[ORAL ARGUMENT NOT YET SCHEDULED]

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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

JAMES H. ROANE, JR., et al.,
Appellees

v.

WILLIAM P. BARR, ATTORNEY GENERAL, et al.,
Appellants

No. 20-5206

EMERGENCY MOTION TO STAY OR VACATE PRELIMINARY INJUNCTION BARRING THREE FEDERAL EXECUTIONS

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INTRODUCTION AND SUMMARY OF ARGUMENT

For the second time in three days, the district court has entered a "[l]ast-minute stay," *Barr v. Lee*, No. 20A8 at 3, 591 U.S. __ (S. Ct. July 14, 2020), halting multiple federal executions just hours before one is scheduled to occur.[1] This is the district court's third preliminary injunction barring these executions. The first was vacated by this Court in April 2020 after expedited appellate proceedings, *In re FBOP Execution Protocol Cases*, 955 F.3d 106 (D.C. Cir. 2020) (per curiam) (*Execution Protocol Cases*), and the Supreme Court subsequently denied review of this Court's decision, see 2020 WL 3492763. The second was summarily vacated by the Supreme Court yesterday, less than 24 hours after the district court entered it, on the ground that "the plaintiffs have not established that they are likely to succeed on the merits of their" claim. *Lee*, No. 20A8 at 1-2. The Court further explained that the district court had erred in entering an execution-day injunction, which "'should be the extreme exception, not the norm,'" and that "plaintiffs' executions may proceed as planned." *Id.* at 3 (quoting *Bucklew v. Precythe*, 139 S. Ct. 1112, 134 (2019)). Pursuant to that order, the government carried out the execution of Daniel Lewis Lee yesterday.

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[1] Purkey's execution is currently stayed by the Seventh Circuit. *See Purkey v. United States*, No. 19-3318 (7th Cir. July 2, 2020). The government's motion to vacate that stay is pending before the Supreme Court. *See Watson v. Purkey*, No. 20A-4 (S. Ct.). Today's execution was initially scheduled for 4 p.m., but in light of the district court's day-of-execution injunctions on this and another claim (on which the government is also seeking relief in this Court, *see* Case No. 20-5207 (D.C. Cir.)), the government is planning to conduct the execution no earlier than 7 p.m. to allow additional time for this Court and potentially the Supreme Court to conduct review.

Despite that clear direction, the district court this morning issued another execution-day injunction, this time on the theory—articulated in just three paragraphs of reasoning, despite having been presented to the court over eight months ago—that the lethal-injection protocol violates the Federal Food, Drug, and Cosmetic Act (FDCA) because it does not require a prescription for the drug compound used to execute plaintiffs. A12–13. The court's holding is irreconcilable with the Supreme Court's seminal decisions in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), and *Heckler v. Chaney*, 470 U.S. 821, 837 (1985), and with a 26-page Office of Legal Counsel (OLC) addressing precisely this question, *see* A19-A44. The district court's latest injunction, relying on a concededly tertiary rationale, is even less defensible than its first two, and it defies the Supreme Court's direction yesterday in *Lee*. The government accordingly respectfully requests that this Court stay or vacate this third preliminary injunction, effective immediately, "so that the plaintiffs' executions may proceed as planned." *Lee*, No. 20A8 at 3.[2]

[2] As with the district court's execution-day injunction on Monday, the government plans to file a similar application for a stay in the Supreme Court. Given the time constraints caused by the district court's delayed ruling—which it admitted in connection with even its ruling on Monday was "unfortunate" and at the "last minute," Dkt. 135, at 3—the government has no choice but to request relief from this Court at the same time. If the Court chooses to vacate rather than stay, the government requests that it issue its mandate forthwith.

STATEMENT

A. Background

The "Constitution allows capital punishment," and Congress has authorized the death penalty for the most egregious federal crimes since 1790. *Bucklew v. Precythe*, 139 S. Ct. 1112, 1122 (2019). It "necessarily follows that there must be a" lawful "means of carrying" out executions. *Baze v. Rees*, 553 U.S. 35, 47 (2008) (plurality opinion); *see Glossip v. Gross*, 135 S. Ct. 2726, 2732-2733 (2015).

In the Nation's early years, hanging was the "standard method of execution" for both States and the federal government. *Glossip*, 135 S. Ct. at 2731; *see Execution Protocol Cases*, 955 F.3d at 108-109. Over time, States replaced hanging with new methods of execution such as electrocution and lethal gas, each of which was adopted precisely because it was considered "more humane" than its predecessors. *Baze*, 553 U.S. at 62 (plurality opinion). The "progress toward more humane methods of execution" eventually "culminat[ed] in [a] consensus on lethal injection." *Baze*, 553 U.S. at 62 (plurality opinion). Most states initially used a three-drug protocol, but anti-death-penalty advocacy result in one drug being removed from the market. AR870-71. In 2019, the Supreme Court in *Bucklew* rejected an Eighth Amendment challenge to Missouri's single-drug pentobarbital protocol by an inmate with an "unusual medical condition." 139 S. Ct. at 1118, crediting expert testimony that pentobarbital would "render Mr. Bucklew fully unconscious and incapable of experiencing pain within 20 to 30 seconds," *id.* at 1132.

Three months after the Court's decision in *Bucklew*, after "extensive study," *Execution Protocol Cases*, 955 F.3d at 110 (per curiam), BOP completed a revised execution protocol adopting the same single-drug pentobarbital protocol approved in that case. AR868-875. At least fourteen states use pentobarbital in their lethal-injection protocols, and a number of these states use only pentobarbital. A18. More than half of all executions in the United States since 2018 have used such a protocol. *Id.* After reviewing BOP's recommendation, the Attorney General in July 2019 directed BOP to adopt its proposed protocol using the single-drug pentobarbital, with flexible IV procedures. AR868.

B. Prior Proceedings

1. The plaintiffs in this case are federal inmates who have been convicted of capital offenses and sentenced to death. Wesley Ira Purkey was found guilty of kidnapping, raping, and murdering a sixteen-year-old high-school sophomore after transporting her across state lines. *See United States v. Purkey*, 428 F.3d 738, 744–45 (8th Cir. 2005). Dustin Lee Honken was found guilty of five murders, including killing a federal witness, the witness's girlfriend, and the girlfriend's two young daughters. *United States v. Honken*, 541 F.3d 1146, 1148 (8th Cir. 2008). And Keith Nelson was convicted of kidnapping a ten-year-old girl rollerblading through her neighborhood, raping her, and murdering her after transporting her across state lines. *See United States v. Nelson*, 347 F.3d 701, 705 (8th Cir. 2003). Each of these

convictions—all at least fifteen years old—has been upheld on direct appeal and in post-conviction proceedings.[3]

2. This Court is familiar with its prior proceedings in this case culminating in its vacatur of the district court's first injunction on April 7, 2020. *See Execution Protocol Cases*, 955 F.3d at 108–113. Plaintiffs' two requests to stay the mandate were unsuccessful, as were their petition for a writ of certiorari and application for a Supreme Court stay. *See* No. 19A1050, 19-1348 (S. Ct.) (denied June 29). Throughout this Court's and the Supreme Court's review, the district court retained jurisdiction to address plaintiffs' remaining claims not on appeal. *See, e.g.*, 16 Charles Alan Wright et al., *Federal Practice & Procedure* § 3921.2 (3d ed. 2020) (Wright & Miller). Plaintiffs, however, did not seek another preliminary injunction on their remaining claims until June 19, after BOP on June 15 announced their execution dates for July 15, July 17, and August 28.

