But if a federal statute required that members of a firing squad first be certified marksmen, the government could not execute a death row inmate until it ensured that the members of its firing squad were so certified.

Even if equitable relief is not necessary to pause the upcoming executions, however, it is my view that the district court also erred in denying plaintiffs an injunction preventing defendants from continuing to violate the FDCA. The district court denied the injunction for want of irreparable harm, and my colleagues affirm. Because I believe that error is of continued importance, I dissent from Part III.B of the opinion.

The FDCA is protective legislation. *See POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 115 ("[T]he FDCA protects public health and safety."). Its statutory safeguards exist to ensure that drugs are correctly administered and their potential adverse effects minimized, in light of current medical knowledge and the circumstances of the individual. *See Brown & Williamson*, 529 U.S. at 134 (noting FDA's mission includes "protect[ing] the public health by ensuring that . . . drugs are safe and effective" (citation omitted)). Its applicability does not depend on specific vulnerabilities of the recipients of controlled substances. Rather, it categorically imposes safety procedures to mitigate risk of bodily harm from the

administration of powerful medications with complex characteristics. Included among the statute's protections is its requirement that some drugs be dispensed only with a prescription from a medical professional. The government's decision to ignore such statutory protections subjects those affected to substantial and unnecessary risks of bodily injury, illness, and suffering. Unlike commercial harms, which are readily remedied by damages, harms to the body have long been treated as irreparable. Set aside for a moment the fact that the Plaintiffs here are on death row and that the medication at issue is intended to be used in lethal injections. A plan by the government to inject *anyone* with therapeutic, *non*-lethal drugs disbursed and administered in violation of the FDCA would pose precisely the type of health risks that the FDCA is intended to prevent. The fact that the government here proposes to engage in this conduct in the context of executions does not change the calculus—there remains the irreparable harm that is inherent in the administration of barbiturates without medical guidance. Certain risks against which the FDCA's requirements would ordinarily shield, like those to future health, are not relevant once an inmate is executed. But risks of potential physical degradation and a painful and prolonged dying process could be minimized were the government to follow the FDCA's mandates.

The district court did not question the type of harm in this case; after all, the Plaintiffs painted quite a clear picture of the damage flash pulmonary edema can do to an inmate during execution, and presented expert evidence that that damage is done while an inmate is still sensate. What the district court questioned was the likelihood of that harm. At one point in the court's order denying Plaintiffs their injunction, it faulted them for failing to show "that they *will suffer* irreparable injury," Order at 35, *In re FBOP*, 19-mc-145 (D.D.C. Sept. 20, 2020) (*quoting Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139,

162 (2010)). Later it suggested the problem was that they had not shown the harm was sufficient likely. But "[i]n the context of safety regulations, risk is itself the harm prohibited by law. Exposure to that harm thus is irreparable injury." *Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 614 & n. 39 (D.C. Cir. 1980). Consider an official agency policy of sending truck drivers out onto the roads without seatbelts, or of serving meats to employees stored at a temperature below what federal regulations require. In either of these cases the agency would be subject to an injunction without a further evidentiary showing of how likely it was that the drivers or diners were to be injured. Where a legal mandate protecting bodily health and safety is concerned, the law itself reflects the regulatory or legislative judgment that the driver and the diner are likely to suffer harm if that mandate is ignored.

I thus disagree that a certain showing of any one specific risk is required before a court can enjoin the government from continuing to disregarding health- and safety-related mandates. But assuming the Plaintiffs did have to show that the risks they expect to face from the government's refusal to comply with the FDCA, the record suggests the district court may erroneously equated the showing of irreparable harm sufficient to enjoin a violation of the FDCA with the showing needed to support injunctive relief on Eighth Amendment grounds. Before the Supreme Court's July decision in *Barr v. Lee*, 140 S. Ct. 2590 (2020), the district court found that Plaintiffs' evidence on the complaint alone "overwhelmingly indicate[d] that the 2019 Protocol is very likely to cause Plaintiffs extreme pain and needless suffering during their executions." Memorandum Opinion at 9-10, *In re FBOP*, 19-mc-145 (D.D.C. July 13, 2020), ECF No. 135. The court cited Plaintiffs' experts' declarations demonstrating "that the majority of inmates executed via pentobarbital injection suffered flash pulmonary edema during the procedure."

Memorandum Opinion at 9-10, *In re FBOP*, 19-mc-145 (D.D.C. July 13, 2020), ECF No. 135. Recognizing the key issue as timing—whether the inmates could feel the effects of flash pulmonary edema, as Plaintiffs alleged, or whether they were insensate when it occurred, as the government argued—the district court concluded the Plaintiffs had the better of the evidence. *Id.* at 12. Only after the Supreme Court vacated a preliminary injunction on Plaintiffs' Eighth Amendment claim did the district court find that Plaintiffs had failed to show irreparable harm. The court did initially enter an injunction on the FDCA violation, but it failed in that order to discuss irreparable harm, and we remanded its order on that ground that same day. The court then held an evidentiary hearing on the issue of irreparable harm and denied the injunction for want of a showing that Plaintiffs were "likely" to suffer flash pulmonary edema. Memorandum Opinion at 36, *In re FBOP*, 19-mc-145 (D.D.C. Sept. 20, 2020), ECF No. 261. Even then, however, the court "continue[d] to be concerned at the possibility that inmates will suffer excruciating pain during their executions." *Id.* at 36.

If the district court treated as interchangeable the evidentiary requirements for an injunction under the Constitution and the statute, that was legal error. According to Supreme Court precedent, the Eighth Amendment sets a constitutional floor on the pain and degradation to which a death row inmate may be subjected during an execution; it does not guarantee a prisoner a painless death. *Bucklew v. Precythe*, 139 S. Ct. 1112, 1124 (2019). The purpose of the statutory protections of the FDCA, in contrast, is to guard patients from various risks that medical guidance and supervision might eliminate. Thus, even where harms are not unconstitutional under the Eighth Amendment, they may nonetheless give rise to statutory violations under the FDCA entitling plaintiffs to redress. On their Eighth Amendment claim, plaintiffs must

demonstrate that their method of execution involves a "substantial risk of severe pain." *Glossip v. Gross*, 576 U.S. 863, 882 (2015). This necessarily means the Eighth Amendment permits at least methods of execution that impose a less-than-substantial risk of pain. But no similar threshold applies under the FDCA. Thus, while the evidence of flash pulmonary edema the plaintiffs brought to bear on their Eight Amendment claim may also bear on their FDCA claim, the statute guards against the risks of avoidable pain at lower levels as well.

I believe that the risk of harm flowing from the FDCA violation in this case readily meets the threshold for irreparable injury. In any event, the record suggests that the district court may have applied the threshold of expected harm required for an Eighth Amendment injunction to deny the injunction under the FDCA. Rather than affirming the denial of the FDCA injunction, we should have clarified the distinction and remanded to give the court an opportunity to reconsider whether the record supports enjoining the FDCA violation.

The government further asserts that, even assuming Plaintiffs have shown irreparable harm, the balance of equities and public interest weigh against an injunction barring them from executing additional Plaintiffs pending compliance with the FDCA. The district court did not reach these equities, but they merit comment as an important and recurring aspect of the plaintiffs' method-of-execution challenges.

The public interest as the government contends sees it requires adherence to the current execution schedule. Appellee Br. 39-40. It is our responsibility as courts "to ensure that method-of-execution challenges to lawfully issued sentences are resolved fairly and expeditiously." *Barr v. Lee*, 140 S. Ct. 2590, 2591 (2020) (citation omitted). But Plaintiffs have thus

far pressed their concededly nonfrivolous claims with dispatch, and the government has made no showing of delay that will result if they comply with the FDCA.

The government suggests that Plaintiffs' challenges "have already been the subject of multiple rounds of litigation," *id.* at 7, but the "rounds of litigation" to which it refers were the result of a series of individual plaintiffs each seeking to enjoin executions scheduled to take place before resolution of the merits of their promptly and plausibly pleaded claims. Plaintiffs sought those injunctions precisely so that they would have an opportunity to litigate their claims. The particular method of execution plaintiffs would face—including the extent to which it would be determined by state law—was only quite recently determined, *see In re FBOP Protocol Cases*, 955 F.3d at 110-11, and we recognized when we resolved those claims under the FDPA and APA that, "regardless of our disposition, several claims would remain open on remand." *Id.* at 113. Three of those claims are now before us. It is difficult to see what more plaintiffs might have done to obtain earlier rulings on the merits of their claims. Time that the government and the courts have reasonably required cannot weigh against plaintiffs' entitlement to a permanent injunction. And, for its part, the government has not introduced any evidence that it would be unable promptly to obtain a prescription if it sought to do so.

The public interest that the sentences be promptly carried out must be weighed against the public interest in adhering to applicable legal requirements, including the FDCA's controls on drug administration. And the Plaintiffs have aligned interests in avoiding the elevated risks of severe and gratuitous pain from administration of pentobarbital absent the requisite statutory safeguards. On this record, it would appear that Plaintiffs' interest in avoiding those elevated risks outweighs

the government's interest in proceeding with the executions as scheduled without obtaining the required prescriptions.

For these reasons, I would have reversed and remanded the district court's decision to deny injunctive relief for the FDCA violation.

RAO, *Circuit Judge*, concurring in part, concurring in the judgment, and dissenting in part: The district court held that the government's decision to administer pentobarbital for lethal injections without a prescription violates the Federal Food, Drug & Cosmetic Act ("FDCA") and so is contrary to law under the Administrative Procedure Act ("APA"). The district court also dismissed Plaintiffs' Eighth Amendment claim for failure to state a claim and granted summary judgment to the government on Plaintiffs' Federal Death Penalty Act ("FDPA") claim. The majority properly vacates the district court's dismissal of the Eighth Amendment claim and affirms the grant of summary judgment on the FDPA claim. The majority then concludes that binding circuit precedent mandates the application of the FDCA to drugs administered for capital punishment and orders the district court to set aside the Protocol under the APA until the government procures prescriptions for the lethal injection drugs. I disagree that this conclusion is required by our precedent. Moreover, application of the FDCA to drugs used in lethal injections is inconsistent with the statutory text and the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). In any event, Plaintiffs have no authority to challenge the Food and Drug Administration's decision not to enforce the FDCA in this context. *See Heckler v. Chaney*, 470 U.S. 821, 837–38 (1985). Accordingly, I respectfully concur in part, concur in the judgment, and dissent in part.

* * *

I agree with the majority that the district court correctly granted summary judgment for the government on the FDPA claim. I also concur in the judgment that the district court erred when it dismissed Plaintiffs' Eighth Amendment claim for failure to state a claim, FED. R. CIV. P. 12(b)(6). Plaintiffs needed only to plead factual allegations, accepted as true, sufficient to state a plausible claim that the government's protocol violates the Eighth Amendment. *See Ashcroft v. Iqbal*,

556 U.S. 662, 678 (2009); *accord Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). To constitute a violation of the Eighth Amendment based on the method of execution, the Supreme Court has held a plaintiff must establish that the method creates "a demonstrated risk of severe pain" and propose "an alternative that is feasible, readily implemented, and in fact significantly reduces a substantial risk of severe pain." *Glossip v. Gross*, 576 U.S. 863, 877–78 (2015) (cleaned up).

Plaintiffs' pleadings, taken as true, plausibly support the claim that the use of pentobarbital poses a demonstrated risk of severe pain. Yet after the Supreme Court held that Plaintiffs were unlikely to succeed on the merits of this claim in the context of preliminary injunctive relief, *see Barr v. Lee*, 140 S. Ct. 2590 (2020) (per curiam), the district court took that as a suggestion that the claim would fail and dismissed it. To be sure, Plaintiffs face an exceptionally high bar to succeed on the *merits* of their method-of-execution claim, as no such claim has yet to succeed at the Supreme Court. *See Bucklew v. Precythe*, 139 S. Ct. 1112, 1124 (2019); *see also Glossip*, 576 U.S. 877; *Baze v. Rees*, 553 U.S. 35 (2008). The Court has warned against "transform[ing] courts into boards of inquiry charged with determining 'best practices' for executions, with each ruling supplanted by another round of litigation touting a new and improved methodology." *Baze*, 553 U.S. at 51. In the current round of this litigation, it remains to be seen whether Plaintiffs can prevail on the merits of their Eighth Amendment claim, but the district court erred by dismissing the claim at the pleading stage. Because little more need be said on this error, I concur only in the judgment with respect to this issue.

* * *

I dissent with respect to the majority's holding that the 2019 Protocol should be set aside to the extent that it permits the use of pentobarbital for executions without a prescription. While we are bound by previous decisions of our circuit, no case conclusively holds that the FDCA regulates drugs when used for lethal injection in the course of an otherwise lawful execution. The majority relies on *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013); however, that case did not resolve the question of whether the FDCA applies to lethal injection drugs. Rather in *Cook*, the court accepted the FDA's concession that an imported lethal injection drug was an "unapproved new drug," and used that concession to conclude that the FDA was required to refuse admission to any foreign drug that appeared to violate FDCA provisions on misbranded and unapproved new drugs. *See id.* at 11 (cleaned up). Thus, we merely assumed the applicability of the FDCA to lethal injection drugs in the context of the FDA's enforcement obligations over foreign drugs imported to the United States. An assumption cannot bind us on this important question of statutory interpretation.[1] *See, e.g.*, *Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 170 (2004) ("Questions which merely lurk in the record, neither brought to the attention of the court nor ruled upon, are

[1] Neither am I persuaded by the district court's analysis of the question in *Cook*'s underlying proceeding, *Beaty*, 853 F. Supp. 2d at 42. The district court's holding that, by declining to apply the FDCA to lethal injection drugs, the FDA had "undermined the purpose of the [statute] and acted in a manner contrary to the public health," *id.*, significantly expanded the agency's jurisdiction, but did not explain how application of the FDCA to drugs obtained for lethal injection is consistent with the text of the FDCA and Supreme Court precedent.

not to be considered as having been so decided as to constitute precedents.") (quoting *Webster v. Fall*, 266 U.S. 507, 511 (1925)). Earlier in this litigation, this court concluded that the applicability of the FDCA was a necessary premise of the *Cook* decision. *See In re Federal Bureau of Prisons' Execution Protocol Cases*, No. 20-5206, slip op. at 3 (D.C. Cir. July 15, 2020). The district court had stayed Plaintiffs' executions, holding that they had demonstrated a likelihood of success on the merits of their FDCA claims; we refused to allow one of the executions to move forward, denying the government's motion for a stay pending appeal. *Id.* at 2. This court did not explicitly hold that the FDCA applies to drugs used in lethal injections. Instead, in the context of assessing whether the government had established a likelihood of success on the merits, we suggested that the government had not met the high bar to establish that *Brown & Williamson* should prevent the application of the FDCA. *Id*. at 3. The next day, the Supreme Court vacated the district court's injunction without comment. *Barr v. Purkey*, No. 20A10, 2020 WL 4006821, at *1 (U.S. July 16, 2020).

The majority also relies on this court's holding in *Chaney v. Heckler* for the proposition that the FDA has jurisdiction over drugs used for lethal injection. 718 F.2d 1174, 1179–82 (D.C. Cir. 1983), *rev'd*, 470 U.S. at 838. Even if the Supreme Court declined to resolve this question explicitly in *Heckler*, 470 U.S. at 828, our court's jurisdictional finding was based on the understanding that "Congress clearly intended that the [FDCA's] 'coverage be as broad as its literal language indicates,'" *Chaney*, 718 F.2d at 1179 (citation omitted). Our literal and expansive reading of the FDA's jurisdiction in *Chaney* conflicts with the Supreme Court's later decision in *Brown & Williamson*, which rejected a broad assertion of jurisdiction by the FDA over tobacco products and cautioned courts to read statutes in the context of other enacted laws to

ensure "a symmetrical and coherent regulatory scheme." *Brown & Williamson*, 529 U.S. at 133 (citation omitted). In sum, none of our earlier decisions mandate that we interpret the FDCA to require a prescription for the government's use of pentobarbital for lethal injections.

Therefore, I would proceed to address the statutory question directly. The government vigorously contests the applicability of the FDCA to drugs used in lethal injections, a question with significant implications for the administration of the death penalty by federal and state governments. The government maintains that, when a drug's intended use is to effectuate capital punishment by the federal government or a state, it is not subject to regulation under the FDCA. Appellees' Br. 26 (citing Whether the FDA Has Jurisdiction over Articles Intended for Use in Lawful Executions, slip op. O.L.C., 2019 WL 2235666 (May 3, 2019)). Squarely faced with a dispute over the meaning of the statute, I would proceed to interpret the text of the FDCA in a manner that comports with its structure and history, other significant laws enacted by Congress, and binding Supreme Court precedent. *See Brown & Williamson*, 529 U.S. at 133.

First, the FDCA grants the FDA the authority to regulate all "drugs" and "devices," which include, among other things, any "articles (other than food) intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(C). While the FDA's authority is expansive, it is not without limit. The Supreme Court has explained that we must understand this broad authority in light of specific provisions of the FDCA, as well as other statutory frameworks that might preclude jurisdiction even when it would otherwise appear to be included in the literal meaning of the FDCA. *See Brown & Williamson*, 529 U.S. at 133 ("[T]he meaning of one statute may be affected by other Acts, particularly where Congress has

spoken subsequently and more specifically to the topic at hand.").

Here, applying the requirements of the FDCA to lethal injection drugs does not cohere with the text and structure of the whole statute. In particular, Plaintiffs seek to require the government to obtain a prescription for the use of execution drugs. Section 353 of the FDCA, which requires an oral or written prescription for "[a] drug intended for use by man which (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, *is not safe for use* except under the supervision of a practitioner licensed by law to administer such drug; or (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A)–(B) (emphasis added). This language makes clear that the prescription requirement is designed with the therapeutic benefit of the patient in mind. The other relevant provisions identified by the district court—premarket approval by the FDA and labeling requirements—share this focus. Each of these provisions serves to protect the public by ensuring that a product is safe for its intended *therapeutic* use. Indeed, the Supreme Court has recognized that the FDCA "generally requires the FDA to prevent the marketing of any drug or device where the potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." *Brown & Williamson*, 529 U.S. at 134 (cleaned up); *see also United States v. Rutherford*, 442 U.S. 544, 555 (1979) ("[T]he Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use.").

