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.