On July 13, 2020—more than nine months after plaintiffs first sought a preliminary injunction on their claims, three months after the court of appeals vacated the district court's first injunction, and 30 days after BOP rescheduled plaintiffs' executions—the district court preliminarily enjoined plaintiffs' executions for the

[3] *See, e.g.*, *Purkey v. United States*, 729 F.3d 860 (8th Cir. 2013), *reh'g denied*, 729 F.3d 860 (8th Cir. 2013), *cert. denied*, 135 S. Ct. 355 (2014); *Honken v. United States*, 42 F. Supp. 3d 937 (N.D. Iowa 2013) (vacating non-capital convictions under 28 U.S.C. § 2255, but otherwise denying relief), *aff'd*, No. 14-1329 (8th Cir. May 2, 2014), *cert. denied*, 136 S. Ct. 29 (2015); *Nelson v. United States*, 909 F.3d 964, 966 (8th Cir. 2018), *cert. denied* 140 S. Ct. 1129 (2020).

second time. This time, the court held that plaintiffs were likely to succeed on their claim that BOP's execution protocol violated the Eighth Amendment. Dkt. 135. The court did not rule on plaintiffs' other claims for relief.

The government immediately appealed and simultaneously asked this Court and the Supreme Court for an emergency stay or vacatur of the district court's injunction. Later that evening, this Court denied the government's motion, deferred ruling on the government's motion to vacate that injunction, and ordered expedited briefing on the government's appeal. *See* Case No. 20-5199 (D.C. Cir.). The Supreme Court, however, then summarily vacated the preliminary injunction in the early morning hours of July 14, holding that "plaintiffs have not established that they are likely to succeed on the merits of their Eighth Amendment claim." *Barr v. Lee*, No. 20A8 at 1, 591 U.S. __ (2020) (per curiam). The Supreme Court further noted courts' "responsibility 'to ensure that method-of-execution challenges to lawfully issued sentences are resolved fairly and expeditiously,' so that 'the question of capital punishment' can remain with 'the people and their representatives, not the courts, to resolve.'" *Id.* at 3 (quotation mark omitted). "In keeping with that responsibility," the Court "vacate[d] the District Court's preliminary injunction so that the plaintiffs' executions may proceed as planned." *Id.* Accordingly, BOP carried out Lee's execution later that morning.

On July 15, less than 12 hours before Purkey's scheduled execution, the district court issued the injunction that is the subject of appeal here—the court's *third*. Dkt.

145, 146. The court rejected plaintiffs' contentions that the Protocol was arbitrary and capricious under the Administrative Procedure Act (APA), violated the Controlled Substances Act (CSA), and violated their constitutional rights to counsel and access to the courts. Dkt. 145, at 7-11, 13-14. But it barred plaintiffs' executions on the ground that BOP's protocol failed to comply with the FDCA. *Id.* at 12-13.

ARGUMENT

Under the familiar standards for a stay or injunction pending appeal, *see Nken v. Holder*, 556 U.S. 418, 426 (2009) (quotation omitted), this Court should enter immediate relief given the overwhelming likelihood that the injunction will not withstand appellate review and the profound public interest in implementing the plaintiffs' lawfully imposed sentences without further delay.

I. The District Court Likely Erred In Invalidating the Federal Protocol Under The Federal Food, Drug, And Cosmetic Act.

The district court concluded that the federal protocol governing plaintiffs' scheduled lethal injections violates the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, because it does not require the federal government to obtain a prescription for the pentobarbital to be used in plaintiffs' executions, allegedly in violation of 21 U.S.C. § 353(b)(1). *See* Dkt. 145, at 12–13. But the statutory text and context make clear that the FDCA's requirements do not apply to lethal agents intended for use in capital punishment. To the contrary, that Congress enacted in the FDPA a detailed execution framework without referencing the FDCA

provides powerful evidence of its common-sense view that lethal-injection drugs should not be treated like ordinary pharmaceuticals in the respects relevant here. Likewise, the lack of any apparent objection from the executive, legislative, or judicial branches to the hundreds of state executions conducted by lethal injection of substances that have never been required to meet the FDCA's prescription requirements strongly reinforces that those statutes do not apply in this context. And in all events, death-sentenced inmates are precluded from trying to enforce the FDCA against the BOP, as enforcement of the statute's applicable provisions is committed to the unreviewable discretion of the Food and Drug Administration (FDA).

1. a. Plaintiffs' FDCA claim conflicts with that statue's text and structure as construed by *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). There, the Supreme Court held that the FDA lacks jurisdiction to regulate articles intended for a use not traditionally regulated by FDA (there, customarily marketed tobacco products) when (1) other statutes clearly assume such articles will remain lawful and available for that use, but (2) if regulated under the FDCA, would be prohibited. *See Brown & Williamson*, 529 U.S. at 143 (holding that "there is no room for tobacco products within the FDCA's regulatory scheme" because "they cannot be used safely for any therapeutic purpose, and yet they cannot be banned"). "[T]he meaning of one statute may be affected by other Acts," the Court explained, "particularly where Congress has spoken subsequently and more specifically to the topic at hand." *Id.* at 133.

That is the case here. Just as Congress "foreclosed the removal of" tobacco "from the market," *Brown & Williamson*, 529 U.S. at 137, it has foreclosed plaintiffs' attempt to make it impossible to use lethal-injection drugs in executions. Federal law authorizes the death penalty for dozens of federal crimes, and the FDPA directs that such sentences be imposed "in the manner prescribed by the law of the [sentencing] State," 18 U.S.C. § 3596. When Congress enacted the FDPA in 1994, many states permitted execution exclusively by lethal injection, and lethal injection was the sole method of execution prescribed by federal regulation. 28 C.F.R. § 26.3(a)(4); *see* 57 Fed. Reg. 56,536, 56,536 (Nov. 30, 1992). Today, all States that provide for a death penalty allow lethal injection as one (often the sole) method. If lethal substances and other articles intended for use in capital punishment were regulated by the FDCA, however, such lawful executions could never take place. "Several provisions in the [FDCA] require the [Food and Drug Administration] to determine that the *product itself* is safe as used by consumers"—that is, that "the product's probable therapeutic benefits … outweigh its risk of harm." *Brown & Williamson*, 529 U.S. at 140; see 21 U.S.C. § 355(b)(1), (d). That standard is inapposite for drugs intended to cause death as part of an execution. *See* A19–44 (*Whether the Food & Drug Admin. Has Jurisdiction over Articles Intended for Use in Lawful Executions*, 2019 WL 2235666, at *8 (O.L.C. May 3, 2019) (concluding that "there is no way products intended to carry out capital punishment could ever satisfy that test"); *see also United States v. Rutherford*, 442 U.S.

544, 556 (1979) (explaining that under the FDCA, "a drug is unsafe if its potential for inflicting death . . . is not offset by the possibility of therapeutic benefit").

Indeed, the reading of the FDCA embraced by plaintiffs and the district court would mean that articles used in executions such as electric chairs, lethal gas, and perhaps even firing-squad rifles would be regulated by the Act. But in the many decades over which the FDCA and capital punishment have coexisted, it does not appear that anyone has seriously advanced that argument. And for good reason: "If the FDCA applied to electric chairs, gallows, gas chambers, firearms used in firing squads, and substances used in lethal-injection protocols, the statute would effectively ban those articles. Yet the Constitution and laws of the United States presuppose the continued availability of capital punishment for the most heinous federal and state crimes." A28 (AR947).

b. In any event, the district court erred in concluding that plaintiffs can seek relief based on their allegation that BOP will violate the FDCA by adhering to its protocol. *See* A10; Preliminary Injunction Motion, Dkt. No. 102, at 28–33. As the Supreme Court has explained, "[t]he FDA's decision not to take … enforcement actions" to prevent the use of drugs intended for use in lethal injection is "not subject to judicial review under the APA." *Heckler v. Chaney*, 470 U.S. 821, 837–38 (1985); *see also* 5 U.S.C. § 701(a)(2). Thus, plaintiffs could not sue the FDA directly for failing to enforce the statute as plaintiffs wish.