By contrast, drugs used for the purpose of lethal injection have a certainty of inflicting death. There is no corresponding

therapeutic benefit of a drug used to administer a lethal injection in the context of capital punishment. To apply the FDCA's careful balancing of therapeutic risks and benefits to execution drugs would distort the Act's framework.

Moreover, such an expansive application of the FDCA would run headlong into the numerous statutes Congress has enacted providing for capital punishment. Since 1790, Congress has authorized the death penalty for various violations of federal law. *See, e.g.*, An Act for the Punishment of Certain Crimes § 33, 1 Stat. 112, 119 (Apr. 30, 1790); *see also* Act of June 19, 1937, ch. 367, 50 Stat. 304, 304 (repealed 1984). Most recently, Congress enacted the Federal Death Penalty Act of 1994, which reestablished the federal death penalty and provides for the U.S. marshal to "supervise implementation of the sentence in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a). In 1994, as today, lethal injection is one of the most common methods of execution and, in many States, the exclusive method of execution. The 1994 Act unambiguously assumes the continued availability of drugs necessary for execution by lethal injection.

The general terms of the FDCA cannot be reconciled with this separate and distinct scheme for capital punishment, reenacted by Congress against a background of expanding use of lethal injection by the States. *See Brown & Williamson*, 529 U.S. at 137 (finding relevant to the analysis that Congress had "foreclosed the removal of tobacco products from the market"). The majority's interpretation of the FDCA creates a significant and entirely novel impediment to this method of capital punishment, not only for federal executions, but also for State executions. Yet the Supreme Court has repeatedly upheld lethal injection as a constitutional method of execution. *See, e.g.*, *Baze v. Rees*, 553 U.S. 35, 40–41 (2008) (explaining that

the progress of states towards a more humane method of capital punishment "has led to the use of lethal injection by every jurisdiction that imposes the death penalty").

Furthermore, the FDA's longstanding policy of declining jurisdiction over lethal injection drugs reinforces the propriety of not extending the FDCA's requirements here. *See Brown & Williamson*, 529 U.S. at 146. The FDCA was enacted in 1938, Act of June 25, 1938, ch. 675, 52 Stat. 1040, and lethal injection has been used as a method of execution since the 1970s. From the first use of otherwise FDA-approved drugs in capital punishment, the FDA has not attempted to exercise jurisdiction over drugs or devices intended to carry out lawful sentences of capital punishment.[2] This commonsense approach is consistent with the overarching purpose of the FDCA—to ensure that drugs and devices in interstate commerce are safe and effective for their intended uses. The intended use of a drug or device in the capital punishment context is to end human life. It is "implausible … that the FDA is required to exercise its enforcement power to ensure that States only use drugs that

[2] After *Beaty* entered an injunction requiring the FDA to block foreign shipments of sodium thiopental, in 2015, the FDA blocked Texas's attempt to import the drug for use in capital punishment. *See* Letter from Todd W. Cato, Director, Southwest Import District Office at 1–2 (Apr. 20, 2017). The FDA expressly asserted jurisdiction over lethal injection drugs for the first time, but its decision was premised on the fact that Texas conceded that the sodium thiopental was a "drug" within the meaning of the FDCA, and that the "FDA is bound by the terms of the order issued" in *Beaty*. *Id.* The government's more recent, considered position is reflected in the 2019 Office of Legal Counsel Memorandum, Whether the FDA Has Jurisdiction over Articles Intended for Use in Lawful Executions, slip op. O.L.C., 2019 WL 2235666 (May 3, 2019).

are 'safe and effective' for human execution." *Heckler*, 470 U.S. at 827.

The district court here held that when "the government argues that a lethal injection drug is legally and constitutionally permissible because it will ensure a 'humane' death, it cannot then disclaim a responsibility to comply with federal statutes enacted to ensure that the drugs operate humanely." J.A. 558. This appears to conflate the general requirement that executions comport with the Eighth Amendment with the purpose of the FDCA to ensure that a product's anticipated therapeutic benefit outweighs its risk of harm. *See Brown & Williamson*, 529 U.S. at 140. The fact that executions should be carried out in a humane manner does not mean the FDCA applies. I express no opinion on the policy arguments regarding the purported advantages of requiring a prescription for lethal injection drugs—I simply do not think the FDCA includes such a requirement. Therefore Congress, rather than the courts, must decide how to resolve such policy questions in the sensitive area of capital punishment.

* * *

Even if the FDCA applied in this case, these Plaintiffs cannot challenge the FDA's nonenforcement decision. As the Court held in *Heckler*, the "FDA's decision not to take … enforcement action[]" to prevent the use of drugs intended for use in lethal injection is "not subject to judicial review under the APA." 470 U.S. at 837–38. The FDCA specifically confers such enforcement authority on the government. *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, *or to restrain violations*, of this chapter shall be by and in the name of the United States.") (emphasis added). This is not an enforcement proceeding, but it is an

attempt by the Plaintiffs to restrain violations of the FDCA. Section 337 gives that authority to the government.

Despite the absence of a private right of action in the FDCA, the district court held that the APA provides a private right of action for agency actions "not in accordance with law" under 5 U.S.C. § 706(2)(A). Mem. Op., *Roane v. Barr*, No. 19-mc-145, at *5 (ECF No. 213) (D.D.C. Aug. 27, 2020). Acknowledging that the FDCA does not contain a private right of action, the district court relied on *Chrysler Corp. v. Brown*, 441 U.S. 281, 316–18 (1979), to find that the APA could nonetheless supply what the statute lacked: a right to enforce the FDCA's premarketing, labeling, and prescription requirements against the federal government. Mem. Op. at *5.

The district court's holding appears to conflict with the Supreme Court's acknowledgement that an APA action is precluded by federal statutory schemes that foreclose private party enforcement. The APA confers a general cause of action upon persons "adversely affected or aggrieved by agency action within the meaning of a relevant statute," 5 U.S.C. § 702, but withdraws that cause of action to the extent the relevant statute "preclude[s] judicial review," 5 U.S.C. § 701(a)(1). *See Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 352–53 (1984) (holding that Congress intended to preclude consumer challenges to milk marketing orders and such a holding would not frustrate the statute's objectives). "Whether and to what extent a particular statute precludes judicial review" is by necessity a fact specific inquiry that turns on the express statutory language, structure, purpose, and history, and the nature of the administrative action involved. *Id.* at 345. It is not enough to assume, as the district court did, that the APA can provide the right of action here. Such an assumption is unwarranted under the FDCA, which places enforcement authority exclusively with the government. *Cf. Buckman Co. v.*

Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001); *Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013) ("Although citizens may petition the FDA to take administrative action … private enforcement of the statute is barred."). Because enforcement of the FDCA is committed to the government, private litigants cannot sue to enforce its provisions.

APPENDIX C

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*	)	Case No. 19-mc-145 (TSC)
THIS DOCUMENT RELATES TO:	)	
ALL CASES	)	

ORDER

Pursuant to Federal Rule of Civil Procedure 59(e), Plaintiffs have moved for alteration or amendment of: 1) the court's August 20, 2020 dismissal of Plaintiffs' Eighth Amendment claim (ECF No. 238); 2) the court's September 20, 2020 Order denying injunctive relief as to Plaintiffs' Food, Drug, and Cosmetic Act (FDCA) claims, (ECF No. 282); and 3) the court's September 20, 2020 entry of summary judgment in favor of Defendants as to Plaintiffs' Federal Death Penalty Act (FDPA) claims, (ECF No. 298). For the reasons set forth below, all three motions are DENIED.

I. LEGAL STANDARD

Federal Rule of Civil Procedure 59(e) permits a party to move to alter or amend a judgment "no later than 28 days after the entry of the judgment."[1] A motion under Rule 59(e) "is discretionary and need not be granted unless the district court finds that there is an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." *Firestone v. Firestone*, 76 F.3d 1205, 1208 (D.C. Cir.

[1] It is undisputed that Plaintiffs' motions are timely under Rule 59(e).

1996) (internal quotation marks omitted); *see also Leidos, Inc. v. Hellenic Republic*, 881 F.3d 213, 217 (D.C. Cir. 2018) (same). However, such a motion "may not be used to relitigate old matters, or to raise arguments or present evidence that could have been raised prior to the entry of judgment." *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 485 n.5 (2008).

II. EIGHTH AMENDMENT CLAIMS

On August 20, 2020, this court entered partial final judgment in favor of Defendants as to Plaintiff's Eighth Amendment claim in Count II of their Amended Complaint. Based on the Supreme Court's reasoning in *Barr v. Lee*, the court found that "[s]o long as pentobarbital is widely used . . . no amount of new evidence will suffice to prove that the pain pentobarbital causes reaches unconstitutional levels." (ECF No. 193, Aug. 15 Order at 4 (discussing *Barr v. Lee*, 140 S. Ct. 2590 (2020) (per curiam)).) This conclusion was premised, in part, on the Supreme Court's observation that Plaintiffs' Eighth Amendment claim faced "an exceedingly high bar" given that single-dose pentobarbital "has become a mainstay of state executions . . . [h]as been used to carry out over 100 executions, without incident . . . [and h]as been repeatedly invoked by prisoners as a *less* painful and risky alternative to the lethal injection protocols of other jurisdictions." *Lee*, 140 S. Ct. at 2591; *see also id.* (citing *Bucklew v. Precythe*, 139 S. Ct. 1112, 1124 (2019)) ("This Court has yet to hold that a State's method of execution qualifies as cruel and unusual."). The court further concluded that even if it "found in favor of Plaintiffs on all alleged facts," including evidence that an inmate would be virtually certain to suffer the effects of flash pulmonary edema, "there would be no Eighth Amendment violation because the evidence of pain would not satisfy *Lee*'s high bar for an objectively intolerable risk of pain." (Aug. 15 Order at 3, 5.) Indeed, the Supreme Court considered most of the evidence Plaintiffs

presented and found no viable Eighth Amendment challenge to the use of single-dose pentobarbital. *See Lee*, 140 S. Ct. at 2591.

Plaintiffs offer no grounds that merit an alteration of the court's prior judgment. First, they contend that the court's judgment was a clear error predicated on "an overly broad reading of the Supreme Court's per curiam order in *Barr v. Lee* as foreclosing any Eighth Amendment challenge to the use of pentobarbital in lethal injection." (ECF No. 238 at 1). Plaintiffs also present new evidence from the September 22, 2020 execution of William LeCroy. The court addresses each in turn.

A. Clear Error

Plaintiffs seek to relitigate at least two arguments that the court has already considered and rejected, and the court finds no clear error in its previous analysis. For instance, Plaintiffs argue that "the Supreme Court raised th[e] bar substantially for the [] plaintiffs in *Lee* because they sought what it deemed '*last-minute intervention* by a Federal Court.'" (*Id.* at 8 (emphasis supplied by Plaintiffs) (noting also that *Lee* "is best understood to hold only that a plaintiff's expert declarations, when contested by the government's own experts, are insufficient to make the heightened showing to justify last-minute relief").) But after considering a similar argument presented by former Plaintiff Keith Nelson, the court determined that the timing of the injunctive relief sought in *Lee* was "neither dispositive nor weighty." (*See* Aug. 15 Order at 4.) Plaintiffs here present nothing which changes that conclusion.

Relatedly, Plaintiffs also contend that the Supreme Court considered the Eighth Amendment claim in *Lee* on a motion for a preliminary injunction, and therefore this court is not precluded from finding that Plaintiffs have nonetheless adequately stated a claim for relief. But, again, the court already considered and rejected that argument: "[i]t is true that the standards for

a motion to dismiss and a preliminary injunction are distinct, but that does not mean this court can ignore *Lee*'s general language regarding the Eighth Amendment standard." (*Id.* at 4–5.)

Finally, Plaintiffs argue that this court's assessment of *Lee* cannot be squared with the D.C. Circuit's August 25, 2020 denial of former Plaintiff Keith Nelson's motion for a stay pending appeal of the judgment at issue. In Plaintiffs' view, "[i]f the D.C. Circuit shared this Court's broad reading of *Lee*, it could have denied Nelson a stay with no analysis whatsoever." (ECF No. 238 at 9 (discussing *In re Bureau of Prisons' Execution Protocol Cases*, No. 20-5252, at *4 (D.C. Cir. Sept. 10, 2020)).) But, as the Circuit noted, it did not consider the merits of this court's dismissal of Count II, but rather whether Nelson would have been irreparably harmed absent a stay pending appeal. *In re Execution Protocol Cases*, No. 20-5252, at *4. Accordingly, the court finds nothing in the D.C. Circuit's decision on the Nelson appeal to cause it to reconsider its interpretation of *Lee*.

B. New Evidence

Plaintiffs also argue that newly submitted evidence from the LeCroy execution calls into question the court's dismissal of Plaintiffs' Eighth Amendment claim. In their view, the new evidence and other intervening events "have hopelessly discredited the Government's 'competing evidence' that motivated the ruling in *Lee*." (ECF No. 293 at 2.) The court disagrees.

As an initial matter, as Plaintiffs acknowledge, the court does not weigh factual evidence on a motion to dismiss. (*Id.* at 1.) Furthermore, the court did not dismiss the Eighth Amendment claim because of "competing" evidence. In fact, it credited Plaintiffs' evidence before concluding that there was no Eighth Amendment violation. Assuming Plaintiffs are correct that LeCroy suffered from flash pulmonary edema while still conscious, that fact does not alter the

court's conclusion that such new evidence will not suffice to show that the pain pentobarbital causes reaches unconstitutional levels so long as pentobarbital is widely used. (*See* Aug. 15 Order at 4 (citing *Lee*, 140 S. Ct. 2590).) Evidence from the LeCroy execution simply adds another data point in support of an argument the Supreme Court has already rejected as insufficient to state a viable Eighth Amendment claim.

The court has not identified a "clear error" in its reasoning, or newly discovered evidence, which merits an alteration or amendment of the judgment dismissing Count II of the Amended Complaint.

III. FDCA CLAIMS

Plaintiffs next ask the court to reconsider its judgment denying injunctive relief on their FDCA claims. In its September 20 Memorandum Opinion, the court found that the government's use of pentobarbital that was not prescribed, and did not meet other FDCA requirements, constituted agency action contrary to law in violation of the Administrative Procedure Act. The court concluded, however, that Plaintiffs were not entitled to injunctive relief because they had failed to show irreparable harm arising from the statutory violation.

Plaintiffs now argue that the evidence from the LeCroy execution now clears this hurdle. But they ignore key language from the court's September 20 Opinion: "Assuming the BOP finds a doctor to write prescription, Plaintiffs will still be executed using pentobarbital. Thus, the prescription requirement does not in and of itself ensure that Plaintiffs will [] be protected from flash pulmonary edema during their executions." (ECF No. 261, Sept. 20 Mem. Op. at 36.) Plaintiffs have not presented any legal authority that undermines this conclusion.

The court also explained in its September 20 Opinion that "while [it] continues to be concerned at the possibility that inmates will suffer excruciating pain during their executions,

Plaintiffs have not established that flash pulmonary edema is 'certain' or even 'likely' to occur before an inmate is rendered insensate." (*Id.*) Plaintiffs' new evidence does not change this finding.

Plaintiffs point to three unsworn accounts of LeCroy's execution indicating that LeCroy's "torso began to jerk and contract uncontrollably," (ECF No. 282-1, Hale Account at 1); that "[h]is eyelids grew heavy while his midsection began to heave uncontrollably," (ECF No. 282-2, Tarm AP Article at 1); and that "[h]is stomach started going up and down intensely" and "[h]is mouth quivered as he was gasping for air," (ECF No. 282-3, Kudisch Local News Article at 2). Defendants present other unsworn statements contradicting these accounts. (*See* ECF No. 291-1, Trigg Local News Article at 2; ECF No. 291-2, Desk Local News Article at 1.) None of these accounts causes the court to change its ruling. [2]

Defendants also submitted a sworn declaration from Eric Williams, Warden of the Federal Correctional Institution at Greenville, Illinois, who attended LeCroy's execution. (*See* ECF No. 291-5, Williams Decl.) Williams recounts that "[s]hortly after the lethal injection substances were administered, I heard LeCroy take a deep breath. Subsequently he snored loudly one time . . . [T]he rise and fall of his abdomen was very apparent. It did not appear to me, however, that LeCroy was experiencing discomfort, or that he was struggling for air." (*Id.* ¶¶ 7–8.)

[2] Plaintiffs also supply supplemental declarations from Dr. Gail Van Norman and Dr. Mark Edgar, both of whom agree that the accounts presented by Plaintiffs indicate that LeCroy suffered from flash pulmonary edema while insensate. (*See* ECF No. 282-4; ECF No. 282-5.) Defendants' experts submit supplemental declarations refuting these conclusions. (*See* ECF No. 291-3; ECF No. 291-4.) The court has already considered the testimony of these experts, and, while their analysis considers the "new evidence", their conclusions remain the same.

Even assuming Plaintiffs' new evidence establishes that LeCroy suffered the effects of flash pulmonary edema while still conscious, such evidence only confirms that the onset of flash pulmonary edema is possible upon the administration of pentobarbital. But as the court has already explained, given Supreme Court precedent, that is not enough to warrant injunctive relief. (*See* Sept. 20 Mem. Op. at 36.) Plaintiffs would need to supply evidence that casts doubt on the more than 100 executions carried out using pentobarbital and which refutes data upon which the Supreme Court has relied in finding that pentobarbital will not cause an unconstitutional level of pain. The evidence presented here falls far short.