Plaintiffs' inability to force the FDA to act does not mean that plaintiffs themselves may seek relief for BOP's supposed violations of the FDCA. On the contrary, in the FDCA itself, Congress specified "all … proceedings for the enforcement, or *to restrain* violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a) (emphasis added). This requirement forecloses actions by private parties seeking to restrain third parties' putative violations of the FDCA's general strictures, leaving "the United States with nearly exclusive enforcement authority" over those matters; "[p]rivate parties may not bring enforcement suits." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014). The federal government clearly does not believe that it is violating the FDCA by using pentobarbital to conduct lethal injections, and that judgment is reserved to the Executive Branch by the FDCA's plain terms. The district court's conclusion that plaintiffs may end-run the nonreviewability of the FDA's enforcement decisions by invoking the APA against BOP cannot be squared with the Supreme Court's instructions to the contrary. *See, e.g.*, *Block v. Community Nutrition Inst.*, 467 U.S. 340, 351 (1984) (APA action is precluded by federal statutes even where they *implicitly* foreclose certain private-party enforcement, let alone where, as here, they expressly do so).

2. The district court gave two brief reasons for its conclusion that the FDCA *does* apply to lethal-injection drugs: (1) this Court's decision in *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013), regarding the FDCA's import provisions; and (2) its view that the

government's efforts to ensure a humane death necessitates the FDCA's application to the drugs used to effectuate death. A12–13. Neither is sustainable.

a. Contrary to the district court's conclusion, *Cook* does not undermine the government's interpretation of the FDCA. There, this Court addressed a specific FDCA provision regarding the FDA's treatment of imported drugs, concluding that FDA was *required* to apply that provision to drugs "destined for" lethal-injection use in "state correctional facilities." 733 F.3d at 11. The Court rested its analysis on the particular language of that import provision, 21 U.S.C. § 381(a), which provides that the FDA "shall" take certain actions with respect to the import of drugs manufactured at "an unregistered establishment" that "appear" to violate that provision. *Id.* at 8–10. The Court's holding turned on the scope of the agency's enforcement discretion under section 381. *Id.* at 8.

In *Cook*, however, this Court did not address whether the FDCA applies to lethal injection drugs in the first place. 733 F.3d at 11 (noting that "the FDA [had] conceded before the district court that the … shipments" were a covered "unapproved new drug") (quotation marks omitted). It therefore does not control the issue before this Court here. And in any event, the Court's conclusion that *Chaney* does not preclude review of the FDA's enforcement choices under section 381(a) regarding drugs manufactured in unregistered foreign establishments has no application here. The prescription and compounding provisions of the FDCA that plaintiffs invoke, *see* 21 U.S.C. §§ 353(b), 353b, are distinct from the import provisions

in Section 381. *Cook*, 733 F.3d at 6–7. Indeed, in *Chaney* itself, the Supreme Court rejected an attempt to compel enforcement of Section 355, which those compounding provisions turn on. *See* 470 U.S. at 824, 835–36; 21 U.S.C. § 353b(a) (providing that Section 355 "shall not apply to a drug compounded" at facilities meeting various criteria).[4]

Critically, even if *Cook* somehow did apply beyond section 381, it would not permit plaintiffs here to sue to enforce the FDCA's provisions. The *Cook* plaintiffs sought to require the *FDA* to take enforcement actions—they did not seek to enforce the FDCA directly themselves against an allegedly regulated party. Accordingly, this Court had no occasion in *Cook* to address Section 337's prohibition on private enforcement actions. Courts have repeatedly rejected private individuals' attempt to

[4] After the government pointed out in its previous appeal in this case that plaintiffs' reliance on Section 355 of the FDCA squarely conflicted with the Supreme Court's decision in *Chaney* regarding that provision, plaintiffs stripped references to it from their request for a preliminary injunction. *Compare* Dkt. 29, at 22 (Honken's original motion for a preliminary injunction, asserting that absent "a prescription, the compounded drug is subject to the FDCA's onerous drug-approval process under 21 U.S.C. § 355, and thus, the Defendants' compounded drug is an illicit, misbranded, and unapproved 'new drug' under the FDCA"), *with* Dkt. 102 (plaintiffs' June 2020 motion for a preliminary injunction, referring to "rules … facilities must follow when compounding drugs in order to be exempt" from the FDCA's premarketing, labeling, and new-drug approval requirements, but citing only Section 353, not Section 355). The gravamen of plaintiffs' complaint remains the same, however: that pentobarbital exists as an "FDA-approved drug[]," and that the federal government must therefore comply with the FDCA's prescription and compounding rules applying to drugs approved by the FDA under Section 355. *See* Dkt. 92, at 14-15.

enforce the FDCA's provisions themselves.[5] Thus, even under *Cook*'s logic, plaintiffs have no basis to ask this Court to second-guess the government's decisions regarding the FDCA's intersection with lethal-injection drugs.

b. Nor are lethal-injection drugs subject to the FDCA simply because the government took care to ensure that it chose a drug with the goal of causing a humane and painless death. *See* A12–13. The government's effort to make sure it chose a protocol rendering the inmate insensate demonstrates its commitment to compliance with the Eighth Amendment. It does not demonstrate that a drug intended for use to execute an inmate has "probable therapeutic benefits … outweigh[ing] its risk of harm," *Brown & Williamson*, 529 U.S. at 140, such that they could plausibly be subject to regulation under the FDCA.

3. At a minimum, the district court's holding that the FDCA provisions assuring the safety and efficacy of drugs apply to substances intended to effectuate a death sentence is so contrary to common sense that district court could not have permissibly concluded that plaintiffs are likely to succeed on this claim. *Cf. Bucklew*, 139 S. Ct. at 1134; *Davis v. Shoop*, No. 2:16-CV-495, 2020 WL 3255145, at *50 (S.D. Ohio June 16, 2020) (rejecting a reading of the FDCA and CSA that would "make lethal injection—the federal government's intended method of execution—

[5] *See, e.g.*, *Irick v. Ray*, No. 3:10-1004, 2010 WL 4810653, at *4 (M.D. Tenn. Nov. 19, 2010), *aff'd*, 628 F.3d 787 (6th Cir. 2010) (concluding that "no private right of action exists under either the CSA or the FDCA, and therefore, any injury allegedly suffered by the Plaintiff cannot be redressed through a declaratory judgment action").

impossible" as "dubious, if not absurd"). The district court's conclusion on this score once again falls short of "the showing required to justify last-minute intervention by a Federal Court." *Barr v. Lee*, No. 20A8, at 3.

II. The Balance Of Equities Strongly Favors Staying Or Vacating The Preliminary Injunction.

Even apart from the merits, the injunction is likely to be vacated on appeal because the additional required considerations—likelihood of irreparable harm, the public interest, and the balance of equities—all weigh heavily against further injunctive relief. *Glossip*, 135 S. Ct. at 2736.

First, any cognizable "irreparable harm" that plaintiffs will suffer "in the absence of preliminary relief" is minimal, at best. *Glossip,* 135 S. Ct. at 2736 (citation omitted). To be sure, death is an irreparable harm, but that cannot be the irreparable harm supporting this injunction, because all agree that plaintiffs "do not challenge the federal government's authority to execute them." *Execution Protocol Cases*, 955 F.3d at 145 (Tatel, J., dissenting). Indeed, plaintiffs could not raise such a challenge in this APA suit. *See Hill v. McDonough*, 547 U.S. 573, 580 (2006).

The alleged harms actually underlying this injunction are far narrower and less compelling. The *only* basis of the injunction is that plaintiffs cannot be executed under the federal protocol unless BOP obtains a prescription for the lethal agent. But the district court did not hold (and, in light of the vacatur of its prior injunction could not hold) that executing plaintiffs without a prescription would violate the Eighth

Amendment or any substantive right. Plaintiffs' asserted harm thus amounts exclusively to the technical violation of the FDCA, not to any real-world harm, and accordingly cannot support an injunction—particularly on the day of the execution. *Cf. Winter v. NRDC*, 555 U.S. 7, 32-33 (2008) (vacating injunction in part because, while respondents alleged harm to marine life, their "ultimate legal claim" required only preparation of an environmental impact statement, not cessation of the allegedly harmful conduct); *Execution Protocol Cases*, 955 F.3d at 126-129 (Katsas, J., concurring) (concluding that the first injunction in this case should have been vacated on equitable considerations even apart from the merits).