The Supreme Court has made its position clear. Pentobarbital "has become a mainstay of state executions," *Lee*, 140 S. Ct. at 2591; "[h]as been used to carry out over 100 executions, without incident," *id.*; does not carry the risks of "drowning, suffocating, and being burned alive from the inside out, " *Zagorski v. Parker*, 139 S. Ct. 11 (2018) (Sotomayor, J., dissenting); and "is widely conceded to be able to render a person fully insensate," *id.* at 11–12. The court is constrained by these findings and, particularly given the history of this case, finds nothing new which warrants injunctive relief.

IV. FDPA Claims

Finally, Plaintiffs ask the court to reconsider its conclusion that Defendants are entitled to summary judgment as to the FDPA claims in Count V of the Amended Complaint. In that count, Plaintiffs alleged that the 2019 Protocol violates § 3596(a) of the FDPA, which requires that a federal execution be carried out "in the manner prescribed by the law of the State in which the sentence is imposed," 18 U.S.C. § 3596(a). In support of their argument, Plaintiffs identified several state laws which, in their view, conflicted with the 2019 Protocol.

In its September 20 Opinion, the court found that while the Bureau of Prisons was required to adhere to execution protocols in state statutes and regulations, Defendants were entitled to summary judgment as to the alleged discrepancies between the 2019 Protocol and state laws. In particular, the court found that the 2019 Protocol did not conflict with a Georgia law requiring the presence of two physicians at an execution given Defendants' stated intention to comply with that provision. The court also found no conflict between the 2019 Protocol and a Texas law setting forth execution scheduling restrictions because the only Plaintiff to whom that provision applied had not requested that his execution be scheduled in accordance with that law.

Plaintiffs contend that the court's conclusions are premised on an "error of law." (ECF No. 298 at 1.) They argue that: 1) Defendants' stated intention to adhere to relevant state law is insufficient to warrant judgment in Defendants' favor as to Count V, and 2) the court's rationale has been undermined by the circumstances of LeCroy's execution on September 22, 2020. (*Id.*)

Even if the court agreed that Defendants had violated the FDPA, Plaintiffs have not shown how they are irreparably harmed by the alleged state law violations. The court has already noted its skepticism that the Bureau of Prisons' denial of a request to be executed after 6 p.m. in accordance with Texas law "would constitute irreparable harm." (Sept. 20 Mem. Op. at 31.)[3] Similarly, the court does not see how a plaintiff would be irreparably harmed by the presence of only one physician at the execution to certify that death has superseded, especially since that certification is made well after the inmate has been rendered insensate.

In any event, the court is not convinced that the evidence Plaintiffs proffer supports a finding that Defendants have run afoul of the FDPA. Plaintiffs point to several news articles in

[3] It is for this reason that the court also will deny Plaintiffs' request to "alter its judgment to clarify" that the ruling regarding the alleged violation of Article 43.14(a) of Texas's Code of Criminal Procedure applies only to Plaintiff Vialva. (*See* ECF No. 298 at 7.)

which eyewitnesses reported seeing only one physician during LeCroy's execution, in violation of Georgia Code § 17-10-41. But these unsworn statements are contradicted by Defendants' sworn statement from a prison official who certified that "[a] second physician examined LeCroy and confirmed the pronouncement of death." (Williams Decl. ¶ 10.) The court has no basis on which to doubt the veracity of this sworn statement.

Plaintiffs also submitted a copy of a request made by Plaintiff Orlando Hall to the Warden of Federal Correctional Complex, Terre Haute, asking to be executed after 6 p.m. in accordance with Article 43.14 of the Texas Code of Criminal Procedure. That request has been granted. (*See* ECF No. 301-1 (noting that "Mr. Hall's execution is scheduled for 6 pm Terre Haute time").) Thus, Plaintiffs have failed to identify a statutory violation.

Finally, Plaintiffs point out that once the Ninth Circuit determined the agency was not required to do so, the Bureau of Prisons did not comply with Arizona laws governing on-site accommodations for counsel at Lezmond Mitchell's execution. But the court cannot fault Defendants for acting in accordance with leave granted by the Ninth Circuit, especially since Mitchell's claim was not part of this litigation. Plaintiffs have therefore failed to show a "clear error" in the court's disposition of their FDPA claims.

Date: November 3, 2020

Tanya S. Chutkan
TANYA S. CHUTKAN
United States District Judge

APPENDIX D

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*	)	Case No. 19-mc-145 (TSC)
THIS DOCUMENT RELATES TO:	)	
ALL CASES	)	

MEMORANDUM OPINION

Plaintiffs are inmates on federal death row who challenge Defendants' efforts to execute them pursuant to the 2019 Federal Bureau of Prisons' Execution Protocol (the 2019 Protocol or the Protocol). Defendants have filed an omnibus motion for summary judgment on Plaintiffs' Administrative Procedure Act (APA) claims and a motion to dismiss all remaining claims pursuant to Fed. R. Civ. P. 12(b)(6). All Plaintiffs have moved for partial summary judgment, (ECF No. 236), as to the violations of the Food, Drug, and Cosmetic Act (FDCA) in Count XI of the Amended Complaint, (ECF. No. 92).[1] Most of these claims have been addressed in one way or another by this court or the Court of Appeals for the District of Columbia Circuit, and it is the court's intention to enter final judgment on most of the remaining claims.[2]

[1] Plaintiff William Emmett LeCroy has advised the court that he joins this motion. His contrary-to-law FDCA claims appear in Count V of his Amended Complaint. (*See* ECF No. 245.)

[2] The court has not yet ruled on Plaintiff Norris Holder's applied Eighth Amendment claim (ECF No. 94), and Plaintiffs' motion, (ECF No. 238), to alter the court's August 20, 2020 judgment, (ECF No. 205).

For the reasons set forth below, Defendants' omnibus motion is GRANTED in part. The court DENIES Defendants' motion as to the FDCA claims in Count XI, but the motion is GRANTED in all other respects except as to Norris Holder's as-applied Eighth Amendment challenge. Accordingly, Plaintiffs' motion for partial summary judgment on the FDCA claims in Count XI (and in Count V of Plaintiff LeCroy's Amended Complaint) is GRANTED, but the injunctive relief sought therein is DENIED for all Plaintiffs except Norris Holder.[3]

I. BACKGROUND

A. 2004 Execution Protocol

In 2005, James H. Roane, Jr., Richard Tipton, and Cory Johnson, three federal death row inmates, sued, alleging that their executions were to be administered under an unlawful and unconstitutional execution protocol. *Roane v. Gonzales*, 1:05-cv-02337 (D.D.C.), ECF No. 1 ¶ 2. The court preliminarily enjoined their executions. *Roane*, ECF No. 5. Four other death row inmates intervened, and their executions were enjoined as well. *See Roane*, ECF Nos. 23, 27, 36, 38, 67, and 68. During this litigation, Defendants produced a 50-page document (the 2004 Main Protocol) outlining the Bureau of Prisons' (BOP) execution procedures. *Roane*, ECF No. 179-3. Defendants then produced two three-page addenda to the 2004 Main Protocol. *See Roane*, ECF No. 177-3 (Addendum to Protocol, July 1, 2007) (the 2007 Addendum); ECF No. 177-1 (Addendum to Protocol, Aug. 1, 2008) (the 2008 Addendum). In 2011 the Department of Justice (DOJ) announced that the BOP did not have the drugs it needed to implement the 2008 Addendum. *See* Letter from Office of Attorney General to National Association of Attorneys General, (Mar. 4, 2011), https://files.deathpenaltyinfo.org/legacy/documents/2011.03.04.holder.letter.pdf. Defendants informed the court that the BOP "has decided to modify its lethal

[3] The court will rule separately on Plaintiff Holder's request for injunctive relief.

injection protocol but the protocol revisions have not yet been finalized." *Roane*, ECF No. 288 at 2. In response, the court stayed the *Roane* litigation. No further action was taken in the cases for over seven years.

B. 2019 Execution Protocol

On July 24, 2019, the DOJ announced a new addendum to the execution protocol, (ECF No. 39-1, Admin. R. at 874–78), replacing the three-drug protocol of the 2008 Addendum with a single drug: pentobarbital sodium. (*Id.* at 879–80.) The BOP also adopted a new protocol to replace the 2004 Main Protocol. (*Id.* at 1021–72.) The 2019 Protocol provides for three injections, the first two containing 2.5 grams of pentobarbital in 50 milliliters of diluent each, and the third containing 60 milliliters of a saline flush. (*Id.* at 880.) The 2019 Protocol does not refer to the form or source of the drug, or measures of quality control, and its description of the intravenous administration of the drug simply provides that the BOP Director or designee "shall determine the method of venous access" and that "[i]f peripheral venous access is utilized, two separate lines shall be inserted in separate locations and determined to be patent by qualified personnel." (*Id.*)

Following this announcement, the court held a status conference in *Roane* on August 15, 2019. (*See* Minute Entry, Aug. 15, 2019.) In addition to the *Roane* plaintiffs, the court heard from counsel for three other federal death row inmates, all of whom cited the need for additional discovery on the new protocol. (*See* ECF No. 12, Status Hr'g Tr.) Defendants indicated that they were unwilling to stay the executions, and the court bifurcated discovery and ordered Plaintiffs to complete 30(b)(6) depositions by February 28, 2020, and to file amended complaints by March 31, 2020. (*See* Minute Entry, Aug. 15, 2019.)

1. November 20, 2019 Preliminary Injunction

Four inmates with scheduled execution dates filed complaints or motions to intervene in the *Roane* action challenging the 2019 Protocol, and each inmate subsequently moved to preliminarily enjoin his execution.[4] On November 20, 2019, the court granted the four Plaintiffs' motions for preliminary injunction, finding that they had demonstrated a likelihood of success on their claims that the 2019 Protocol exceeds the authority set forth in the Federal Death Penalty Act (FDPA). (*See* ECF No. 50, Nov. 20, 2019 Mem. Op. at 13, 15; ECF No. 50, Nov. 20, 2019 Order.) The court did not rule on Plaintiffs' other claims, including that the 2019 Protocol is arbitrary and capricious under the Administrative Procedure Act (APA), that it violates the Food, Drug, and Cosmetic Act (FDCA) and the Controlled Substances Act (CSA), that it violates Plaintiffs' right to counsel in violation of the First, Fifth, and Sixth Amendments, and that it is cruel and unusual in violation of the Eighth Amendment. (*Id.* at 13.) Following the court's order, three more death row inmates filed complaints which in turn were consolidated with *Roane*.[5] The court denied Defendants' motion to stay the court's preliminary injunction. (*See* Minute Order, Nov. 22, 2019.) The D.C. Circuit likewise denied Defendants' motion to stay, *In re Fed. Bureau of Prisons' Execution Protocol Cases*, No. 19-5322 (D.C. Cir. Dec. 2,

[4] Daniel Lewis Lee filed his complaint on August 23, 2019 (*see Lee v. Barr*, 1:19-cv-02559 (D.D.C.), ECF No. 1), and his motion for a preliminary injunction on September 27, 2019. (ECF No. 13, Lee Mot. for Prelim. Inj.) On August 29, 2019, Alfred Bourgeois moved to preliminarily enjoin his execution. (ECF No. 2, Bourgeois Mot. for Prelim. Inj.) Dustin Lee Honken filed an unopposed motion to intervene in *Lee v. Barr*, which was granted. (ECF No. 26, Honken Mot. to Intervene.) He then moved for a preliminary injunction on November 5, 2019. (ECF No. 29, Honken Mot. for Prelim. Inj.) Wesley Ira Purkey filed a complaint and a motion for a preliminary injunction under a separate case number, 1:19-cv-03214, which was consolidated with *Roane*. (ECF No. 34, Purkey Mot. for Prelim. Inj.)

[5] These plaintiffs are Norris G. Holder, Jr., 1:19-cv-3520; Brandon Bernard, 1:20-cv-474; and Keith Dwayne Nelson, 1:20-cv-557.

2019), as did the United States Supreme Court on December 6, 2019. *Barr v. Roane*, 140 S. Ct. 353 (2019). However, three Justices issued a statement indicating their belief that Defendants were likely to prevail on the merits. *Id.*

On November 21, 2019, Defendants filed an interlocutory appeal of the court's November 20, 2019 Order. (*See* ECF No. 52.) On April 7, 2020, the D.C. Circuit reversed. *Execution Protocol Cases*, 955 F.3d at 108. Neither of the two Judges on the panel who voted to reverse agreed on the FDPA's statutory requirements, but they nonetheless rejected on the merits Plaintiffs' claim that the federal government was required by the FDPA to follow procedures set forth in state execution protocols. *Id.* at 112 (per curiam). The panel expressly declined to rule on Plaintiffs' remaining statutory and constitutional claims, as "the government did not seek immediate resolution of all the plaintiffs' claims" and the claims "were neither addressed by the district court nor fully briefed in this Court." *Id.* at 113. The Court of Appeals denied Plaintiffs' petition for rehearing en banc on May 15, 2020, and the Supreme Court denied Plaintiffs' application for a stay of the mandate and petition for a writ of certiorari on June 29, 2020. *Bourgeois*, 2020 WL 3492763.

Meanwhile, Plaintiffs filed their Amended Complaint on June 1, 2020, (ECF No. 92, Am. Compl.), the same day Holder filed a separate supplemental complaint, (ECF No. 94.)

2. July 13, 2020 Preliminary Injunction—Eighth Amendment Claims

On June 15, 2020, the DOJ and BOP scheduled new execution dates for three Plaintiffs in the case: Daniel Lewis Lee on July 13, 2020, Wesley Ira Purkey on July 15, 2020, Dustin Lee Honken on July 17, 2020, and Keith Dwayne Nelson on August 28, 2020. (ECF No. 99.)

On July 13, 2020, the court preliminarily enjoined the executions of Lee, Purkey, Honken, and Nelson, finding that they had demonstrated a likelihood of success on the merits of

their claim that the 2019 Protocol is cruel and unusual in violation of the Eighth Amendment. Once again, it did not rule on their other statutory and constitutional claims. (*See* ECF No. 135, July 13 Mem. Op. at 18, 22.) The D.C. Circuit declined to stay or vacate the court's injunction, *see Execution Protocol Cases*, No. 20-5199 (D.C. Cir. July 13, 2020), but the Supreme Court vacated the injunction early in the morning of July 14, 2020. *Barr v. Lee*, No. 20A8, 2020 WL 3964985 (U.S. July 14, 2020) (per curiam). Hours later, Defendants executed Lee.

3. July 15, 2020 Preliminary Injunction—Remaining Claims

On July 15, 2020, the court preliminarily enjoined the executions of Purkey, Honken, and Nelson, finding that they had demonstrated a likelihood of success on the merits of their claims that the 2019 Protocol violates the FDCA (ECF No. 145, July 15 Mem. Op. at 28.) The court found, however, that Plaintiffs were unlikely to succeed on their claims that the 2019 Protocol is arbitrary and capricious under the APA, violates the CSA, and deprives Plaintiffs of their right to counsel under the First, Fifth, and Sixth Amendments.

The D.C. Circuit declined to stay or vacate the court's injunction, *see Execution Protocol Cases*, No. 20-5210 (D.C. Cir. July 16, 2020), but the Supreme Court vacated the injunction without addressing the merits on July 16, 2020. *Barr v. Purkey*, No. 20A10, 2020 WL 4006821 (U.S. July 16, 2020) (per curiam). Later that week, Defendants executed Purkey and Honken.

4. Motion to Dismiss Regarding Plaintiffs' Eighth Amendment Claims

On July 31, 2020, Defendants filed their combined motion to dismiss and for summary judgment. (ECF Nos. 169, 170, Defs. Mot.)

On August 15, the court granted Defendants' motion as to the Eighth Amendment claims in Count II of the Amended Complaint. (ECF No. 193, Aug. 15 Order.) In the light of the Supreme Court's ruling in *Lee*, the court found that, absent particular medical circumstances, the

use of pentobarbital would withstand Eighth Amendment scrutiny despite evidence of excruciating pain.

5. August 27, 2020 Permanent Injunction—FDCA Claims

Given his impending execution, on August 4, 2020, Plaintiff Keith Nelson filed an emergency cross-motion for summary judgment on the pending FDCA claims (ECF No. 180), one of which the court had already determined was likely to succeed on the merits. (*See* July 15 Mem. Op. at 13.)

On August 27, 2020, the court entered judgment in favor of Nelson on Count XI of the Amended Complaint and enjoined Defendants from proceeding with Nelson's execution until the government could "comply with the requirements of the [(FDCA)]," (ECF No. 213, Aug. 27 Mem. Op. at 13.) The court found that the use of pentobarbital for lethal injection was subject to the FDCA, and that the government's intent to use it without satisfying the FDCA's premarketing, labeling, and prescription requirements was unlawful. (*Id.* at 10.) The court rejected Nelson's contention that DOJ's failure to explain its violation of the FDCA and the FDA commissioner's failure to bring an enforcement action were arbitrary and capricious. (*Id.* at 11–12.)

Defendants immediately appealed, and the D.C. Circuit vacated the injunction on the basis that "inter alia, there [were] insufficient findings and conclusions that irreparable injury will result from the statutory violation found by [this] court." *Execution Protocol Cases*, No. 20-5260 (D.C. Cir. Aug. 27, 2020) (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006); *Withrow v. Larkin*, 421 U.S. 35, 44–45 (1975)).

On August 28, 2020, Nelson filed an emergency request for the court to clarify and/or amend its August 27th judgment. (ECF No. 222.) After a hearing that same day, the court

denied Nelson's request because he failed to demonstrate the requisite irreparable harm to warrant injunctive relief. (ECF No. 226.) Defendants executed Nelson later that afternoon.