Indeed, the district court's handling of the case strongly reinforces the absence of cognizable irreparable harm. The court expressly declined to rely on plaintiffs' FDCA claim in its execution-day injunction on Monday, even though the court knew that the government planned to execute Lee that day (as it ultimately did early Tuesday). Dkt. 135 at 18 n.6. If the court's position was that lack of a prescription actually constituted cognizable irreparable harm, the court surely would have issued such a holding *before Lee was executed*. After all, the court's FDCA holding here is only a few paragraphs long and easily could have been part of its Monday injunction. The court's own decision not to issue such relief undermines the court's assertion that the asserted harm is irreparable and therefore does not warrant an injunction even apart from the merits. *Cf. Winter*, 555 U.S. at 32 (noting that an "injunction is a matter of

equitable discretion; it does not follow from success on the merits as a matter of course").

Second, the Supreme Court has repeatedly emphasized the public's "powerful and legitimate interest in punishing the guilty," *Calderon v. Thompson*, 523 U.S. 538, 556 (1998) (citation omitted), by "carrying out a sentence of death in a timely manner," *Baze*, 553 U.S. at 61 (plurality opinion). Once a criminal defendant is tried, convicted, sentenced, and exhausts all permissible appeals and collateral challenges, the need for "finality acquires an added moral dimension." *Calderon*, 523 U.S. at 556. "Only with an assurance of real finality can the [government] execute its moral judgment in a case" and "the victims of crime move forward knowing the moral judgment will be carried out." *Id.*

As the Supreme Court recognized in vacating the district court's prior execution-day injunction, "[t]hose interests have been frustrated in this case." *Bucklew*, 139 S. Ct. at 1133. Plaintiffs were each convicted and sentenced to death more than 15 years ago, and each has exhausted all permissible opportunities for further review. Their executions have already been postponed for six months based on an injunction that proved (predictably) to be "without merit." 955 F.3d at 112; *see* 140 S. Ct. at 353 (statement of Alito, J.). Particularly given the unwarranted delay that resulted from its first two errors, the district court should been "sensitive to the [government's] strong interest in enforcing its criminal judgments without undue interference from the

federal courts." *Hill*, 547 U.S. at 584. The district court again gave insufficient weight to that weighty interest.

Finally, "the balance of equities" weighs "strongly in favor of the" government and therefore against the injunction. *Winter*, 555 U.S. at 26. Plaintiffs committed "heinous" murders of children and others with a brutality staggering even in the realm of capital offenses. 140 S. Ct. at 353 (statement of Alito, J.). Purkey and Nelson kidnapped, raped, and murdered girls. 955 F.3d at 127 (Katsas, J., concurring). Honken murdered four people, including six- and ten-year-old girls, "execution-style, by shooting each in the head." *Id.* Despite that shockingly inequitable conduct, "they continue to litigate with a vengeance" to try to control the precise details of their death—an opportunity they denied to the victims of their crimes. *Id.* at 128; *cf. Bucklew*, 139 S. Ct. at 1124. In addition to the dispositive legal flaws in the injunction, it is manifestly unsupported by equity.

III. The Injunction Should Be Stayed Or Vacated.

Given that plaintiffs have "not established that they are likely to succeed on the merits of their" FDCA claim, it follows directly from the Supreme Court's order yesterday that the district court's injunction in this case should be stayed or vacated "so that the plaintiffs' executions may proceed as planned. *Lee*, No. 20A8, at 1-3. As the Supreme Court emphasized, federal courts have a responsibility "to ensure that method-of-execution challenges to lawfully issued sentences are resolved fairly and

expeditiously," so that "the question of capital punishment" can remain with "the people and their representatives, not the courts, to resolve." *Id.* at 3.

The district court disregarded that directive of the Supreme Court by issuing another execution-day injunction of precisely the kind the court vacated yesterday. Although the Supreme Court made clear yesterday that execution-day injunctions should be an "extreme exception," *Lee*, No. 20A8, at 3 (citation omitted), the district court suggested that its admittedly "last minute" injunction today was justified by the government's haste in scheduling executions, A16–17. But the Supreme Court necessarily rejected that rationale in *Lee*, and the district court's injunction is contrary to *Lee* for that reason as well. Indeed, in the other execution-day order issued today (on which the government is separately seeking emergency relief), the district court appeared to criticize "the Supreme Court's prioritization of that pace over additional legal process." Case No., 19-cv-3570 (D.D.C.), Dkt. 36, at 2. The district court, however, is not free to depart from the Supreme Court's direction.

If anything, vacatur of today's execution-day injunction is even more clearly warranted than it was for Monday's. The merits rationale in this case is even more strained, as evidenced by the court's own decision not to rely on it before Lee was executed, though it easily could have done so. Likewise, the district court's delay is even more "abusive" here, because it easily could have addressed these issues much earlier—and at the very least in its order Monday—given that they have long been pending before the court and are not affected by any recent developments. *Gomez v.*

U.S. Dist. Ct. for N. Dist., 503 U.S. 653, 654 (1992). And the equities supporting an injunction here are much weaker than those invoked in its Monday execution-day injunction. There, the district court concluded (erroneously) that plaintiffs would be subjected to cruel and unusual pain based on the injection of pentobarbital. But here, the court's injunction relies only on the asserted harm of an absent prescription. Other courts have repeatedly declined to grant stays of execution on that rationale. *See, e.g., Durr v. Strickland*, No. 10-cv-288, 2010 WL 1610592, at *4 (S.D. Ohio Apr. 15, 2010) (declining to stay an execution based on claims that a State "would be acting in technical violation of federal law"), *aff'd*, 602 F.3d 788 (6th Cir. 2010); *Ringo v. Lombardi*, No. 09-cv-4095, 2010 WL 4103201, at *1–2 (W.D. Mo. Oct. 18, 2010) (similar).

For these reasons, this Court should stay or immediately vacate the district court's injunction of the protocol so that "plaintiffs' execution may proceed as planned." Lee, 20A8, at 3.

CONCLUSION

This Court should stay or vacate, effective immediately, the district court's preliminary injunction barring these federal executions.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this motion satisfies the type-volume limitation in Rule 27(d)(2)(A) because it contains 5,191 words. This brief also complies with the typeface and type-style requirements of Rule 32(a)(5) and Rule 32(a)(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

/s/ Melissa N. Patterson
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CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system, except for the following, who will be served by email:

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ADDENDUM

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:	)	
Lee v. Barr, et al., 19-cv-2559	)	
Purkey v. Barr, et al., 19-cv-3214	)	
Nelson v. Barr, et al., 20-cv-557	)	

MEMORANDUM OPINION

After a hiatus in federal executions of over fifteen years, on July 25, 2019, the U.S. Department of Justice (DOJ) announced plans to execute five inmates who had been sentenced to death under the federal death penalty statute.[1] *See* Press Release, Dep't of Justice, Federal Government to Resume Capital Punishment After Nearly Two Decade Lapse (July 25, 2019), https://www.justice.gov/opa/pr/federal-government-resume-capital-punishment-after-nearly-two-decade-lapse. To implement these executions, the Federal Bureau of Prisons (BOP) adopted a new execution protocol: the 2019 Protocol. (ECF No. 39-1, Admin. R. at 1021–75.)

On November 20, 2019, the court preliminarily enjoined the executions of four inmates: Alfred Bourgeois, Daniel Lewis Lee, Dustin Lee Honken, and Wesley Ira Purkey. (ECF No. 50, Mem. Op. (2019 Order), at 15.) The court found that these four Plaintiffs had demonstrated a

[1] Plaintiffs Bourgeois, Mitchell, Lee, and Purkey were sentenced under the Federal Death Penalty Act, 18 U.S.C. §§ 3591–3599. Plaintiff Honken was sentenced under the Anti-Drug Abuse Act of 1988, 21 U.S.C. § 848(e).

likelihood of success on the merits of their claims that the 2019 Protocol violates the Federal Death Penalty Act (FDPA), but the court did not rule on their other statutory and constitutional claims. (*Id.* at 13–14.) In April of this year, a divided D.C. Circuit panel vacated the preliminary injunction. *In re Fed. Bureau of Prisons' Execution Protocol Cases*, 955 F.3d 106, 113 (D.C. Cir. 2020), *cert. denied sub nom. Bourgeois v. Barr*, No. 19-1348, 2020 WL 3492763 (June 29, 2020). That Court based its ruling solely on the Plaintiffs' claims under the FDPA and the APA, and noted that "regardless of our disposition, several claims would remain open on remand." *Execution Protocol Cases*, 955 F.3d at 113 (per curiam).