C. The Present Dispute

With regard to the claims in the Amended Complaint, the court has previously: (1) dismissed Count II (Eighth Amendment violation) for failure to state a claim as to all Plaintiffs but Norris Holder (*see* Aug. 15 Order); (2) granted summary judgment in favor of Defendants as to Count X (failure to exercise enforcement authority) and the alleged FDCA violations in Count VIII (failure to explain violations of the FDCA), (ECF No. 214); (3) denied Defendants' motion for summary judgment as to the FDCA component of Count XI (violation of the FDCA), (*id.*); and (4) entered summary judgment in favor of former Plaintiff Keith Nelson (but no other Plaintiff) as to the FDCA component of Count XI, (*id.*).

Defendants argue that they are entitled to judgment as a matter of law under Fed. R. Civ. P. 12(b)(6) on the following remaining claims in the Amended Complaint: the non-APA claims in Counts I (Fifth Amendment Due Process violation), III (deliberate indifference), IV (access to counsel), and VII (unconstitutional delegation of legislative power). Defendants seek summary judgment on the APA claims in Counts V (ultra vires agency action), VI (violation of notice-and-comment rulemaking), VIII (arbitrary and capricious agency action), IX (failure to enforce the CSA), and XI (violation of the CSA).

Defendants' motion has been fully briefed. The remaining Plaintiffs have moved for partial summary judgment only as to the FDCA claims in Count XI (and Count V of Plaintiff LeCroy's Amended Complaint). (ECF No. 236, Pls. Mot. for Partial Summ. J.)

II. DISCUSSION

A. Defendants' Motion to Dismiss for Failure to State a Claim

1. Legal Standards

A motion to dismiss under Rule 12(b)(6) for failure to state a claim "tests the legal sufficiency of a complaint." *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible when the factual content allows the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Plaintiff's factual allegations need not be "detailed," but "the Federal Rules demand more than 'an unadorned, the-defendant-unlawfully-harmed-me accusation.'" *McNair v. District of Columbia*, 213 F. Supp. 3d 81, 86 (D.D.C. 2016) (quoting *Iqbal*, 556 U.S. at 678). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements" are insufficient. *Iqbal*, 556 U.S. at 678.

While a court generally does not consider matters beyond the pleadings on a motion to dismiss, it may consider "the facts alleged in the complaint, documents attached as exhibits or incorporated by reference in the complaint, or documents upon which the plaintiff's complaint necessarily relies even if the document is produced not by the plaintiff in the complaint but by the defendant in a motion to dismiss[.]" *Ward v. D.C. Dep't of Youth Rehab. Servs.*, 768 F. Supp. 2d 117, 119–20 (D.D.C. 2011) (internal quotation marks and citations omitted); *see also Equal Emp't Opportunity Comm'n v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624 (D.C. Cir. 1997).

2. Fifth Amendment Due Process—Count I

In Count I of their Amended Complaint, Plaintiffs allege that Defendants' failure to disclose material information regarding the development of the 2019 Protocol and the procedures that will be used to carry out their executions deprives them of their lives and liberty without adequate due process as guaranteed by the Fifth Amendment. (Am. Compl. ¶¶ 119, 121.) Their claim is based on their argument that the Due Process Clause requires the government to allow them to "determin[e] all aspects of the 2019 Protocol that violate provisions of federal law or constitute cruel and unusual punishment." (*Id.* ¶ 119.)

"The Fifth Amendment Due Process Clause protects individuals from deprivations of 'life, liberty, or property, without due process of law.'" *Atherton v. District of Columbia Office of Mayor*, 567 F.3d 672, 689 (D.C. Cir. 2009) (citing U.S. Const. amend. V). A procedural due process violation "occurs when an official deprives an individual of a liberty or property interest without providing appropriate procedural protections. Liberty interests arise out of the Constitution itself or 'may arise from an expectation or interest created by state laws or policies.'" *Id.* (quoting *Wilkinson v. Austin*, 545 U.S. 209, 221 (2005)).

There is no question that "[b]eing deprived of life unequivocally implicates a constitutionally protected interest." (Am. Compl. ¶ 118 (internal quotation marks omitted); Defs. Mot. at 22.) But Plaintiffs have already received the due process to which they are entitled for their life interests by virtue of their criminal trials and appeals; the legality of their death sentences is not before the court. Therefore, Plaintiffs' life interests are not implicated in challenging the 2019 Protocol. *See Zink v. Lombardi*, 783 F.3d 1089, 1109 (8th Cir. 2015) ("The prisoners in this case already have received due process for the deprivation of their life interests:

They were convicted and sentenced to death after a trial in Missouri court, and their convictions and sentences were upheld on appeal.").

Plaintiffs' liberty interest in disclosure fares no better. "A due process right to disclosure requires an inmate to show a cognizable liberty interest in obtaining information about execution protocols." *Trottie v. Livingston*, 766 F.3d 450, 452 (5th Cir. 2014). Plaintiffs have not identified a cognizable liberty interest in information about the 2019 Protocol that could lead to potential claims. *See Lewis v. Casey*, 518 U.S. 343, 354 (1996) (explaining that the state need not "enable [a] prisoner to *discover* grievances, and to *litigate effectively* once in court"). Courts have routinely found no due process rights implicated when a death row inmate claims he has not received enough information about an execution protocol. *See, e.g.*, *Phillips v. DeWine*, 841 F.3d 405, 420 (6th Cir. 2016) (finding plaintiff had no due process right to the identity of individuals and entities that participate in the lethal injection process); *Jones v. Comm'r, Ga. Dep't of Corr.*, 811 F.3d 1288, 1292–93 (11th Cir. 2016) (quoting *Wellons v. Comm'r, Ga. Dep't of Corr.*, 754 F.3d 1260, 1267 (11th Cir. 2014)) ("Neither the Fifth, Fourteenth, or First Amendments afford [a prisoner] the broad right to know where, how, and by whom the lethal injection drugs will be manufactured, as well as the qualifications of the person or persons who will manufacture the drugs, and who will place the catheters."); *Zink*, 783 F.3d at 1108 (8th Cir. 2015) ("The prisoners' claim that they are unable to discover information regarding the execution protocol is thus insufficient as a matter of law to state a due process claim."); *Trottie*, 766 F.3d at 452 (finding that uncertainty regarding the effect of an execution drug was not a "cognizable liberty interest" and, thus, did not trigger "a due process right to disclosure"); *Sells v. Livingston*, 750 F.3d 478, 481 (5th Cir. 2014) (discussing *id.*) ("No appellate decision ha[s] yet held that obtaining information about execution protocols was a liberty interest, which meant that

failing to disclose could not be a due-process violation."); *Sepulvado v. Jindal*, 729 F.3d 413, 420 (5th Cir. 2013) ("There is no violation of the Due Process Clause from the uncertainty that Louisiana has imposed [] by withholding the details of its execution protocol."); *Williams v. Hobbs*, 658 F.3d 842, 852 (8th Cir. 2011) (finding that plaintiffs' inability to gain more information about an execution protocol did not amount to a due process violation).

Despite the case law, Plaintiffs argue that this Circuit held otherwise in *Roane v. Leonhart*, 741 F.3d 147 (D.C. Cir. 2014). The court is unpersuaded. In *Roane*, the D.C. Circuit ordered that Jeffrey Paul (a plaintiff in this case) be allowed to intervene in the challenge to the 2004 Protocol, which included a due process challenge to Defendants' refusal to disclose execution procedures. *Id.* at 149, 152. In response to Defendants' argument that the claims had become moot since a three-drug protocol would no longer be used, the Court found that Paul's "due process challenge, which attack[ed] a refusal to disclosure procedures that will be used [in the execution], is an independent claim that remains live." *Id.* at 150. The court does not read this as endorsing the claim's merits; the D.C. Circuit was addressing only whether the due process challenge was moot, as Plaintiffs concede in their opposition brief.[6] (*See* ECF No. 184, Pls. Opp'n at 16.) Thus, Plaintiffs have not identified a case in any Circuit finding that a death-row inmate has a due process right to disclosure of information about an execution protocol.

Plaintiffs also argue that because the BOP Director has the discretion to amend the execution procedures, a plaintiff may not receive sufficient notice and opportunity to challenge the manner of his execution, which is what occurred with the Lee and Purkey executions. (Am.

[6] Plaintiffs also argue that this court's subsequent grant of an unopposed preliminary injunction in *Roane* indicates the court's view that the due process claim was likely to succeed on the merits. (*See* Pls. Opp'n at 16.) The court took no position on the merits of the due process claim in its two-sentence order, however. (*See Roane*, ECF No. 336.)

Compl. ¶ 120.) But, although 28 C.F.R. § 26.4 requires the warden of the designated facility to "notify the prisoner under sentence of death of the date designated for execution at least 20 days in advance," Plaintiffs can point to no case establishing a *constitutionally* protected interest to sufficient notice of an execution. (Although the court has previously expressed its concern with the government's haste to execute Plaintiffs before their claims have been fully litigated, ultimately, Plaintiffs have not identified a due process violation that would warrant relief on Count I.

3. Deliberate Indifference—Count III

In Count III, Plaintiffs allege that the means of execution established in the 2019 Protocol constitutes deliberate indifference to a substantial risk of serious harm, thereby violating the Fifth and Eighth Amendments. (Am. Compl. ¶¶ 132–34.) They argue that Defendants have chosen to disregard substantial risks that the 2019 Protocol will cause "severe pain and suffering, including a sensation of drowning or asphyxiation" that creates an experience of "panic," "terror," and "agony." (Pls. Opp'n at 13 (citing ECF No. 24, Normal Decl. at 34) (internal quotation marks omitted).) Defendants urge the court to dismiss these claims for the same reasons the court dismissed Plaintiffs' other Eighth Amendment claims, namely that the use of pentobarbital does not rise to the level of cruel and unusual punishment. (Defs. Mot. at 10; ECF No. 193, Aug. 15 Order (dismissing Plaintiffs' Eighth Amendment claims in Count II).) Having already determined that "the use of pentobarbital will withstand Eighth Amendment scrutiny, no matter the evidence of excruciating pain," the court concludes that Plaintiffs' deliberate indifference claims similarly fail. (Aug. 15 Order at 5.)

"A prison official's 'deliberate indifference' to a substantial risk of serious harm to an inmate violates the Eighth Amendment." *Farmer v. Brennan*, 511 U.S. 825, 828 (1994). To

state a viable deliberate indifference claim, a plaintiff must show that a prison official "knows of and disregards an excessive risk to inmate health or safety." *Id.* at 837 (noting also that prison officials "must both be aware of facts from which the inference could be drawn that a substantial risk of serious harms exists, and he must also draw the inference.").

The Supreme Court has made clear that the government's use of pentobarbital under the 2019 Protocol does not present a substantial or excessive risk of serious harm. *See Lee*, 2020 WL 3964985, at *1 (explaining that pentobarbital "has become a mainstay of state executions" and "[h]as been used to carry out over 100 executions, without incident"); *Zagorski v. Parker*, 139 S. Ct. 11, 11–12 (2018) (Sotomayor, J., dissenting) (noting that pentobarbital does not carry the risks of "drowning, suffocating, and being burned also from the inside out" and "is widely conceded to be able to render a person fully insensate"). As the court already posited in dismissing Count II of the Amended Complaint, "[s]o long as pentobarbital is widely used . . . no amount of new evidence will suffice to prove that the pain pentobarbital causes reaches unconstitutional levels." (Aug. 15 Order at 4.) Absent deliberate indifference, there is no Fifth[7] or Eighth Amendment violation as presented in Count III.

To the extent Plaintiffs argue that a deliberate indifference claim is distinct from and invokes a lower standard than "cruel and unusual punishment," they have not shown so convincingly. (*See* Pls. Opp'n at 13 ("[D]eliberate indifference need not involve torturous pain and suffering in order to be actionable as a wrongful deprivation of appropriate medical care.").) Nor have they identified a case in which a court denied a method-of-execution challenge but

[7] Plaintiffs argue that when an individual is harmed by a government agent's deliberate indifference, the individual has a viable Substantive Due Process claim under the Fifth Amendment. (*See* Am. Compl. ¶ 129 (quoting *West v. Atkins*, 487 U.S. 42, 58 (1988) (Scalia, J., concurring).)

nonetheless upheld a deliberate indifference claim based on the same facts. Accordingly, Count III fails to state a claim for relief.

4. Access to Counsel—Count IV

In Count IV, Plaintiffs claim that the 2019 Protocol violates their right to counsel and access to the courts guaranteed by the First, Fifth, and Sixth Amendments. Plaintiffs argue that because they have a constitutional right to counsel in order to assert violations of their fundamental rights, they also have the right to have their counsel monitor the execution for possible Eighth Amendment violations. (*See* Pls. Opp'n at 18–19.)

The 2019 Protocol permits up to two defense attorneys to be present as witnesses during their client's execution (Admin. R. at 1024), and while it does not allow witnesses to bring their cell phones with them, an attorney "may request" the use of their phone if "legitimate need arises," and "will have immediate access to [a phone] outside of the witness room." (ECF No. 111-3, Decl. of Tom Watson, at 3.)

Plaintiffs contend that the 2019 Protocol impermissibly prohibits counsel from viewing the setting of the IVs, from communicating with their clients during the execution, and from having a quick and easy means of communicating with the court. (Pls. Opp'n at 19.) While these are all serious concerns, Plaintiffs fail to show that this access is constitutionally mandated. As Defendants note, the cases on which Plaintiffs rely are both out-of-Circuit and factually distinct. *See, e.g.*, *Cooey v. Strickland*, No. 04-cv-1156, 2011 WL 320166, at *6 (S.D. Ohio Jan. 28, 2011) (declining to decide whether the Constitution mandated that counsel be present at the execution where Ohio law already permitted counsel to be present). Plaintiffs suggest that the court adopt Justice Thomas' concurrence in *Lewis*, 518 U.S. at 380–82 (Thomas, J., concurring), in which he wrote that the Due Process Clause requires a right to access the courts to assert

violations of fundamental rights. That single concurrence, while compelling, cannot be the basis for this court to find that Plaintiffs have stated a claim for relief.

Plaintiffs' remaining arguments in support of their claims in Count IV are similarly unpersuasive. First, they contend that the absence of controlling precedent and the novelty of their claimed constitutional rights precludes the government from meeting its burden under Rule 12(b)(6). (Pls. Opp'n at 19. ("[I]n the absence of *controlling* precedent. . . such novelty precludes Defendants from demonstrating, as a matter of law, that Plaintiffs do not state a claim for relief that is plausible on its face" (internal citations and quotation marks omitted)).) The court declines Plaintiffs' invitation to find the lack of supporting precedent to be grounds upon which to stake a claim.

Finally, Plaintiffs also argue that Defendants' decision to utilize the 2019 Protocol during the COVID-19 pandemic infringes their right to counsel by forcing counsel to risk their own health and safety to attend Plaintiffs' executions. As the court has already explained however, these problems are not the result of the 2019 Protocol, or indeed any of Defendants' actions, but of the pandemic itself. (July 15 Mem. Op. at 14.) Furthermore, these claims closely resemble the pandemic-related claims brought by spiritual advisors and family members in separate litigation, and which were rejected by the courts. *See Hartkemeyer v. Barr*, No. 20-cv-336 (S.D. Ind. July 14, 2020), ECF No. 84 (denying preliminary injunction based on APA and Religious Freedom Restoration Act claims), *appeal filed*, No. 20-2262 (7th Cir. July 14, 2020); *Peterson v. Barr*, No. 20-2252, 2020 WL 3955951 (7th Cir. July 12, 2020) (vacating preliminary injunction based on APA claims).

Accordingly, Count IV of the Amended Complaint will be dismissed.

5. Unconstitutional Delegation of Power—Count VII

In Count VII, Plaintiffs argue that if the court finds that § 3596 of the FDPA authorizes the Attorney General to establish a federal execution protocol, "then the statute has failed to provide an intelligible principle" which constitutes "a forbidden delegation of legislative power." (Am. Compl. ¶ 158 (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928) (internal quotation marks omitted).) In support of this argument, Plaintiffs detail Congress's repeated refusal to pass laws expressly granting the Attorney General authority to develop a federal execution protocol. (*See* Pls. Opp'n at 22–25.)

Plaintiffs fail to state a claim for unconstitutional delegation power. First, "failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a [] statute." *Execution Protocol Cases*, 955 F.3d at 122 (Katsas, J., concurring) (quoting *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994)).

More fundamentally, the statute itself cannot fairly be read as lacking an intelligible principle. As Plaintiffs note, a "nondelegation inquiry always begins (and often almost ends) with statutory interpretation." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019). And in the last hundred years, the Supreme Court has "found the requisite 'intelligible principle' lacking in only two statutes, one of which provided literally no guidance for the exercise of discretion, and the other of which conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474 (2001) (citing *Panama Refin. Co. v. Ryan*, 293 U.S. 388 (1935); *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935)); *see also* Keith E. Whittington & Jason Iuliano, *The Myth of the Nondelegation Doctrine*, 165 U. Penn. L. Rev. 379, 380 (2017) (describing a "predictable pattern" in nondelegation doctrine cases whereby a

court invokes the doctrine and the Supreme Court "inevitably grants certiorari and overturns the appellate decision").

Here, the FDPA delivers sufficient guidance. It provides that the U.S. Marshal "shall supervise implementation of the sentence in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a). In this sentence alone, Congress vested the U.S. Marshal with authority to oversee an execution *and* constrains the exercise of that authority to the limits of relevant state law. This is far different from the two cases where Congress failed to supply an intelligible principle.

B. Defendants' Motion for Summary Judgment

1. Legal Standards

"When reviewing motions for summary judgment in a suit seeking review of an agency's actions, the standard under Fed. R. Civ. P. 56(a) does not apply." *Beyond Nuclear v. U.S. Dep't of Energy*, 233 F. Supp. 3d 40, 47 (D.D.C. 2017) (citing *Coe v. McHugh*, 968 F. Supp. 2d 237, 239 (D.D.C. 2013)). Rather, the 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). The court's review is "highly deferential" and begins with a presumption that the agency's actions are valid. *Envt'l. Def. Fund, Inc. v. Costle*, 657 F.2d 275, 283 (D.C. Cir. 1981). The court is "not empowered to substitute its judgment for that of the agency," *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), but instead must consider only "whether the agency acted within the scope of its legal authority, whether the agency has explained its decision, whether the facts on which the agency purports to have relied have some basis in the record, and whether the agency considered the relevant factors," *Fulbright v. McHugh*, 67 F.