On June 15, 2020, the DOJ and BOP scheduled new execution dates for three of the four Plaintiffs whose executions had been preliminarily enjoined by the 2019 Order: Lee on July 13, 2020, Purkey on July 15, 2020, Honken on July 17, 2020, and Keith Dwayne Nelson on August 28, 2020. (ECF No. 99, Defs. Notice Regarding Execution Dates.)

On July 13, 2020, the court preliminarily enjoined the executions of Lee, Purkey, Honken, and Nelson. (ECF No. 135, Mem. Op. (2020 Order) at 22.) The court found that these four Plaintiffs had demonstrated a likelihood of success on the merits of their claims that the 2019 Protocol is cruel and unusual in violation of the Eighth Amendment, but once again did not rule on their other statutory and constitutional claims. (*Id.* at 18.) The D.C. Circuit declined to stay or vacate the court's injunction, *see In re Fed. Bureau of Prisons' 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 (July 14, 2020) (per curiam). Four justices dissented. *Id.* at *2–3. Hours later, Defendants executed Daniel Lewis Lee.

Two more Plaintiffs are scheduled to be executed this week, and a third next month. Because these Plaintiffs are scheduled to be executed before their claims can be fully litigated, they have asked this court, pursuant to Federal Rule of Civil Procedure 65 and Local Rule 65.1, to preliminarily enjoin Defendants from executing them while they litigate their remaining claims.[2] (ECF No. 102, Pls. Mot. for Prelim. Inj.; *see also* ECF No. 144, Emergency Notice Requesting Ruling on Pending Mot.)

I. BACKGROUND

In 2005, 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, the government produced a 50-page document (2004 Main Protocol) outlining BOP execution procedures. *Roane*, ECF No. 179-3. The government 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 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.

[2] On July 2, 2020, the Seventh Circuit temporarily stayed Purkey's execution. *Purkey v. United States*, No. 19-3318, 2020 WL 3603779 (7th Cir. July 2, 2020). As of this filing, that stay is still in place. Because the Seventh Circuit affirmed the district court's denial of Purkey's petition for writ of habeas corpus, and only temporarily stayed his execution "pending the completion of proceedings in the Seventh Circuit," however, this court finds it appropriate to preliminarily enjoin his execution as well as those of the other Plaintiffs. *Id.* at *11.

letter.pdf. The government informed the court that the BOP "has decided to modify its lethal 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. On July 24, 2019, the DOJ announced a new addendum to the execution protocol, (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 makes no reference 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 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.) The government indicated that it was 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.)

Four inmates with scheduled execution dates filed complaints or motions to intervene in the *Roane* action challenging the 2019 Protocol, and each subsequently moved to preliminarily

enjoin their executions.[3] 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 statutory authority. (2019 Order at 13, 15.) 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 additional death row inmates filed complaints under separate case numbers, which in turn were consolidated with *Roane*.[4] Defendants moved to stay the court's preliminary injunction, which the court denied. (*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, 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.*

Defendants also filed an interlocutory appeal of the court's 2019 Order on November 21, 2019. (*See* ECF No. 52.) On April 7, 2020, the D.C. Circuit reversed. *Execution Protocol*

[3] 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, Bourgeois moved to preliminarily enjoin his execution. (ECF No. 2, Bourgeois Mot. for Prelim. Inj.) 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.) 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.)

[4] 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.

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 agreed that Plaintiffs were unlikely to prevail on the merits of their claims that the 2019 Protocol exceeds statutory authority. *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, Holder Compl.)

Now, after the intervening litigation described above, *see*, *supra*, at 2, two Plaintiffs—Purkey and Honken—are scheduled to be executed this week, and the third, Nelson, next month. Plaintiffs request that the court rule on their remaining statutory and constitutional claims prior to those dates. (Emergency Notice Requesting Ruling on Pending Mot.)

II. ANALYSIS

The court's 2019 and 2020 Orders set forth the legal standard for considering a motion for a preliminary injunction, an "extraordinary remedy" requiring courts to assess four factors: (1) the likelihood of the plaintiff's success on the merits, (2) the threat of irreparable harm to the plaintiff absent an injunction, (3) the balance of equities, and (4) the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20, 24 (2008) (citations omitted); *John Doe Co. v. Consumer Fin. Prot. Bureau,* 849 F.3d 1129, 1131 (D.C. Cir. 2017). The D.C. Circuit has

traditionally evaluated claims for injunctive relief on a sliding scale, such that "a strong showing on one factor could make up for a weaker showing on another." *Sherley v. Sebelius,* 644 F.3d 388, 392 (D.C. Cir. 2011). It has been suggested, however, that a movant's showing regarding success on the merits "is an independent, free-standing requirement for a preliminary injunction." *Id.* at 393 (quoting *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1296 (D.C. Cir. 2009) (Kavanaugh, J., concurring)).

A. Likelihood of Success on the Merits

Plaintiffs contend that the 2019 Protocol (1) is arbitrary and capricious under the APA; (2) violates the CSA and FDCA; and (3) deprives Plaintiffs of their right to access the courts and counsel under the First, Fifth, and Sixth Amendments. (Pls. Mot. for Prelim. Inj. at 1.) The court addresses Plaintiffs' likelihood of success on the merits on each of these claims in turn. Although most of their claims are without merit, the court finds that Plaintiffs' have demonstrated a likelihood of success on their FDCA claims.

1. Arbitrary and Capricious

As a preliminary matter, the court agrees with Plaintiffs that review of the 2019 Protocol is not cabined by the D.C. Circuit's holding that the Protocol is a procedural rule. Regardless of whether the APA's notice-and-comment provisions apply, the arbitrary and capricious standard is "among the most notable" constraints on agency decisionmaking, and the court must consider it. *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015). Likewise, the court must be able to consider evidence outside the administrative record in order to determine whether the agency considered all relevant factors. *Level the Playing Field v. FEC*, 381 F. Supp. 3d 78, 89 (D.D.C. 2019), *aff'd*, 961 F.3d 462 (D.C. Cir. 2020).

On the other hand, in reviewing an agency action under the arbitrary and capricious standard, the court must not "substitute its own judgment for that of the agency." *Mayo v. Reynolds*, 875 F.3d 11, 19–20 (D.C. Cir. 2017) (citation omitted). Its task is to ensure, after considering the relevant factors, that Defendants acted "within the bounds of reasoned decisionmaking." *Balt. Gas and Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 104 (1983). In other words, the court must decide whether there has been clear error by the agency. *See id.* at 96; *Marsh v. Oregon Nat. Res. Council*, 490 U.S. 360, (1989) ("[I]n making the factual inquiry concerning whether an agency decision was 'arbitrary or capricious,' the reviewing court 'must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.") (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).)

Plaintiffs argue that Defendants failed to consider three relevant factors before finalizing the 2019 Protocol: (1) the risk of flash pulmonary edema during the execution process, (2) the risk of faulty IV insertion during the execution process, and (3) the risks associated with compounding pharmacies in acquiring pentobarbital. None of these rises to the level of arbitrariness or capriciousness for an APA violation.

Plaintiffs convincingly show that, in developing the 2019 Protocol, Defendants did not consider the risk of flash pulmonary edema. (*See* ECF No. 118, Pls. Reply at 5.) This court has previously outlined the "excruciating suffering" associated with pulmonary edema. (*See* 2020 Order at 9–12.) However, the court is bound by the Supreme Court's holding that, given Defendants' contention that pulmonary edema occurs post-mortem or after the inmate has been rendered insensate, this risk does not justify last-minute judicial intervention. *Barr v. Lee*, 2020 WL 3964985, at *2.