Supp. 3d 81, 89 (D.D.C. 2014) (quoting *Fund for Animals v. Babbitt*, 903 F. Supp. 96, 105 (D.D.C. 1995)).

2. Arbitrary and Capricious—Count VIII

In Count VIII, Plaintiffs allege that the DOJ and BOP have not provided sufficient explanations for: the adoption of the 2019 Protocol and the procedures contained therein; the use of pentobarbital as an execution drug; the failure to comply with applicable laws, including the CSA and FDCA[8]; and the absence of safeguards to prevent the significant risk of pain and suffering from acute pulmonary edema and the use of sub-potent or improperly compounded drugs. (Am. Compl. ¶ 163.) Thus, they contend, the 2019 Protocol was not the product of reasoned decision-making and constitutes arbitrary and capricious agency action in violation of the APA. (*Id.* ¶ 164.) But the record before the court does not support these arguments.

The record shows that the BOP explained how it arrived at the details and procedures set forth in the 2019 Protocol. (*See* Admin. R. at 929–34.) It explained that it needed a new protocol because the availability of sodium pentothal, a drug used in its previous protocol, had declined. (Admin. R. at 930.) It then "benchmarked with state practices, reviewed case law, consulted with medical professionals, and reviewed available professional literature." (*Id.*) It concluded that pentobarbital was frequently used for lethal injections, was "litigation tested," and achieved "a deeper level of unconsciousness" than other contenders. (*Id.* at 931, 932.) Furthermore, it settled on a one-drug, rather than three-drug, protocol for three reasons: i) "there are complications inherent in obtaining multiple drugs (availability obstacles) and navigating the respective expiration dates", ii) "acquiring and storing one drug is administratively more

[8] The court has already found that DOJ and BOP's failure to explain non-compliance with the FDCA requirements did not violate the APA.

efficient", and iii) "administering one drug reduced the risk of errors during administration." (*Id.* at 931.) The record also indicates that the BOP consulted with medical professionals and reviewed expert testimony to assess the safety of pentobarbital. (*See id.* at 401–524, 527–761.) Finally, the BOP explained that it "secured a compounding pharmacy to store the API [(active pharmaceutical ingredient)] and to convert the API into injectable form as needed . . . [and] conferred with DEA to ensure the compounding pharmacy is properly registered." (*Id.* at 933.)

Although an agency can always provide more explanation for its actions, the record here is sufficient to fend off a challenge that the adoption of the 2019 Protocol was not the product of rational decision-making. And, at the very least, the record dispenses with the contention that the DOJ and BOP failed to provide "*any* explanation for their planned used of pentobarbital as an execution drug." (Am. Compl. ¶ 163 (emphasis supplied).)

Plaintiffs' opposition brief makes clear that the crux of Count VIII is the BOP's alleged failure to consider the risk of flash pulmonary edema, the risk of faulty IV placement, and the dangers of using a compounded drug, but these arguments have already been litigated and rejected. While the Protocol "does not discuss the risk of flash pulmonary edema specifically, the BOP need not consider every possible risk associated with its chosen method of execution." *Execution Protocol Cases*, No. 20-5206, slip op. at 2 (D.C. Cir. July 17, 2020). And the BOP's analysis was enough to pass muster under the arbitrary and capricious standard. *Id.* As for the risk of faulty IV placement, both this court and the D.C. Circuit concluded that the BOP had in fact studied "the difficulties of IV-line placement" and that its decision "to allow medically trained personnel to determine how best to place the IV line was [not] unreasonable." *Id.* (citing Admin. R. at 931–32); (July 15 Mem. Op at 9.) Finally, the court has already found that, under Supreme Court precedent, the BOP's decision to use a compounded form of pentobarbital where

domestic supplies are unavailable was not arbitrary or capricious. (July 15 Mem. Op. at 9 (citing *Bucklew v. Precythe*, 139 S. Ct. 1112, 1125 (2019).)

Plaintiffs efforts to revive these arguments are unavailing. They argue that while this court denied a request for a preliminary injunction on their arbitrary and capricious claim, it did not resolve their claim "that the 2019 Protocol and the accompanying Administrative Record lack adequate explanations for the challenged policy decision." (Pls. Opp'n at 27.) The court fails to see how its conclusion that none of these allegations rose "to the level of arbitrariness or capriciousness for an APA violation" leaves anything left to be decided on this issue. (July 15 Mem. Op. at 8.)

In their sole remaining claim in Count VIII, Plaintiffs allege that the government acted arbitrarily and capriciously in failing to discuss its non-compliance with the CSA. (Am. Compl. ¶ 172.) Defendants are entitled to summary judgment here because, as discussed below, there is no CSA violation.

3. Ultra Vires Agency Action—Count V

In Count V of their Amended Complaint, Plaintiffs allege that the 2019 Protocol constitutes ultra vires agency action in violation of § 3596(a) of the FDPA.[9] That provision requires that in carrying out a death sentence, "the Attorney General shall release the person sentenced to death to the custody of a United States marshal, who shall supervise implementation

[9] In Count V, Plaintiffs also allege that Defendants' development of the Protocol without requisite authority violates the Take Care Clause of the U.S. Constitution. But Plaintiffs did not respond to Defendants' summary judgment argument on this claim, and therefore appear to have abandoned it. In any event, it is not clear that the Take Care Clause claim presents a justiciable controversy. *See Citizens for Responsibility & Ethics in Wash. v. Trump*, 302 F. Supp. 3d 127, 138–40 (D.D.C. 2018). And even assuming such a claim is justiciable, the one presented in the Amended Complaint is another iteration of Plaintiffs' improper delegation claim, which the court finds unavailing.

of the sentence in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a). Plaintiffs argue that the Protocol conflicts with this directive because it "implement[s] a protocol that differs in material respects from the applicable states." (Am. Compl. ¶ 146.) Furthermore, in their view, the Protocol does not require a U.S. Marshal to supervise the implementation of a death sentence—that responsibility, they contend, has been impermissibly delegated to the BOP. (*Id.* ¶ 147.)

Defendants argue that the claims in Count V have already been rejected by the D.C. Circuit, which directed that judgment be entered in Defendants' favor on these issues. (Defs. Mot. at 31.) This contention is unsupported by the record. In its November 2019 order granting a preliminary injunction, the court found that Plaintiffs were likely to succeed on the merits of their claim that the 2019 Protocol exceeds statutory authority. In so concluding, it found that "the FDPA gives decision-making authority regarding 'implementation'" of federal death sentences to states, and therefore, to the extent the Protocol creates a single procedure, "it is not authorized by the FDPA." (ECF No. 50, Nov. 20 Mem. Op. at 7, 12.) It also posited that the requirement that executions be carried out "in the manner prescribed" by state law referred to both the selection of the execution method and the procedures utilized during the execution.

Two Judges on the D.C. Circuit rejected this interpretation and directed the entry of judgment on the "primary FDPA claim," i.e. that the Protocol contravenes the FDPA requirement that executions be implemented in accordance with the execution procedures of the state where the inmate was sentenced. *Execution Protocol Cases*, 955 F.3d at 112. However, those Judges took different paths to that conclusion. Judge Katsas concluded that the FDPA "regulates only the top-line choice among execution methods, such as the choice to use lethal injection instead of hanging or electrocution." *Id.* But Judge Rao found that the FDPA requires

the government "to follow execution procedures set forth in state statutes and regulations, but not execution procedures set forth in less formal state execution protocols." *Id.* She also concluded that because the 2019 Protocol allows the government to depart from its procedures to comply with state statutes and regulations, it did not run afoul of the FDPA. *Id.*

Judge Tatel, in dissent, agreed with this court's assessment and found that "section 3596(a), best understood, requires federal executions to be carried out using the same procedures that states use to execute their own prisoners—procedures set forth not just in statutes and regulations, but also in protocols issued by state prison officials pursuant to state law." *Id.* at 146. Judge Tatel addressed Defendants' complaint that this result would require it to follow every nuance of the state protocols, writing that "section 3596(a) requires the federal government to follow only 'implementation' procedures, which plaintiffs define as those procedures that 'effectuat[e] the death,' including choice of lethal substance, dosages, vein-access procedures, and medical personnel requirements." *Id.* at 151 (internal citations omitted).

In light of this plurality decision, the court cannot grant summary judgment as to all the claims in Count V. Plaintiffs correctly point out that the panel did not issue a precedential opinion on two additional arguments: i) whether the 2019 Protocol illegally delegates authority to the BOP that rightfully belongs to the U.S. Marshal; and ii) whether the 2019 Protocol conflicts with the manner of execution prescribed by the "law" of each relevant state involved here, which the controlling opinion (Judge Rao's) defines as the relevant state's statutes and formal regulations. (*See* Pls. Opp'n at 32.) Thus, the court must once again enter the thicket.

i. The U.S. Marshal's Authority to "Supervise"

Plaintiffs' claim that the 2019 Protocol improperly assigns the U.S. Marshal's authority to the BOP fails as a matter of law.[10] In Plaintiffs' view, the BOP has usurped from the Marshal the "primary authority to determine the manner of federal executions," which includes the authority to "formulate" an execution protocol, to "select" which drugs are used, and to "order execution personnel to depart from the established procedures." (Pls. Opp'n at 33.) This argument finds no support in the text of the FDPA.

Section 3596 requires that the U.S. Marshal "supervise implementation" of the death sentence. The critical word here is "supervise,"[11] which is undefined in the statute. The court must therefore rely on its plain meaning. "To 'supervise' is to 'superintend' or 'oversee,'" but not to "formulate," "determine," or "select" the manner of federal execution. *Execution Protocol Cases*, 955 F.3d at 134 (Rao, J., concurring) (citing Supervise, Merriam Webster's Collegiate Dictionary (11th ed. 2014)); (*see also* Pls. Opp'n at 33.)

Statutory history supports the conclusion that "supervise" does not mean the U.S. Marshal has the exclusive authority to carry out federal executions or to institute procedures for doing so. In prior death penalty statutes, Congress used more expansive language in describing the U.S. Marshal's duties during an execution. For instance, in the 1937 version, Congress provided that the U.S. Marshal was "charged with the execution of the sentence." *See* 50 Stat. at

[10] Judge Katsas previously found this claim unconvincing on the merits. Judge Rao found that, because Plaintiffs did not raise the issue before this court in the preliminary injunction briefing, it was waived on appeal. But, as Defendants acknowledge, Judge Rao's opinion did "not substantively address the question." (ECF No. 191, Defs. Reply at 17.)

[11] As Judge Rao explained in her concurrence, "[t]he ordinary meaning of 'implementation of the sentence' includes more than 'inflicting the punishment of death.'" *Execution Protocol Cases*, 955 F.3d at 133 (Rao, J., concurring); (*see infra* at 29.) Neither party has advanced an alternative meaning of the term "implementation." (*See* Pls. Opp'n at 33.)

304. This language is more akin to the dominant role Plaintiffs ascribe, or at least, leaves room for Plaintiffs' interpretation.

The 2019 Protocol does not divest the U.S. Marshal of this supervisory authority. In fact, it mandates that the U.S. Marshal is to "oversee the execution and to direct which other personnel may be present at it." *In Re Fed. Bureau of Execution Protocol Cases*, 955 F.3d at 124 (Katsas, J.) (referencing Admin. R. at 885). The execution cannot begin without the Marshal's approval, and it is the Marshal who certifies that the execution has been carried out. *Id.* (referencing Admin. R. at 895, 899). The court therefore concludes that the U.S. Marshal supervises—i.e., oversees and superintends over—the execution.

Furthermore, the fact that the U.S. Marshal must supervise an execution does not preclude other DOJ components from participating. Indeed "all functions of agencies and employees of the Department of Justice"—of which both the Marshals Service and the BOP are parts—"are vested in the Attorney General." Thus, any authority inherent in the Attorney General's power to enforce a death sentence that has not been specifically assigned to a DOJ component may be delegated. *See* 28 U.S.C. §§ 509, 510; *United States v. Giordano*, 416 U.S. 505, 514 (1974) (finding unexceptional the proposition that the Attorney General may freely delegated his power where Congress does not say otherwise).[12]

The 2019 Protocol, as written, still provides the U.S. Marshal the power to supervise the implementation of a death sentence. Therefore, the court finds that the 2019 Protocol does not

[12] Defendants takes this argument a step further and argue that even if the supervisory authority granted to U.S. Marshal includes the authority to develop execution procedures, the Attorney General may freely reassign that power to another DOJ component. *See Execution Protocol Cases*, 955 F.3d at 125. The court need not resolve this argument, having already concluded that the Protocol does not divest the Marshal of supervisory duties.

improperly delegate authority to the BOP. The government is entitled to summary judgment as to this aspect of Count V.

ii. Relevant State Statutes and Regulations

Defendants argue that there are no surviving claims in Count V. The court disagrees. The D.C. Circuit's opinion leaves two remaining scenarios which preclude the court from granting summary judgment as to Count V without further discussion. The first arises when the Protocol conflicts with a state's top-line method of execution such as lethal injection, electrocution, etc. All three Circuit Judges agreed that this would violate the FDPA. *See Execution Protocol Cases*, 955 F.3d at 112 ("Judge Katsas concludes that the FDPA regulates only the top-line choice among execution methods . . . [while] Judge Rao concludes that the FDPA also requires the federal government to follow execution procedures set forth in state statutes and regulations."); *id.* at 146 (Tatel, J., dissenting) ("I agree with Judge Rao that the term 'manner' refers to more than just general execution method . . . section 3596(a), best understood, requires federal executions to be carried out using . . . procedures set forth not just in [state] statutes and regulations, but also in protocols issued by state prison officials."). The second is when the Protocol conflicts with a state statute or regulation, which Judges Rao and Tatel agreed would violate the FDPA.

Plaintiffs point to three state statutes which they allege conflict with the Protocol's "top-line method" of execution. Whereas the Protocol specifies that Plaintiffs are to be executed by lethal injection, South Carolina (where Plaintiff Fulks was sentenced) and Virginia (where Plaintiffs Tipton, Johnson, and Roane were sentenced) allow inmates to choose between execution by lethal injection or electrocution. S.C. Code. § 24-3-530(A); VA Code Ann. § 53.1-

234. Missouri law (where Plaintiff Holder was sentenced) allows for execution by either lethal injection or lethal gas. Mo. Rev. Stat. § 546.720.1.

The court asked Defendants to file a notice indicating whether they were prepared to deviate from the procedures of the 2019 Execution Protocol to accommodate these statutes. (Minute Order, Sept. 14, 2020.) In that notice, Defendants stated that "the government will not execute any plaintiff whose sentence was issued in federal court in Virginia or South Carolina and is subject to the FDPA without complying with those provisions of S.C. Code § 24-3-530(A) or Va. Code Ann. § 53.1-234." (ECF No. 247, Defs. Notice at 5.) And while Missouri has a law on the books that allows an inmate to be executed by lethal gas, the choice of which method to use does not appear to rest with the inmate as it does in South Carolina and Virginia. *See* Mo. Rev. Stat. § 546.720.1. Thus, the court is satisfied that there is no live controversy as to the alleged discrepancies between the 2019 Protocol and the relevant South Carolina, Virginia, and Missouri laws. *See Nat'l Black Police Ass'n v. District of Columbia*, 108 F.3d 346, 349 (D.C. Cir. 1997) (en banc) ("Even where litigation poses a live controversy when filed . . . a federal court [must] refrain from deciding it if events have so transpired that the decision will neither presently affect the parties' rights nor have a more-than-speculative chance of affecting them in the future" (internal citations and quotation marks omitted)).

Beyond the state laws discussed above, Plaintiffs have identified the following state statutes and regulations that conflict with the 2019 Protocol:

- A Georgia statute (applicable to Plaintiffs Battle and LeCroy) requiring the presence of "two physicians to determine when death supervenes." Ga. Code § 17-10-41.

- An Arkansas statute (applicable to Plaintiff Paul) requiring "[c]atheters, sterile intravenous solution, and other equipment" used in executions "be sterilized and prepared in a manner that is safe and commonly performed in connection with the intravenous administration of drugs of that type." Ark. Code § 5-4-617(f).

- An Arkansas statute (applicable to Plaintiff Paul) requiring execution drugs to be (1) FDA-approved, (2) obtained from an FDA-registered facility, or (3) obtained from a nationally accredited compounding pharmacy. Ark. Code § 5-4-617(d).

- A Texas statute (applicable to Plaintiffs Bernard, Bourgeois, Hall, Robinson, and Webster) mandating that executions shall take place "at any time after the hour of 6 p.m. on the day set for the execution." Tex. Code of Crim. Proc. Art. 43.14(a).

The D.C. Circuit's prior decision in this litigation requires Defendants to adhere to these statutes. As Judge Rao wrote, while "formal state law often specifies little more than the method of execution, the federal government is nonetheless bound by the FDPA to follow the level of detail prescribed by state law." *Execution Protocol Cases*, 955 F.3d at 133. Judge Tatel found that the FDPA "best understood, requires federal executions to be carried out using . . . procedures set forth not just in [state] statutes and regulations, but also in protocols issued by state prison officials." *Id.* at 146.

In responding to Plaintiff LeCroy's motion for a preliminary injunction and in its September 15 notice to the court, Defendants advance a narrower reading of Judge Rao's opinion and a more expansive one of Judge Tatel's. (*See* Defs. Opp'n to LeCroy Mot. at 16–17; *see also* Defs. Notice at 2.) Pointing to a Seventh Circuit opinion, Defendants contend that Judge Rao's interpretation of the FDPA is limited to state laws and regulations governing procedures for effectuating death. (*Id.* at 17). In the Seventh Circuit's view, the debate among the D.C. Circuit Judges "was limited to state laws, regulations, and protocols governing *procedures for effectuating death*." *Peterson v. Barr*, 965 F.3d 549, 554 (7th Cir. 2020) (discussing *Execution Protocol Cases*, 955 F.3d at 122); *see also United States v. Mitchell*, No. 20-9909, 2020 WL 4815961 (9th Cir. Aug. 19, 2020) (adopting the Seventh Circuit's reading of *Execution Protocol Cases*, 955 F.3d at 122). The court is not bound by other Circuits' interpretation of D.C. Circuit

precedent and cannot square their limited reading with the language in either Judge Rao or Judge Tatel's opinions.

For instance, in discussing her understanding of the word "implementation," Judge Rao explained that "the ordinary meaning of 'implementation of the death sentence' includes more than 'inflicting the punishment of death' . . . [it includes] additional procedures involved in carrying out the sentence of death." *Execution Protocol Cases*, 955 F.3d at 133 ("the term 'implementation' is commonly used to refer to a range of procedures and safeguards surrounding executions"). She also explained that such "implementation" would include details such as the time, date, place, and method of execution, all of which can fairly be read to include the state statutes Plaintiffs have identified. *Id.* at 134 (quoting Implementation of Death Sentences in Federal Cases, 58 Fed. Reg. 4,898, 4,901–02 (Jan. 19, 1993)).

Similarly, Defendants read Judge Tatel's opinion as acknowledging that the FDPA incorporates "only those state procedures 'that effectuate death,' such as 'choice of lethal substances, dosages, vein-access procedures, and medical-personnel requirements,'" which apply to protocols as well as statutes and regulations. (Defs. Opp'n to LeCroy Mot. at at 6–7 (citing *Execution Protocol Cases*, 955 F.3d at 151).) The court does not share this expansive interpretation; in its view, Judge Tatel was responding to Defendants' contention that his reading would require it to follow "every nuance of state *protocols*." *Execution Protocol Cases*, 955 F.3d at 151 (emphasis supplied) (internal quotation marks omitted). Judge Tatel's dissent did not address whether this type of de minimis exception applied to state statutes and regulations. *See id.*

Even if the court agreed with Defendants' broad reading of Judge Tatel's dissent, all the state statutes Plaintiffs have cited in their opposition involve procedures that effectuate death.

The Georgia statute requiring two physicians to certify when death supervenes was no doubt enacted to ensure that death has been effectuated. Furthermore, that statute, as well as the Arkansas laws, are the types of procedures Judge Tatel found effectuate death. *See id.* (citing "choice of lethal substances, dosages, vein access-procedures, and medical-personnel requirements" as examples). Finally, the Texas statute governs when death is to be effectuated and prevents the state from rescheduling an execution after normal court hours despite the pendency of any remaining legal challenges and without providing notice to the prisoners' attorneys—as was the case with the Lee execution.

Despite these findings, the court nonetheless concludes that Defendants are entitled to summary judgment as to the alleged discrepancies between the 2019 Protocol and state law. Defendants state that they intend to comply with Georgia's requirement that two physicians be present at the execution to determine when death supersedes. (Defs. Notice at 2); Ga. Code § 17-10-41. They also state that they intend to comply with the sterilization requirements set forth in § 5-4-617(f) of the Arkansas Code. (Defs. Notice at 4.) Furthermore, as Defendants point out, there is no violation of Arkansas Code § 5-4-617(d), as the government will be using a pentobarbital solution obtained from an FDA-registered facility. (*See* Admin. R. at 1084; ECF No. 36-1, Decl. of Raul Campos ¶ 3.)

With regard to the scheduling requirements in Texas criminal procedure code Article 43.14, Defendants proffer that "BOP will consider, and *may* choose to accommodate, the request of any Plaintiff sentenced by a federal court in Texas who wishes to have an execution scheduled for after 6p.m." as an "administrative grace." (Defs. Notice at 3–4 (emphasis supplied).) Putting aside the question of whether agreeing to execute an inmate after 6 p.m. can be characterized as an act of "grace," Defendants must comply with the Texas provision because it is incorporated

into the FDPA by virtue of D.C. Circuit precedent. *See Execution Protocol Cases*, 955 F.3d at 133 (Rao, J., concurring) ("[T]he federal government is [] bound by the FDPA to follow the level of detail prescribed by state law.").

Nevertheless, the court does not see a controversy here. Christopher Vialva is the only plaintiff sentenced to death in Texas with a scheduled execution date. The court is unaware that he has requested to be executed after 6 p.m. And even if that request has been made and the BOP denied it, it is unlikely this would constitute irreparable harm. To warrant injunctive relief, a plaintiff must demonstrate, inter alia, that he will "suffer[] an irreparable injury, *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006), which must be "both certain and great" and "of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm," *Wis. Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985; (*see infra* Sec. C.) The court understands the concern that "[t]he ability to schedule an execution at any time of day or night" would allow "Defendants to reschedule and carry out . . . executions almost immediately after the expiration or vacatur of a stay, despite the pendency of additional legal challenges, and with or without notice to the prisoners' attorneys." (Pls. Opp'n at 37.) This is injury is far from "certain," however.

Though the court disagrees with Defendants' interpretation of the D.C. Circuit's decision in *Execution Protocol Cases*, it nonetheless finds that, based on the record before it, Defendants are entitled to summary judgment as to all the claims in Count V.

4. Notice-and-Comment Rulemaking—Count VI

Two Judges of this Circuit have already found that the 2019 Protocol is a procedural rule and thus not subject to the notice-and-comment procedures of the APA. *Execution Protocol*

Cases, 955 F.3d at 112, 144–45; (s*ee also* ECF No. 209, Order on Mot. to Strike at 2.) Accordingly, Defendants are entitled to summary judgment on Count VI.

5. CSA Claims—Counts VIII, IX, and XI

Plaintiffs contend that the 2019 Protocol violates the Controlled Substances Act because it does not require Defendants to obtain a valid written prescription for the pentobarbital it will use to execute them. *See* 21 U.S.C. § 829(a) (requiring valid prescription, issued for a legitimate medical purpose, in dispensing any controlled substance to an "ultimate user"); 21 C.F.R. § 1308.12 (listing pentobarbital as a Schedule II controlled substance).

Plaintiffs' CSA claims fail under the Supreme Court's decision in *Gonzales v. Oregon,* 546 U.S. 243, 272–74 (2006), in which the Court held that the CSA is primarily "a statute combating recreational drug use," and must be read in light of that statutory purpose. *Id.* at 272. In ruling on a challenge to the use of Schedule II controlled drugs for physician assisted suicide, the Court found that "the prescription requirement is better understood as a provision that ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. . . . To read prescriptions for assisted suicide as constituting 'drug abuse' under the CSA is discordant with the phrase's consistent use throughout the statute." *Id.* at 274. This holding appears to exclude from the CSA dispensing lethal injection drugs during an execution. Accordingly, Defendants are entitled to summary judgment on Counts VIII, IX, and the CSA claims in Count XI.

C. Plaintiffs' Partial Motion for Summary Judgment—Count XI

For the reasons set forth in its August 27, 2020 Memorandum Opinion, the court finds that the remaining Plaintiffs are entitled to summary judgment as to the FDCA claims in

Count XI. (*See generally* Aug. 27 Mem. Op.)[13] To recapitulate, the court found that the pentobarbital the government intends to use in executions is subject to the FDCA and fails to meet the premarketing, labeling, and prescription requirements therein. Thus, the government's use, under the 2019 Protocol, of pentobarbital that has not been prescribed and does not meet other statutory requirements of the FDCA constitutes agency action that is contrary to law in violation of the APA.

1. Standard for Irreparable Harm

Given these statutory violations, Plaintiffs ask the court to enjoin their executions. (Pls. Mot. for Partial Summ. J. at 1.) "A finding of a statutory violation does not automatically require the court to issue an injunction." *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, (D.D.C. 2000) (citing *Weinberger v. Romero–Barcelo*, 456 U.S. 305, 313 (1982) ("The grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to [enjoin the conduct] under any and all circumstances, and a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law.")). To merit injunctive relief, Plaintiffs must show that: (i) they have "suffered an irreparable injury"; (ii) remedies available at law, such as monetary damages, are inadequate to compensate them for their injury; (iii) "considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted"; and (iv) "the public interest would not be disserved by a permanent injunction." *See eBay Inc,* 547 U.S. at 391.

Having already found that Plaintiffs are entitled to summary judgment as to the FDCA claims in Count XI, the cornerstone here is irreparable injury. It well established that the burden

[13] Accordingly, Plaintiff LeCroy is entitled to summary judgment as to the FDCA claims in Count V of his Amended Complaint.

of demonstrating irreparable injury lies with the movant. *See id.* This presents a "very high bar." *Beck v. Test Masters Educ. Servs. Inc.*, 994 F. Supp. 2d 98, 101 (D.D.C. 2014) (quoting *Coal. for Common Sense In Gov't Procurement v. United States*, 576 F. Supp. 2d 162, 168 (D.D.C. 2008)).[14] The injury must be "both certain and great" and "of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm." *Wis. Gas Co.*, 758 F.2d at 674.

In their most recent pleadings, Plaintiffs appear to push back against the standard articulated for irreparable harm by the D.C. Circuit in *Wisconsin Gas* and similar cases. *See, e.g.*, *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 7–8 (D.C. Cir. 2016) (quoting *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006)) ("The party seeking a preliminary injunction must make two showings to demonstrate irreparable harm . . . the harm must be 'certain and great,' 'actual and not theoretical,' and so 'imminen[t] that there is a clear and present need for equitable relief.'"). For instance, Plaintiff Norris Holder identifies language from the Supreme Court's *Monsanto* decision which suggests that the threat of a future irreparable injury need only be likely, not certain, to warrant injunctive relief. (ECF No. 249, Holder Reply at 2 (citing *Monsanto Co. v. Geerston Seed Farms*, 561 U.S. 139, 162

[14] The court is not confined to the administrative record in assessing irreparable harm. *See Eco Tour Adventures, Inc. v. Zinke*, 249 F. Supp. 3d 360, 369 n.7 (D.D.C. 2017) (citing *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C. Cir. 1989)) ("[E]xtra-record evidence may be used 'in cases where relief is at issue.'"). This is because "[t]he issue of injunctive relief is generally not raised in administrative proceedings below and, consequently, there will usually be no administrative record developed on these issues." *Id.* (citing Steven Sark & Sarah Wald, *Setting No Records: The Failed Attempts to Limit the Record in Review of Administrative Actions*, 36 Admin. L. Rev. 333, 345 (1984)) (internal quotations marks omitted). In fact, "it will often be necessary for a court to take new evidence to fully evaluate claims of irreparable harm." *Id.* (internal quotations marks omitted).

(2010) (noting that a permanent injunction "guard[s] against a[] present or imminent risk of likely irreparable harm")).)

The court does not find that *Monsanto* clearly resolves that question because elsewhere in the same decision, the Supreme Court explained that the "respondents cannot show that they *will suffer* irreparable injury if [the challenged agency agency] was allowed to proceed." *Monsanto*, 561 U.S. at 162 (emphasis supplied); *see also Ctr. for Bio. Diversity v. Ross*, 2020 WL 4816458, at *10 (D.D.C. Aug. 19, 2020) (noting the inconsistency in the Supreme Court's articulation of the irreparable standard in *Monsanto*). To be sure, the Supreme Court has used similar language in other cases. *See, e.g.*, *Winter v. NRDC*, 555 U.S. 7, 20 (2008) ("A plaintiff seeking a preliminary injunction must establish that . . . he is likely to suffer irreparable harm in the absence of preliminary relief."). But even assuming *Monsanto* means a "likelihood" standard of irreparable harm is distinct from a "certainty" standard, it does not matter which standard the court applies in this case. Even under the likelihood of future irreparable harm standard, Plaintiffs do not meet their burden to warrant the extraordinary relief of an injunction.

2. Alleged Injury

While it is certainly true that death is irreparable, it is not the government's violation of the FDCA that would cause this injury. Plaintiffs' death sentences were imposed after trials and their convictions and sentences have been affirmed on appeal.

Rather, Plaintiffs allege that they will face health risks from the use of a drug that has not been certified to ensure a humane death. (*See* ECF No. 248, Pls. Reply in Supp. of Pls Mot. for Partial Summ. J. at 3 (characterizing their injury as "the lack of FDCA-required clinical oversight that would require pentobarbital to be administered in a manner . . . that minimizes the well-documented risk of suffering from the conscious experience of flash pulmonary edema").)

As an initial matter, it is not apparent how securing a prescription would eliminate this alleged harm. Assuming the BOP finds a doctor to write a prescription, Plaintiffs will still be executed using pentobarbital. Thus, the prescription requirement does not in and of itself ensure that Plaintiffs will not be protected from flash pulmonary edema during their executions.

More fundamentally, while the court continues to be concerned at the possibility that inmates will suffer excruciating pain during their executions, Plaintiffs have not established that flash pulmonary edema is "certain" or even "likely" to occur before an inmate is rendered insensate.

The record contains conflicting evidence as to whether pentobarbital can cause flash pulmonary edema before an inmate is rendered unconscious. For instance, Plaintiffs point to declarations submitted by Dr. Gail Van Norman describing the "virtual medical certainty that most, if not all, prisoners will experience excruciating suffering, including sensations of drowning and suffocation" caused by flash pulmonary edema. (Pls. Mot. for Partial Summ. J. at 12 (citing Van Norman Decl. at 7).) Dr. Van Norman states that these risks have been confirmed by the Purkey autopsy results, which revealed that Purkey's lungs "were filled with fluid to the extent of nearly doubling their normal weight, and frothy pulmonary edema fluid filled his main airways all the way up in the trachea." (ECF No. 183-2, Van Norman 2d Supp. Decl. ¶ 5.) Such fluid would have accumulated before death. (*Id.* ¶ 9.) Dr. Van Norman also suggests that the current understanding in the field of anesthesiology is that barbiturates such as pentobarbital diminish only the subjects' responsiveness to stimuli and not their awareness of such stimuli—including the conscious experience of excruciating pain. (*See* Van Norman Decl. at 13, 22–23, 28–29.)

But Defendants offer conflicting evidence suggesting that an inmate would not experience the effects of flash pulmonary edema before becoming insensate. One of their experts, Dr. Kendall Von Crowns, reasons this is because "[d]ue to the large amount of the drug administered, there would not be enough time for pentobarbital to clear from the respiratory and cardiac receptions of the brainstem." (*See* ECF No. 246-1, Crowns Decl. ¶ 12.) Dr. Joseph Antognini supports this position. In his view, "[e]ven if pulmonary edema did occur ante mortem, the inmates would have been profoundly anesthetized (with cessation of brain activity) and would not have experienced any sensations of pulmonary edema." (ECF No. 246-2, Antognini 2d Supp. Decl. ¶ 3h.)

Furthermore, both Drs. Crowns and Antognini refute Dr. Van Norman's evaluation of the Purkey autopsy. Dr. Antognini disputes the study upon which Dr. Van Norman relies to conclude that there is no correlation between lung weight and the interval between death and autopsy. (*Id.* ¶ 29 ("Most likely, the autopsies [in the study cited by Dr. Van Norman] were performed at intervals of several hours (and perhaps days) after death, and the correlation would have been missed.").) And Dr. Crowns posits that "[t]here is no way to determine based on autopsy findings how quickly the pulmonary edema occurred, but even if the edema was from a 'flash' situation it would take minutes to occur," and inmates injected with five grams of pentobarbital can become insensate within seconds. (Crowns Decl. ¶¶ 3, 10.) Dr. Van Norman, in turn, disputes these conclusions. (*See generally* ECF No. 249-1, Van Norman Additional Suppl. Report.)

After considering the conflicting declarations, the court found that the question of whether an inmate will suffer flash pulmonary edema before becoming insensate was one upon which reasonable minds could differ. Thus, in an attempt to make credibility assessments—and

at the urging of both parties, which claimed an evidentiary hearing was needed to rule in their opponent's favor—the court held an evidentiary hearing on September 18 and 19, 2020. Given the narrow issue and the need to rule before an execution scheduled for September 22, 2020, the court allowed the parties the opportunity to cross examine the other side's experts and conduct limited re-direct examination. *See Cobell v. Norton*, 391 F.3d 251, 261 (D.C. Cir. 2004) (noting that a court should hold a hearing to when it must "make credibility determinations to resolve key factual disputes in favor of the moving party" seeking injunctive relief, but that "[t]he circumstances and interests at stake will affect whether an abbreviated or more extensive evidentiary hearing is necessary"). On the first day of the hearing, Defendants chose not to cross-examine Dr. Van Norman and the Plaintiffs elected to rely on the statements made in her declarations and did not call her as a witness. Plaintiffs cross-examined Drs. Crowns and Antognini.

Plaintiffs unsuccessfully attempted to undermine the evidence upon which Dr. Crowns based his conclusion that "[t]here is no way to determine based on autopsy findings how quickly the pulmonary edema occurred." (*See* Crowns Decl. ¶ 10.) Dr. Crowns admitted that his conclusion that most inmates subjected to a lethal dose of pentobarbital do not experience labored breathing indicative of flash pulmonary edema was based on media and eyewitness reports from executions he did not witness. (*See id.* ¶¶ 5, 11.) He also admitted that he was unaware of more recent news reports from the executions of Lee, Honken, Purkey, and Mitchell describing the inmates as showing labored breathing, gasping for breath, or heaving. While the court noted that Dr. Crowns did not review the more recent news reports that contradicted the ones he had reviewed, it does not find this to completely undermine Dr. Crowns' conclusions. Dr. Crowns explained that an inmate's gasping for breath alone does little to answer the question

of whether the inmate was gasping for breath while conscious. As he noted, gasping or labored breathing alone could be indicative of agonal breathing that occurs right before death but after the inmate is rendered unconscious.