Plaintiffs next argue that Defendants failed to consider the risk of faulty IV placement. The evidence before the court suggests that Defendants did consider the risks of faulty IV placement, at least enough to survive the arbitrary and capricious standard. Defendants studied the "after action report" of the botched execution of Clayton Lockett in Oklahoma, in 2014, where faulty IV placement caused Lockett to regain consciousness. (Admin. R. at 931.) Defendants also considered the risks in their consultation with experts (Admin. R. at 442–43), and in their review of the case law. (*See* Admin. R. at 108–400.) The court is sympathetic to Plaintiffs' dissatisfaction with the guidance provided by the 2019 Protocol, particularly given the botched executions of Lockett and others, and the additional difficulties associated with the ongoing COVID-19 crisis. But, based on the record before it, the court finds that Defendants adequately considered the risks of faulty IV placement in designing the 2019 Protocol.

Finally, while the record points to a number of concerns with the 2019 Protocol's use of a compounded form of pentobarbital, these concerns do not rise to the level of an APA violation. Defendants' reliance on what they concede is a non-binding memorandum to assure the court that it will use a compounding pharmacy that complies with the FDA's Current Good Manufacturing Practice requirements is troubling. (*See* ECF No. 113, Defs. Opp. at 31.) Defendants' use of compounding pharmacies, however, must be viewed in light of the Supreme Court's recognition that the government "can't be faulted for failing to use lethal injection drugs that it's unable to procure through good-faith efforts." *Bucklew v. Precythe*, 139 S. Ct. 1112, 1125 (2019) (citing *Glossip v. Gross*, 135 S. Ct. 2726, 2737–38 (2015). While Plaintiffs are correct to highlight the risks of using compounding pharmacies, the Supreme Court has approved the use of a compounded form of pentobarbital where domestic supplies were unavailable, and Defendants' decision to do so was not arbitrary or capricious.

Plaintiffs have thus failed to demonstrate a likelihood of success on the merits of their claims that the 2019 Protocol is arbitrary and capricious under the APA.

2. CSA and FDCA

Plaintiffs' CSA and FDCA claims are similar, as both contend that the 2019 Protocol is in violation of both statutes because the Protocol does not provide for Defendants to obtain a valid written prescription for the pentobarbital it will use to execute Plaintiffs. *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 U.S.C. § 353(b)(1) (requiring valid written or oral prescription in dispensing any controlled substance). *See also* 21 C.F.R. § 1308.12 (listing pentobarbital as a Schedule II controlled substance).

Plaintiffs are not barred by either statute from bringing a private claim. Defendants are correct that the CSA and FDCA are primarily criminal statutes, the enforcement of which is the "nearly exclusive" authority of the United States. *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014). Plaintiffs convincingly counter, however, that they do not seek to supplant the government as the enforcer of these statutes against a third party, but rather simply seek to require the government to comply with the statutes' prescription dispensation requirements. (Pls. Reply at 17–18.) In other words, while they allege that Defendants failed to comply with the CSA and FDCA, it would be more accurate to describe their claims as being brought under the APA for agency action that is "not in accordance with law"—a violation for which the APA does provide a private right of action. 5 U.S.C. §§ 702, 706(2)(A). *See also Chrysler Corp. v. Brown*, 441 U.S. 281, 316–18 (1979) (finding government violations of Trade Secrets Act reviewable even where Act contained no private right of action).

i. *CSA*

A plain reading of the statute indicates that Plaintiffs are correct that the CSA applies to the government's lethal injection procedures. Defendants contend that the CSA does not apply because Plaintiffs are not being "dispensed" pentobarbital, and Plaintiffs are not "patients." (Defs. Opp. at 32–33.) Plaintiffs, however, have amassed a factual record indicating that the Drug Enforcement Agency (DEA) previously advised state officials that the lethal injection process *was* considered "dispensing" the lethal drug, and that licensed professionals *were* required to "prescribe, administer, and dispense" said drugs. (*See* ECF No. 102-6, Decl. of Alan Schoenfeld Ex. 5; ECF No. 102-7, Schoenfeld Decl. Ex. 6.) Defendants' rebuttal that these documents are insufficiently authenticated is not a reason to rush Plaintiffs' executions, but rather a reason to halt them to permit Defendants to challenge their veracity.

However, Defendants also point to *Gonzales v. Oregon*, which, they contend, clearly establishes that the CSA does not apply in the lethal injection context. 546 U.S. 243, 272–74 (2006). In that case the Supreme 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. Thus, "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. Given this holding, dispensation of lethal injection drugs to an inmate would not be covered by the Act. Indeed, Plaintiffs' reply brief does not address *Gonzales*, and they have failed to demonstrate a likelihood of success on the merits on this claim.

ii. *FDCA*

The court's analysis of Plaintiffs' FDCA claims is similar to that of their CSA claims, but here, Plaintiffs are on firmer footing. It is true that the Office of Legal Counsel has previously opined that the FDCA does not apply in the lethal-injection context. *See Whether the Food & Drug Admin. Has Jurisdiction over Articles Intended for Use in Lawful Executions*, 2019 WL 2235666, at *1 (May 3, 2019). This Circuit, however, has found otherwise. In *Beaty v. FDA*, the Court held that lethal injection drugs are "drugs" under the FDCA, and that death-sentenced individuals are permitted to assert violations of the FDCA. 853 F. Supp. 2d 30, 34, 37–42 (D.D.C. 2012), *aff'd in relevant part sub nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013).

Defendants elsewhere argue that, because lethal injection drugs are intended to kill, they could not possibly be regulated by laws intended to ensure that a drug is "safe and effective for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Because violations of the FDCA carry "the risk that the drug[s] will not function as intended," however, the statute must apply in the lethal-injection context, because a lethal injection drug that does not function as intended may "result in conscious suffocation, pain, and cardiac arrest." *Beaty*, 853 F. Supp. 2d at 37. This is especially so where, as here, Defendants have justified the 2019 Protocol on the grounds that pentobarbital will render inmates insensate during the execution process. Where 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 that exist in order to ensure that the drugs operate humanely.

Defendants also raise a rather convoluted argument regarding the FDCA's restrictions on "outsourcing facilities." Essentially, they contend that because the FDCA allows certain

outsourcing facilities to compound pentobarbital in large quantities as "office stock" without obtaining a valid prescription for an identified patient, Defendants are similarly allowed to use outsourcing facilities, because they are not compounding large quantities for office stock, nor are inmates "patients." *See Athenex Inc. v. Azar*, 397 F. Supp. 3d 56, 59 (D.D.C. 2019). For the same reasons stated in its analysis of Plaintiffs' CSA claims, the court finds that Plaintiffs are "patients" for purposes of the FDCA. Moreover, the "office stock" language comes from the *Athenex* opinion, not the statute itself, which clearly states that the FDCA regulations apply to all outsourcing facilities, even those that are not responsible for obtaining the required prescriptions. 21 U.S.C. § 353(b)(d)(4). The court therefore declines to so drastically expand *Athenex*'s holding.

The D.C. Circuit's binding precedent, combined with Plaintiffs' plain reading of the statute, establishes that the 2019 Protocol is likely in violation of the FDCA. Plaintiffs have thus demonstrated a likelihood of success on the merits of their FDCA claims.

3. Access to the Courts and Right to Counsel

Finally, Plaintiffs argue that the 2019 Protocol violates their right to counsel. At its core, Plaintiffs' claim is that, because Plaintiffs have a constitutional right to counsel in order to assert violations of their fundamental rights, they also have the right to have their counsel supervise the execution for possible maladministration in violation of the Eighth Amendment. (*See* Pls. Reply at 18.) The proper question, however, is whether the 2019 Protocol burdens this right.