While the court did not find Dr. Antognini unqualified—as Plaintiffs attempted to show during his cross-examination—his reports and testimony did not carry much weight. For one, Dr. Antognini's research has been primarily on animals and he no longer routinely practices in a clinical setting. Furthermore, most of the studies he cites on pentobarbital are rather old, though the court takes his point that many of the most salient studies on pentobarbital were performed in the 1940s, 50s, and 60s. The court has also taken judicial notice of the fact that Dr. Antognini was found to be not qualified to opine on similar issues in another district court litigation. *See In re Ohio Execution Protocol Litig.*, No. 11-1016-EAS-MRM, slip op. at 4 (S.D. Ohio Jan. 27, 2020) ("There is no indication that this Court or any other has been 'distracted' by Dr. Antognini's opinions, as it has consistently given little or no weight to his reports or testimony in this consolidated litigation."). But while this finding is concerning, the court also notes that the Supreme Court has relied on Dr. Antognini's testimony on the effects of pentobarbital. *See Bucklew v. Precythe*, 139 S. Ct. 1112, 1132 (2019). But even were the court to completely discredit Dr. Antognini's testimony, the evidence in the record does not support Plaintiffs' contention that they are likely to suffer flash pulmonary edema while still conscious.

The court cannot weigh the evidence before it in a vacuum. The Supreme Court has already addressed most of the evidence Plaintiffs have presented in this case and found that it was not enough to warrant injunctive relief. *See Lee*, 2020 WL 3964985 at *2. The Court also emphasized that pentobarbital "[h]as been used to carry out over 100 executions, without incident." *See Lee*, 2020 WL 3964985, at *2. And while the Supreme Court reached these

conclusions while this litigation was in a different procedural posture, the irreparable harm inquiry is similar in both the preliminary and permanent injunction context. *Doe v. Mattis*, 928 F.3d 1, 7 (D.C. Cir. 2019) (explaining that the same requirement of irreparable harm applies to preliminary and permanent injunctions). Given the Supreme Court's decision and the competing evidence in this case, Plaintiffs cannot meet their burden of showing that the harm of flash pulmonary edema is likely, let alone "certain" or "imminen[t]." *Wis. Gas Co.*, 758 F.2d at 674; s*ee also Al-Joudi v. Bush*, 406 F. Supp. 2d 13, 20 (D.D.C. 2005) ("Courts often find a showing of irreparable harm where the movant's health is in imminent danger".).

The same is true for the alleged harm from the government's reliance on bulk compounding to secure a reliable source of pentobarbital. While Plaintiffs argue that the government will subject them "to the risks of compounded drugs [] without any corresponding medical benefit to justify those risks," it is not clear to the court what non-speculative irreparable harm arises from using the government's compounded pentobarbital. (See Pls. Reply at 8 (noting that compounded drugs are "unreliable and dangerous"); *see also* Pls. Mot. for Partial Summ. J. at 13–14.)

During the evidentiary hearing, the court heard competing testimony from Dr. Michaela Almgren and Dr. Peter Swaan regarding their conclusions about the potency and stability of the pentobarbital Defendants intend to use in the executions. This testimony was not particularly helpful because Plaintiffs have not shown that the BOP will be using expired pentobarbital or that the pentobarbital the BOP intends to use was stored in a such a way that would likely cause them to suffer. At most, Plaintiffs showed that such harm was possible, but this is not enough to warrant the extraordinary relief afforded by a permanent injunction.

Having found that Plaintiffs have failed to establish the requisite irreparable harm, the court need not address the remaining factors. *See Wis. Gas Co.*, 758 F.2d at 674 (quoting *Sampson v. Murray*, 415 U.S. 61, 88 (1974) ("The basis for injunctive relief in the federal courts has always been irreparable harm and inadequacy of legal remedies.")

III. CONCLUSION

For the foregoing reasons, the Defendants' motion to dismiss (ECF No. 169) is GRANTED as to Counts I, III, IV, and VII of the Amended Complaint (ECF No. 92) for failure to state a claim. Defendants' motion for summary judgment (ECF No. 170) is likewise GRANTED as to Counts V, VI, VIII, IX, and X, but DENIED as to the FDCA claims in Count XI.

Plaintiffs' motion for partial summary judgment (ECF No. 236) as to Count XI (and Count V of Plaintiff LeCroy's Amended Complaint) is GRANTED, but the court finds that, the statutory violations notwithstanding, Plaintiffs have failed to demonstrate irreparable harm and are therefore not entitled to the injunctive relief sought as to those claims. This ruling will not apply to Plaintiff Norris Holder, whose request for injunctive relief will remain pending.

Date: September 20, 2020

Tanya S. Chutkan
TANYA S. CHUTKAN
United States District Judge

APPENDIX E

(B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (*l*), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol ''Rx only''.

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in sections 4721, 6001, and 6151 of title 26, or to marihuana as defined in section 4761 of title 26.

(c) Sales restrictions

(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term ''drug sample'' means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

§ 353. Exemptions and consideration for certain drugs, devices, and biological products

(a) Regulations for goods to be processed, labeled, or repacked elsewhere

The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term ''coupon'' means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with subsection (b).

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) which is subject to subsection (b), and

(ii)(I) which was purchased by a public or private hospital or other health care entity, or

(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of title 26.

(B) Subparagraph (A) does not apply to—

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b).

For purposes of this paragraph, the term ''entity'' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term ''emergency medical reasons'' includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d) Distribution of drug samples

(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term ''distribute'' does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least an-

nually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(4) In this subsection, the term ''authorized distributors of record'' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

(e) Licensing and reporting requirements for wholesale distributors; fees; definitions

(1) REQUIREMENT.—Subject to section 360eee–2 of this title:

(A) IN GENERAL.—No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person—

(i)(I) is licensed by the State from which the drug is distributed; or

(II) if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary; and

(ii) if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

(B) STANDARDS.—Each Federal and State license described in subparagraph (A) shall meet the standards, terms, and conditions established by the Secretary under section 360eee–2 of this title.

(2) REPORTING AND DATABASE.—

(A) REPORTING.—Beginning January 1, 2015, any person who owns or operates an establishment that engages in wholesale distribution shall—

(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

(I) each State by which the person is licensed and the appropriate identification number of each such license; and

(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

(B) DATABASE.—Not later than January 1, 2015, the Secretary shall establish a database of authorized wholesale distributors. Such database shall—

(i) identify each authorized wholesale distributor by name, contact information, and each State where such wholesale distributor is appropriately licensed to engage in wholesale distribution;

(ii) be available to the public on the Internet Web site of the Food and Drug Administration; and

(iii) be regularly updated on a schedule determined by the Secretary.

(C) COORDINATION.—The Secretary shall establish a format and procedure for appropriate State officials to access the information provided pursuant to subparagraph (A) in a prompt and secure manner.

(D) CONFIDENTIALITY.—Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(3) COSTS.—

(A) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection (b), the Secretary shall license a person engaged in wholesale distribution located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(B) STATE LICENSING FEES.—Nothing in this chapter shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of such distributors.

(4) For the purposes of this subsection and subsection (d), the term ''wholesale distribution'' means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

(A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(B) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act [42 U.S.C. 247d], except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(H) the distribution of a drug by the manufacturer of such drug;

(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 360eee–1(e) of this title;

(L) salable drug returns when conducted by a dispenser;

(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a ''medical convenience kit'') if—

(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 360(b)(2) of this title;

(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 801 et seq.];

(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(iv) in the case of a medical convenience kit that includes a product, the product is—

(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

(II) a product intended to maintain the equilibrium of water and minerals in the body;

(III) a product intended for irrigation or reconstitution;

(IV) an anesthetic;

(V) an anticoagulant;

(VI) a vasopressor; or

(VII) a sympathomimetic;

(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(Q) the distribution of medical gas, as defined in section 360ddd of this title;

(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 360eee(16)(B) of this title and registered under section 360 of this title for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(5) THIRD-PARTY LOGISTICS PROVIDERS.—Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third-party logistics provider under section 360eee(22) of this title shall obtain a license as a third-party logistics provider as described in section 360eee–3(a) of this title and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.

(6) AFFILIATE.—For purposes of this subsection, the term ''affiliate'' means a business

entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has the power to control, both of the business entities.

(f) Veterinary prescription drugs

(1)(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 360b of this title, a conditionally-approved application under section 360ccc of this title, or an index listing under section 360ccc–1 of this title to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

(A) shall be exempt from the requirements of section 352 of this title, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if—

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filling, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 360b, 360ccc, or 360ccc–1 of this title from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.''. A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

(g) Regulation of combination products

(1)(A) The Secretary shall, in accordance with this subsection, assign a primary agency center to regulate products that constitute a combination of a drug, device, or biological product.

(B) The Secretary shall conduct the premarket review of any combination product under a single application, whenever appropriate.

(C) For purposes of this subsection, the term ''primary mode of action'' means the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

(D) The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(i) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction;

(ii) a device, the agency center charged with premarket review of devices shall have primary jurisdiction; or

(iii) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

(E) In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the combination product has any chemical action within or on the human body.

(F) If a sponsor of a combination product disagrees with the determination under subparagraph (D)—

(i) such sponsor may request, and the Secretary shall provide, a substantive rationale to such sponsor that references scientific evidence provided by the sponsor and any other scientific evidence relied upon by the Secretary to support such determination; and

(ii)(I) the sponsor of the combination product may propose one or more studies (which may be nonclinical, clinical, or both) to establish the relevance, if any, of the chemical action in achieving the primary mode of action of such product;

(II) if the sponsor proposes any such studies, the Secretary and the sponsor of such product shall collaborate and seek to reach agreement, within a reasonable time of such proposal, not to exceed 90 calendar days, on the design of such studies; and

(III) if an agreement is reached under subclause (II) and the sponsor conducts one or

more of such studies, the Secretary shall consider the data resulting from any such study when reevaluating the determination of the primary mode of action of such product, and unless and until such reevaluation has occurred and the Secretary issues a new determination, the determination of the Secretary under subparagraph (D) shall remain in effect.

(2)(A)[1](i) To establish clarity and certainty for the sponsor, the sponsor of a combination product may request a meeting on such combination product. If the Secretary concludes that a determination of the primary mode of action pursuant to paragraph (1)(D) is necessary, the sponsor may request such meeting only after the Secretary makes such determination. If the sponsor submits a written meeting request, the Secretary shall, not later than 75 calendar days after receiving such request, meet with the sponsor of such combination product.

(ii) A meeting under clause (i) may—

(I) address the standards and requirements for market approval or clearance of the combination product;

(II) address other issues relevant to such combination product, such as requirements related to postmarket modification of such combination product and good manufacturing practices applicable to such combination product; and

(III) identify elements under subclauses (I) and (II) that may be more appropriate for discussion and agreement with the Secretary at a later date given that scientific or other information is not available, or agreement is otherwise not feasible regarding such elements, at the time a request for such meeting is made.

(iii) Any agreement under this subparagraph shall be in writing and made part of the administrative record by the Secretary.

(iv) Any such agreement shall remain in effect, except—

(I) upon the written agreement of the Secretary and the sponsor or applicant; or

(II) pursuant to a decision by the director of the reviewing division of the primary agency center, or a person more senior than such director, in consultation with consulting centers and the Office, as appropriate, that an issue essential to determining whether the standard for market clearance or other applicable standard under this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] applicable to the combination product has been identified since the agreement was reached, or that deviating from the agreement is otherwise justifiable based on scientific evidence, for public health reasons.

(3) For purposes of conducting the premarket review of a combination product that contains an approved constituent part described in paragraph (4), the Secretary may require that the sponsor of such combination product submit to the Secretary only data or information that the Secretary determines is necessary to meet the standard for clearance or approval, as applicable, under this chapter or the Public Health Service Act, including any incremental risks and benefits posed by such combination product, using a risk-based approach and taking into account any prior finding of safety and effectiveness or substantial equivalence for the approved constituent part relied upon by the applicant in accordance with paragraph (5).

(4) For purposes of paragraph (3), an approved constituent part is—

(A) a drug constituent part of a combination product being reviewed in a single application or request under section 360e, 360(k), or 360c(f)(2) of this title (submitted in accordance with paragraph (5)), that is an approved drug, provided such application or request complies with paragraph (5);

(B) a device constituent part approved under section 360e of this title that is referenced by the sponsor and that is available for use by the Secretary under section 360j(h)(4) of this title; or

(C) any constituent part that was previously approved, cleared, or classified under section 355, 360(k), 360c(f)(2), or 360e of this title for which the sponsor has a right of reference or any constituent part that is a nonprescription drug, as defined in section 379aa(a)(2) of this title.

(5)(A) If an application is submitted under section 360e or 360(k) of this title or a request is submitted under section 360c(f)(2) of this title, consistent with any determination made under paragraph (1)(D), for a combination product containing as a constituent part an approved drug—

(i) the application or request shall include the certification or statement described in section 355(b)(2) of this title; and

(ii) the applicant or requester shall provide notice as described in section 355(b)(3) of this title.

(B) For purposes of this paragraph and paragraph (4), the term ''approved drug'' means an active ingredient—

(i) that was in an application previously approved under section 355(c) of this title;

(ii) where such application is relied upon by the applicant submitting the application or request described in subparagraph (A);

(iii) for which full reports of investigations that have been made to show whether such drug is safe for use and whether such drug is effective in use were not conducted by or for the applicant submitting the application or request described in subparagraph (A); and

(iv) for which the applicant submitting the application or request described in subparagraph (A) has not obtained a right of reference or use from the person by or for whom the investigations described in clause (iii) were conducted.

(C) The following provisions shall apply with respect to an application or request described in subparagraph (A) to the same extent and in the same manner as if such application or request were an application described in section 355(b)(2) of this title that referenced the approved drug:

(i) Subparagraphs (A), (B), (C), and (D) of section 355(c)(3) of this title.

(ii) Clauses (ii), (iii), and (iv) of section 355(c)(3)(E) of this title.

(iii) Subsections (b) and (c) of section 355a of this title.

[1] So in original. No subpar. (B) has been enacted.

(iv) Section 355f(a) of this title.
(v) Section 360cc(a) of this title.

(D) Notwithstanding any other provision of this subsection, an application or request for classification for a combination product described in subparagraph (A) shall be considered an application submitted under section 355(b)(2) of this title for purposes of section 271(e)(2)(A) of title 35.

(6) Nothing in this subsection shall be construed as prohibiting a sponsor from submitting separate applications for the constituent parts of a combination product, unless the Secretary determines that a single application is necessary.

(7) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(8)(A) Not later than 60 days after October 26, 2002, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to ensure the prompt assignment of combination products to agency centers, the timely and effective premarket review of such products, and consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Additionally, the office shall, in determining whether a product is to be designated a combination product, consult with the component within the Office of the Commissioner of Food and Drugs that is responsible for such determinations. Such office (referred to in this paragraph as the ''Office'') shall have appropriate scientific and medical expertise, and shall be headed by a director.

(B) In carrying out this subsection, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with paragraph (1) for the premarket review of such product.

(C)(i) In carrying out this subsection, the Office shall help to ensure timely and effective premarket review that involves more than one agency center by coordinating such reviews, overseeing the timeliness of such reviews, and overseeing the alignment of feedback regarding such reviews.

(ii) In order to ensure the timeliness and alignment of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be responsible to the Office with respect to the timeliness and alignment of the premarket review.

(iii) The Office shall ensure that, with respect to a combination product, a designated person or persons in the primary agency center is the primary point or points of contact for the sponsor of such combination product. The Office shall also coordinate communications to and from any consulting center involved in such premarket review, if requested by such primary agency center or any such consulting center. Agency communications and commitments, to the extent consistent with other provisions of law and the requirements of all affected agency centers, from the primary agency center shall be considered as communication from the Secretary on behalf of all agency centers involved in the review.

(iv) The Office shall, with respect to the premarket review of a combination product—

(I) ensure that any meeting between the Secretary and the sponsor of such product is attended by each agency center involved in the review, as appropriate;

(II) ensure that each consulting agency center has completed its premarket review and provided the results of such review to the primary agency center in a timely manner; and

(III) ensure that each consulting center follows the guidance described in clause (vi) and advises, as appropriate, on other relevant regulations, guidances, and policies.

(v) In seeking agency action with respect to a combination product, the sponsor of such product—

(I) shall identify the product as a combination product; and

(II) may request in writing the participation of representatives of the Office in meetings related to such combination product, or to have the Office otherwise engage on such regulatory matters concerning the combination product.

(vi) Not later than 4 years after December 13, 2016, and after a public comment period of not less than 60 calendar days, the Secretary shall issue a final guidance that describes—

(I) the structured process for managing presubmission interactions with sponsors developing combination products;

(II) the best practices for ensuring that the feedback in such pre-submission interactions represents the Agency's best advice based on the information provided during such pre-submission interactions;[2]

(III) the information that is required to be submitted with a meeting request under paragraph (2), how such meetings relate to other types of meetings in the Food and Drug Administration, and the form and content of any agreement reached through a meeting under such paragraph (2);[3]

(D) In carrying out this subsection, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law.

(E)(i) Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the dispute is clearly premature.

(ii) During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office in resolving the substantive dispute.

(F) The Secretary, acting through the Office, shall review each agreement, guidance, or prac-

[2] So in original. The word ''and'' probably should appear.
[3] So in original. The semicolon probably should be a period.

tice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this subsection. In carrying out such review, the Secretary shall consult with stakeholders and the directors of the agency centers. After such consultation, the Secretary shall determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and shall publish in the Federal Register a notice of the availability of such modified or revised agreement, guidance or practice. Nothing in this paragraph shall be construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

(G) Not later than one year after October 26, 2002 (except with respect to clause (iv), beginning not later than one year after December 13, 2016), and annually thereafter, the Secretary shall report to the appropriate committees of Congress on the activities and impact of the Office. The report shall include provisions—

(i) describing the numbers and types of combination products under review and the timeliness in days of such assignments, reviews, and dispute resolutions;

(ii) identifying the number of premarket reviews of such products that involved a consulting agency center;

(iii) describing improvements in the consistency of postmarket regulation of combination products; and

(iv) identifying the percentage of combination products for which a dispute resolution, with respect to premarket review, was requested by the combination product's sponsor.