The 2019 Protocol permits up to two defense attorneys to be present as witnesses during the execution (Admin. R. at 1024), and while it does not permit witnesses to bring their cell phones into the witness room, 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 Plaintiffs during the execution, and from having a quick and easy means of communicating with the court. (Pls. Mot. for Prelim. Inj. at 35.) While these are all serious concerns, Plaintiffs fail to demonstrate a likelihood of success on the merits of showing that these requests are 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 a right for counsel to be present at the execution where Ohio law already permitted counsel to be present). Plaintiffs' suggestion that the court adopt Justice Thomas' concurrence in *Lewis v. Casey*, in which he wrote that the Due Process Clause requires a right to access the courts to assert violations of fundamental rights, is compelling. 518 U.S. 343, 380–82 (1996) (Thomas, J., concurring). But the court cannot find that Plaintiffs have demonstrated a likelihood of success on the merits of a claim that relies on the concurrence of a single Justice.

Finally, Plaintiffs raise a number of arguments regarding the impact of the COVID-19 crisis on Plaintiffs' access to counsel prior to and during the execution process. These are very serious concerns. However, Defendants correctly note that these problems are not the result of the 2019 Protocol, or indeed any of Defendants' actions, but of the pandemic itself. (Defs. Opp. at 42.) Plaintiffs' objections are understandable, but closely resemble the pandemic-related claims brought by spiritual advisors and family members in separate litigation—claims which have thus far been 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). Given these and other recent developments, the likelihood of success on Plaintiffs' constitutional claims "seems vanishingly small." *Hartkemeyer*, No. 20-cv-336, ECF No. 84 at 5.

B. Irreparable Harm

The court's analysis of irreparable harm is unchanged from its 2019 and 2020 Orders. In order to prevail on a request for preliminary injunction, irreparable harm "must be certain and great, actual and not theoretical, and so imminent that there is a clear and present need for equitable relief to prevent irreparable harm," and it "must be beyond remediation." *League of Women Voters of U.S. v. Newby,* 838 F.3d 1, 7–8 (D.C. Cir. 2016) (citing *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006)) (internal quotation marks and brackets omitted). Here, without injunctive relief, Plaintiffs would be unable to pursue their remaining claims, including the claims that the method of planned execution under the 2019 Protocol is cruel and unusual in violation of the Eighth Amendment, and would therefore be executed under a procedure likely to be unconstitutional. This harm is manifestly irreparable. *See also Wainwright v. Booker*, 473 U.S. 935, 935n.1 (1985) (Powell, J., concurring) (finding irreparable harm "necessarily present in capital cases").

At no point in this litigation have Defendants disputed that Plaintiffs will suffer irreparable harm if they are executed before their claims can be fully adjudicated. Nor has the D.C. Circuit on appeal, and nor has the Supreme Court, even as it vacated the court's 2020 Order on the basis that Plaintiffs had not demonstrated a likelihood of success on the merits of their

Eighth Amendment claims. Based on the record before it, the court finds that Plaintiffs have shown that absent injunctive relief, they will suffer the irreparable harm of being executed before their claims can be fully adjudicated.

C. Balance of Equities

Defendants argue that if the court preliminarily enjoins the 2019 Protocol, they will suffer the harm of having to delay the scheduled execution dates. (*See* Defs. Opp. at 57.) Defendants' interest in the finality of criminal proceedings, especially at the last minute, is compelling. *Calderon v. Thompson*, 523 U.S. 538, 556 (1998). The court once again notes, however, that Defendants waited eight years to establish a new protocol for federal executions. This delay undermines their arguments regarding the urgency and weight of that interest.

Indeed, where the Supreme Court has been sympathetic to the government's need for finality in capital cases, it has generally been in cases where plaintiffs waited until the last minute to bring claims that could have been brought earlier, or engaged in a clear "attempt at manipulation" of the judicial process. *Bucklew*, 139 S. Ct. at 1134 (quoting *Hill v. McDonough*, 547 U.S. 573, 584 (2006)). Here, however, two of the three Plaintiffs filed their complaints shortly after the DOJ announced the 2019 Protocol, months before their initially scheduled executions, and Nelson filed his complaint before Defendants even announced his execution date. Plaintiffs are not raising new claims that they could have brought in their initial complaints, but rather renewing the Eighth Amendment arguments made in their initial motions.

That this order comes at the last minute is unfortunate, but it is no fault of Plaintiffs. Defendants chose to schedule Plaintiffs' executions knowing that their remaining claims were still pending. Defendants further chose to schedule three federal executions, the first in over fifteen years, for the same week, knowing that Plaintiffs' claims raised a number of "novel and

difficult" questions, both in this and other actions. *See Execution Protocol Cases*, No. 20-5199 (D.C. Cir. July 13, 2020). Furthermore, once the Supreme Court vacated this court's preliminary injunction, Defendants chose to execute Lee, beginning the process before dawn, knowing that Lee had pending claims before the court that could not possibly be resolved prior to his execution, including a claim that this court now finds is likely to succeed on the merits. This court agrees that "last-minute stays should be the extreme exception," *Bucklew*, 139 S. Ct. at 1134, but here, it is Defendants' rush to execute Plaintiffs that has led to this extreme exception.

Given this background, the court finds that the potential harm to the government caused by a delayed execution is not substantial, and is far outweighed by the irreparable harm Plaintiffs would face absent an injunction.

D. Public Interest

As noted in the court's 2019 and 2020 Orders, the public interest is not served by executing individuals before they have had the opportunity to avail themselves of the legal process to challenge the legality of their executions. *See Barr v. Roane*, 140 S. Ct. at 353 (Op. of Alito, J., respecting denial of stay or vacatur) (finding it preferable for plaintiffs' claims to be heard on the merits "in light of what is at stake"). *See also Purkey v. United States*, No. 19-3318, 2020 WL 3603779, at *11 (7th Cir. July 2, 2020) ("Just because the death penalty is involved is no reason to take shortcuts—indeed, it is a reason not to do so."); *Harris v. Johnson*, 323 F. Supp. 2d 797, 810 (S.D. Tex. 2004) ("Confidence in the humane application of the governing laws . . . must be in the public's interest."). Accordingly, the court finds that the public interest is served by preliminarily enjoining Plaintiffs' executions because it will allow judicial review of whether the United States Government's planned execution protocol complies with federal law, and to ensure that it does so in the future.

III. CONCLUSION

The court finds that at least one of Plaintiffs' claims has a likelihood of success on the merits, and that absent a preliminary injunction, Plaintiffs will suffer irreparable harm. It further finds that the likely harm that Plaintiffs would suffer if the court does not grant injunctive relief far outweighs any potential harm to Defendants. Finally, because the public is not served by short-circuiting legitimate judicial process, and is greatly served by attempting to ensure that the most serious punishment is imposed in accordance with federal law, the court finds that it is in the public interest to issue a preliminary injunction. Accordingly, having reviewed the parties' filings, the record, and the relevant case law, and for the reasons set forth above, the court will GRANT Plaintiffs' Motion for a Preliminary Injunction. A corresponding order will be issued simultaneously.

Date: July 15, 2020

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

(Slip Opinion)

Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions

May 3, 2019

Articles intended for use in executions carried out by a State or the federal government cannot be regulated as "drugs" or "devices" under the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration therefore lacks jurisdiction to regulate articles intended for that use.

MEMORANDUM OPINION FOR THE ATTORNEY GENERAL

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., grants the Food and Drug Administration ("FDA") the authority to regulate all "drugs" and "devices," which include any "articles (other than food) intended to affect the structure or any function of the body," as well as any components of such articles. *Id*. § 321(g)(1)(C)–(D), (h)(3). Your office has asked us whether FDA has authority to regulate articles used in historically accepted methods of execution. Some of those articles—like electric chairs and gas chambers—exist for the sole purpose of effectuating capital punishment. Others—like substances used in lethal-injection protocols and firearms used by firing squads—have other intended uses.