(H) Nothing in this paragraph shall be construed to limit the regulatory authority of any agency center.

(9) As used in this subsection:

(A) The term ''agency center'' means a center or alternative organizational component of the Food and Drug Administration.

(B) The term ''biological product'' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(C) The term ''market clearance'' includes—

(i) approval of an application under section 355, 357,[4] 360e, or 360j(g) of this title;

(ii) a finding of substantial equivalence under this part;

(iii) approval of a biologics license application under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262); and

(iv) de novo classification under section 360c(a)(1) of this title.

(D) The terms ''premarket review'' and ''reviews'' include all activities of the Food and Drug Administration conducted prior to approval or clearance of an application, notification, or request for classification submitted under section 355, 360(k), 360c(f)(2), 360e, or 360j of this title or under section 351 of the Public Health Service Act [42 U.S.C. 262], including with respect to investigational use of the product.

(June 25, 1938, ch. 675, § 503, 52 Stat. 1051; Oct. 26, 1951, ch. 578, § 1, 65 Stat. 648; Pub. L. 87–781, title I, § 104(e)(2), Oct. 10, 1962, 76 Stat. 785; Pub. L. 91–601, § 6(e), formerly § 7(e), Dec. 30, 1970, 84 Stat. 1673, renumbered Pub. L. 97–35, title XII, § 1205(c), Aug. 13, 1981, 95 Stat. 716; Pub. L. 100–293, §§ 4–6, Apr. 22, 1988, 102 Stat. 96–98; Pub. L. 100–670, title I, § 105, Nov. 16, 1988, 102 Stat. 3983; Pub. L. 101–629, § 16(a), Nov. 28, 1990, 104 Stat. 4526; Pub. L. 102–108, § 2(d), Aug. 17, 1991, 105 Stat. 550; Pub. L. 102–300, § 6(d), June 16, 1992, 106 Stat. 240; Pub. L. 102–353, §§ 2(a)–(c), 4, Aug. 26, 1992, 106 Stat. 941, 942; Pub. L. 104–250, § 5(a), Oct. 9, 1996, 110 Stat. 3155; Pub. L. 105–115, title I, §§ 123(e), 126(a), (c)(1), (2), Nov. 21, 1997, 111 Stat. 2324, 2327, 2328; Pub. L. 107–250, title II, § 204, Oct. 26, 2002, 116 Stat. 1611; Pub. L. 108–282, title I, § 102(b)(5)(F), Aug. 2, 2004, 118 Stat. 903; Pub. L. 113–54, title II, § 204(a)(1)–(4), (b), Nov. 27, 2013, 127 Stat. 630–635; Pub. L. 114–255, div. A, title III, § 3038(a), Dec. 13, 2016, 130 Stat. 1105.)

REFERENCES IN TEXT

The Comprehensive Drug Abuse Prevention and Control Act of 1970, referred to in subsec. (e)(4)(M)(ii), is Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236, which is classified principally to chapter 13 (§ 801 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

The Public Health Service Act, referred to in subsec. (g)(2)(A)(iv)(II), (3), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Section 357 of this title, referred to in subsec. (g)(9)(C)(i), was repealed by Pub. L. 105–115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

CODIFICATION

In subsec. (b)(5), ''sections 4721, 6001, and 6151 of title 26'' and ''section 4761 of title 26'' substituted for ''section 3220 of the Internal Revenue Code (26 U.S.C. 3220)'' and ''section 3238(b) of the Internal Revenue Code (26 U.S.C. 3238(b))'', respectively, on authority of section 7852(b) of Title 26, Internal Revenue Code.

AMENDMENTS

2016—Subsec. (g)(1). Pub. L. 114–255, § 3038(a)(4), added par. (1) and struck out former par. (1) which read as follows: ''The Secretary shall in accordance with this subsection assign an agency center to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

''(A) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction,

''(B) a device, the agency center charged with premarket review of devices shall have primary jurisdiction, or

''(C) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.''

Subsec. (g)(2). Pub. L. 114–255, § 3038(a)(4), added par. (2). Former par. (2) redesignated (7).

Subsec. (g)(3). Pub. L. 114–255, § 3038(a)(1), (4), added par. (3) and struck out former par. (3) which read as follows: ''The Secretary shall promulgate regulations to implement market clearance procedures in accordance

[4] See References in Text note below.

with paragraphs (1) and (2) not later than 1 year after November 28, 1990.''

Subsec. (g)(4) to (6). Pub. L. 114–255, §3038(a)(4), added pars. (4) to (6). Former pars. (4) and (5) redesignated (8) and (9), respectively.

Subsec. (g)(7). Pub. L. 114–255, §3038(a)(2), redesignated par. (2) as (7).

Subsec. (g)(8). Pub. L. 114–255, §3038(a)(3), redesignated par. (4) as (8).

Subsec. (g)(8)(C)(i). Pub. L. 114–255, §3038(a)(5)(A)(i), amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: ''In carrying out this subsection, the Office shall ensure timely and effective premarket reviews by overseeing the timeliness of and coordinating reviews involving more than one agency center.''

Subsec. (g)(8)(C)(ii). Pub. L. 114–255, §3038(a)(5)(A)(ii), inserted ''and alignment'' after ''the timeliness'' in two places.

Subsec. (g)(8)(C)(iii) to (vi). Pub. L. 114–255, §3038(a)(5)(A)(iii), added cls. (iii) to (vi).

Subsec. (g)(8)(G). Pub. L. 114–255, §3038(a)(5)(B)(i), inserted ''(except with respect to clause (iv), beginning not later than one year after December 13, 2016)'' after ''October 26, 2002'' in introductory provisions.

Subsec. (g)(8)(G)(iv). Pub. L. 114–255, §3038(a)(5)(B)(ii)–(iv), added cl. (iv).

Subsec. (g)(9). Pub. L. 114–255, §3038(a)(3), redesignated par. (5) as (9).

Subsec. (g)(9)(C). Pub. L. 114–255, §3038(a)(6)(A), substituted semicolon for comma at end of cl. (i), semicolon for '', and'' at end of cl. (ii), and ''; and'' for period at end of cl. (iii), and added cl. (iv).

Subsec. (g)(9)(D). Pub. L. 114–255, §3038(a)(6)(B), added subpar. (D).

2013—Subsec. (d)(4). Pub. L. 113–54, §204(b), added par. (4).

Subsec. (e). Pub. L. 113–54, §204(a)(1)–(4), added pars. (1) to (6) and struck out former pars. (1) to (3). Prior to amendment, pars. (1) to (3) set out certain disclosure and licensing requirements for wholesale distributors and defined ''authorized distributors of record'' and ''wholesale distribution''.

2004—Subsec. (f)(1)(A)(ii). Pub. L. 108–282, §102(b)(5)(F)(i), substituted ''360b of this title, a conditionally-approved application under section 360ccc of this title, or an index listing under section 360ccc–1 of this title'' for ''360b of this title''.

Subsec. (f)(3). Pub. L. 108–282, §102(b)(5)(F)(ii), substituted ''section 360b, 360ccc, or 360ccc–1'' for ''section 360b''.

2002—Subsec. (g)(1). Pub. L. 107–250, §204(1)(A), substituted ''shall in accordance with this subsection assign an agency center'' for ''shall designate a component of the Food and Drug Administration'' in first sentence of introductory provisions.

Subsec. (g)(1)(A) to (C). Pub. L. 107–250, §204(1)(B), substituted ''the agency center charged'' for ''the persons charged''.

Subsec. (g)(4). Pub. L. 107–250, §204(3), added par. (4). Former par. (4) redesignated (5).

Subsec. (g)(5). Pub. L. 107–250, §204(2), (4), redesignated par. (4) as (5), added subpar. (A), and redesignated former subpars. (A) and (B) as (B) and (C), respectively.

1997—Subsec. (b)(1)(A) to (C). Pub. L. 105–115, §126(c)(1), redesignated subpars. (B) and (C) as (A) and (B), respectively, and struck out former subpar. (A), which read as follows: ''is a habit-forming drug to which section 352(d) of this title applies; or''.

Subsec. (b)(3). Pub. L. 105–115, §126(c)(2), struck out reference to section 352(d) of this title before ''355''.

Subsec. (b)(4). Pub. L. 105–115, §126(a), amended par. (4) generally. Prior to amendment, par. (4) read as follows: ''A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement 'Caution: Federal law prohibits dispensing without prescription'. A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.''

Subsec. (g)(4)(A). Pub. L. 105–115, §123(e)(1), substituted ''section 351(i)'' for ''section 351(a)'' and ''262(i)'' for ''262(a)''.

Subsec. (g)(4)(B)(iii). Pub. L. 105–115, §123(e)(2), substituted ''biologics license application under subsection (a)'' for ''product or establishment license under subsection (a) or (d)''.

1996—Subsec. (f)(1)(A). Pub. L. 104–250 inserted '', other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug,'' after ''other than man'' in introductory provisions.

1992—Subsec. (d)(1). Pub. L. 102–353, §4(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''Except as provided in paragraphs (2) and (3), no representative of a drug manufacturer or distributor may distribute any drug sample.''

Subsec. (d)(2). Pub. L. 102–353, §4(2), substituted ''authorized distributor of record'' for ''distributor'' wherever appearing.

Subsec. (d)(3). Pub. L. 102–353, §4(2), substituted ''authorized distributor of record'' for ''distributor'' and ''authorized distributors of record'' for ''distributors'' wherever appearing.

Subsec. (e)(1). Pub. L. 102–353, §4(3), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''Each person who is engaged in the wholesale distribution of drugs subject to subsection (b) of this section and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors.''

Subsec. (e)(2)(A). Pub. L. 102–353, §2(a), (d), temporarily inserted ''or has registered with the Secretary in accordance with paragraph (3)''. See Termination Date of 1992 Amendment note below.

Subsec. (e)(3). Pub. L. 102–353, §2(b), (d), temporarily added par. (3). Former par. (3) redesignated (4). See Termination Date of 1992 Amendment note below.

Subsec. (e)(4). Pub. L. 102–353, §4(4), inserted ''and subsection (d) of this section'' after ''For the purposes of this subsection''.

Pub. L. 102–353, §2(b), (d), temporarily redesignated par. (3) as (4). See Termination Date of 1992 Amendment note below.

Subsec. (f)(1)(B). Pub. L. 102–353, §2(c), which directed the substitution of ''an order'' for ''and order'', could not be executed because ''and order'' did not appear in subpar. (B).

Subsec. (g)(3). Pub. L. 102–300 substituted ''clearance'' for ''approval''.

1991—Subsec. (c). Pub. L. 102–108, §2(d)(3), redesignated subsec. (c), relating to veterinary prescription drugs, as (f). Former subsec. (f) redesignated (g).

Subsec. (c)(2), (3)(B)(v). Pub. L. 102–108, §2(d)(1), made technical amendment to reference to subsection (b) of this section involving corresponding provision of original act.

Subsec. (d)(3)(E). Pub. L. 102–108, §2(d)(2), made technical amendment to reference to subsection (c)(1) of this section involving corresponding provision of original act.

Subsec. (f). Pub. L. 102–108, §2(d)(4), redesignated subsec. (f), relating to regulation of combination products, as (g).

Pub. L. 102–108, §2(d)(3), redesignated subsec. (c), relating to veterinary prescription drugs, as (f).

Subsec. (g). Pub. L. 102–108, §2(d)(4), redesignated subsec. (f), relating to regulation of combination products, as (g).

1990—Pub. L. 101–629, §16(a)(1), substituted ''Exemptions and consideration for certain drugs, devices, and biological products'' for ''Exemptions in case of drugs and devices'' in section catchline.

Subsec. (f). Pub. L. 101–629, §16(a)(2), added subsec. (f).

1988—Subsec. (c). Pub. L. 100–670 added subsec. (c) relating to veterinary prescription drugs.

Pub. L. 100–293, § 4, added subsec. (c) relating to sales restrictions.

Subsec. (d). Pub. L. 100–293, § 5, added subsec. (d).

Subsec. (e). Pub. L. 100–293, § 6, added subsec. (e).

1970—Subsec. (b)(2). Pub. L. 91–601 included exemption from packaging requirements of subsec. (p) of section 352 of this title.

1962—Subsec. (b)(1)(C). Pub. L. 87–781 substituted ''approved'' for ''effective''.

1951—Subsec. (b). Act Oct. 26, 1951, amended subsec. (b) generally to protect the public from abuses in the sale of potent prescription drugs, and to relieve retail pharmacists and the public from unnecessary restrictions on the dispensation of drugs that are safe to use without supervision of a doctor.

EFFECTIVE DATE OF 2013 AMENDMENT

Pub. L. 113–54, title II, § 204(c), Nov. 27, 2013, 127 Stat. 636, provided that: ''The amendments made by subsections (a) and (b) [enacting section 360eee–2 of this title and amending this section] shall take effect on January 1, 2015.''

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of this title.

TERMINATION DATE OF 1992 AMENDMENT

Pub. L. 102–353, § 2(d), Aug. 26, 1992, 106 Stat. 941, provided that: ''Effective September 14, 1994, the amendments made by subsections (a) and (b) [amending this section] shall no longer be in effect.''

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–293, § 8, Apr. 22, 1988, 102 Stat. 100, provided that:

''(a) GENERAL RULE.—Except as provided in subsection (b), this Act and the amendments made by this Act [amending this section and sections 331, 333, and 381 of this title and enacting provisions set out as notes under this section and section 301 of this title] shall take effect upon the expiration of 90 days after the date of the enactment of this Act [Apr. 22, 1988].

''(b) EXCEPTION.—

''(1) Section 503(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(d)] (as added by section 5 of this Act) shall take effect upon the expiration of 180 days after the date of the enactment of this Act [Apr. 22, 1988].

''(2) The Secretary of Health and Human Services shall by regulation issue the guidelines required by section 503(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(e)(2)(B)] (as added by section 6 of this Act) not later than 180 days after the date of the enactment of this Act. Section 503(e)(2)(A) of such Act shall take effect upon the expiration of 2 years after the date such regulations are promulgated and take effect.''

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub. L. 91–601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–781 effective Oct. 10, 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1951 AMENDMENT

Amendment by act Oct. 26, 1951, effective six months after Oct. 26, 1951, see section 3 of act Oct. 26, 1951, set out as a note under section 333 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

EFFECTIVE MEDICATION GUIDES

Pub. L. 104–180, title VI, § 601, Aug. 6, 1996, 110 Stat. 1593, provided that:

''(a) IN GENERAL.—Not later than 30 days after the date of enactment of this Act [Aug. 6, 1996], the Secretary of the Department of Health and Human Services shall request that national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient drug information database companies, and other relevant parties collaborate to develop a long-range comprehensive action plan to achieve goals consistent with the goals of the proposed rule of the Food and Drug Administration on 'Prescription Drug Product Labeling: Medication Guide Requirements' (60 Fed. Reg. 44182; relating to the provision of oral and written prescription information to consumers).

''(b) GOALS.—Goals consistent with the proposed rule described in subsection (a) are the distribution of useful written information to 75 percent of individuals receiving new precriptions [sic] by the year 2000 and to 95 percent by the year 2006.

''(c) PLAN.—The plan described in subsection (a) shall—

''(1) identify the plan goals;

''(2) assess the effectiveness of the current private-sector approaches used to provide oral and written prescription information to consumers;

''(3) develop guidelines for providing effective oral and written prescription information consistent with the findings of any such assessment;

''(4) contain elements necessary to ensure the transmittal of useful information to the consuming public, including being scientifically accurate, non-promotional in tone and content, sufficiently specific and comprehensive as to adequately inform consumers about the use of the product, and in an understandable, legible format that is readily comprehensible and not confusing to consumers expected to use the product.[;]

''(5) develop a mechanism to assess periodically the quality of the oral and written prescription information and the frequency with which the information is provided to consumers; and

''(6) provide for compliance with relevant State board regulations.

''(d) LIMITATION ON THE AUTHORITY OF THE SECRETARY.—The Secretary of the Department of Health and Human Services shall have no authority to implement the proposed rule described in subsection (a), or to develop any similar regulation, policy statement, or other guideline specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs if, (1) not later than 120 days after the date of enactment of this Act [Aug. 6, 1996], the national organizations described in subsection (a) develop and submit to the Secretary for Health and Human Services a comprehensive, long-range action plan (as described in subsection (a)) which shall be acceptable to the Secretary of Health and Human Services; (2) the aforementioned plan is submitted to the Secretary of Health and Human Services for review and acceptance: *Provided*, That the Secretary shall give due consideration to the submitted plan and that any such acceptance shall not be arbitrarily withheld; and (3) the implementation of (a) a plan accepted by the Secretary commences within 30 days of the Secretary's acceptance of such plan, or (b) the plan submitted to the Secretary commences within 60 days of the submission of such plan if the Secretary fails to

take any action on the plan within 30 days of the submission of the plan. The Secretary shall accept, reject or suggest modifications to the plan submitted within 30 days of its submission. The Secretary may confer with and assist private parties in the development of the plan described in subsections (a) and (b).

''(e) SECRETARY REVIEW.—Not later than January 1, 2001, the Secretary of the Department of Health and Human Services shall review the status of private-sector initiatives designed to achieve the goals of the plan described in subsection (a), and if such goals are not achieved, the limitation in subsection (d) shall not apply, and the Secretary shall seek public comment on other initiatives that may be carried out to meet such goals.''

CONGRESSIONAL FINDINGS

Pub. L. 100–293, § 2, Apr. 22, 1988, 102 Stat. 95, provided that: ''The Congress finds the following:

''(1) American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.

''(2) The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.

''(3) The existence and operation of a wholesale submarket, commonly known as the 'diversion market', prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.

''(4) Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.

''(5) The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.

''(6) The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

''(7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

''(8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers.''