FDA has not historically exercised jurisdiction over articles intended to carry out a lawful sentence of capital punishment. In connection with challenges to FDA's regulatory inaction, the federal courts have addressed when the agency may lawfully decline to enforce the FDCA against such articles. *See, e.g*., *Heckler v. Chaney*, 470 U.S. 821 (1985); *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013). Yet they have not squarely addressed whether FDA has administrative jurisdiction in the first place. Congress has repeatedly authorized the death penalty on the assumption that there are lawful means to carry it out, but the regulation of such articles under the FDCA would effectively require their prohibition because they could hardly be found "safe and effective" for such an intended use. *See FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 137–39 (2000). Consistent with the agency's practice in this area for several decades before 2017, we thus conclude that, when an article's intended use is to

effectuate capital punishment by a State or the federal government, it is not subject to regulation under the FDCA.[1]

I.

The FDCA was first enacted in 1938. Act of June 25, 1938, ch. 675, 52 Stat. 1040. Then, as well as now, the United States and several States authorized the imposition of capital punishment for the most serious offenses. From the time of the FDCA's enactment until very recently, FDA had never claimed authority over the methods by which the federal and state governments carry out executions. That is in no small part because one of the FDCA's fundamental purposes is to ensure that drugs and devices marketed in interstate commerce are safe and effective for their intended uses—a goal that markedly conflicts with the purpose of an execution. In this Part, we summarize the regulatory structure of the FDCA and the history of its intersection with capital punishment.

A.

The FDCA authorizes FDA to regulate drugs and devices. The FDCA defines "drug" to mean:

> (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
>
> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
>
> (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
>
> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C. § 321(g)(1) (paragraph breaks added). Congress has made only superficial changes to this definition since 1938. *Compare* Act of June 25, 1938, § 201(g), 52 Stat. at 1041.

[1] In reaching this conclusion, we have solicited and considered the views of FDA and of the Office of the Associate Attorney General.

The FDCA defines "device" as any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" that does not "achieve its primary intended purposes through chemical action within or on the body"; is not "dependent upon being metabolized for the achievement" of those purposes; and is:

> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals.

21 U.S.C. § 321(h) (paragraph breaks added). The definition of "device" also includes "any component, part, or accessory" of such articles. *Id.*[2]

As the statutory definitions indicate, whether FDA may regulate an article as a "drug" or "device" often depends not just on that article's effect on a human or animal body, but also on whether that effect is intended. *Id.* § 321(g)(1), (h). An article may be a "drug" or "device" for some uses but not for others, depending on the manufacturer's or distributor's intent. For instance, FDA regulates "medical gases," but not chemically identical industrial gases. As FDA has explained, "industrial gases . . . are not drugs" because manufacturers and distributors of industrial gases do not intend their products to treat disease or other conditions, or to otherwise affect the structure or function of the body. Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements, 71 Fed. Reg. 18,039, 18,044 (Apr. 10, 2006); *see* 21 C.F.R. §§ 201.161, 211.94(e). In a similar vein, FDA considers hot tubs, saunas, and treadmills as "devices" only when they are "intended for medical purposes." Physical Medicine Devices; General Provisions and Classification of 82 Devices, 48 Fed. Reg. 53,032, 53,034, 53,044, 53,051–52

[2] Initially, the FDCA defined "device" as "instruments, apparatus, and contrivances, including their components, parts, and accessories" if they were "intended" either "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" or "to affect the structure or any function of the body of man or other animals." Act of June 25, 1938, § 201(h), 52 Stat. at 1041. In 1976, Congress expanded the definition of "device" to its current scope. Medical Device Amendments of 1976, Pub. L. No. 94-295, sec. 3(a)(1)(A), § 201(h), 90 Stat. 539, 575.

(Nov. 23, 1983); *see* 21 C.F.R. §§ 890.5100, 890.5250, 890.5380. Thus, powered treadmills intended "to redevelop muscles or restore motion to joints" are "devices," but those sold solely for recreational purposes are not. 48 Fed. Reg. at 53,044, 53,052; 21 C.F.R. § 890.5380. Likewise, FDA considers tape recordings as "devices" when they are "intended for use in the mitigation, treatment, and cure of disease and other medical conditions" (as in hypnotherapy), but not when they are intended "for behavior modification, self-improvement, habit correction, learning techniques, and simple relaxation." FDA, Compliance Policy Guide § 335.300.

Many of the FDCA's prohibitions are keyed to a product's intended use. The FDCA prohibits distribution of a "new drug" that FDA has not approved as safe and effective for its intended use. *See* 21 U.S.C. § 355(a), (d)(1), (d)(5); *United States v. Caronia*, 703 F.3d 149, 152–53 (2d Cir. 2012). Similarly, the FDCA prohibits distribution of certain devices that present "a potential unreasonable risk of illness or injury," unless FDA has approved them as safe and effective for their intended uses. 21 U.S.C. § 360c(a)(1)(C); *see id.* §§ 331(a), 351(f)(1), 360e(a), (d)(2)(A)–(B). The FDCA also bars distribution of "misbranded" drugs and devices, including those whose labeling lacks adequate directions for their intended uses, *id.* § 352(f)(1), or adequate warnings against unsafe dosages or methods of administration for those uses, *id.* § 352(f)(2). Finally, the FDCA provides that FDA "shall" block the importation of drugs and devices that appear to be unapproved for their intended use or misbranded. *Id.* § 381(a)(3).

Even if FDA has approved an article for one intended use, it still may not be imported, sold, or distributed for another, unapproved use. *See Wash. Legal Found. v. Henney*, 202 F.3d 331, 332–33 (D.C. Cir. 2000). FDA's regulations define the "intended use" of a drug or device with reference to "the objective intent of the persons legally responsible for the labeling" of the article. 21 C.F.R. §§ 201.128 (drugs), 801.4 (devices). That intent "is determined by such persons' expressions" or from "the circumstances surrounding the distribution of the article." *Id.* §§ 201.128, 801.4. The regulations emphasize that "[t]he intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer." *Id.* §§ 201.128, 801.4. "[F]or example, a packer, distributor, or seller [may] intend[] an article for different uses than those intended by the person from whom he received the" drug or device, in which case "such packer, distributor, or seller is required to supply adequate

labeling in accordance with the new intended uses." *Id.* §§ 201.128, 801.4. Likewise, a manufacturer could lawfully distribute an article intending that it be used for an approved purpose, and then later violate the FDCA by distributing the same article intending that it be used for a different, unapproved purpose.

As a general matter, FDA does not regulate the practice of medicine, which includes "off-label" prescribing—that is, when physicians prescribe FDA-approved drugs or devices for non-FDA-approved uses.[3] As the Supreme Court has explained in the context of medical devices, "'off-label' usage . . . (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *see also Caronia*, 703 F.3d at 153. Thus, while the FDCA bars a manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses.

B.

Capital punishment in the United States predates the Republic. For most of the Nation's history, the federal government and the States employed the gallows. Starting in the late nineteenth century, States began using the electric chair and, to a lesser degree, the gas chamber. At least since Thomas Edison's New Jersey laboratory supplied parts for New York's first electric chair in 1890, prison authorities have used interstate suppliers to procure articles necessary for executions.[4] Today, every

[3] *See* Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 1994) ("'[O]nce a [drug] product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens o[f] patient populations that are not included in approved labeling.'") (quoting 12 FDA Drug Bulletin 5 (Apr. 1982)); *see also* 21 U.S.C. § 396.

[4] *See* Stuart Banner, *The Death Penalty: An American History* 183, 197 (2002) (describing New York's purchase of electric-chair components, and Nevada's purchase of hydrocyanic acid for use in the gas chamber from a California source); Scott Christianson, *The Last Gasp: The Rise and Fall of the American Gas Chamber* 6 (2010) (explaining that Eaton Metal Products in Colorado built gas chambers for most of the States that used them); Carol J. Williams, *Maker of Anesthetic Used in Executions is Discontinuing Drug*,

method of execution appears to involve some component that traveled in interstate or foreign commerce.

Beginning in the late 1970s, many States and the federal government adopted lethal injection as the preferred method of execution. Those executions generally used sodium thiopental, a widely administrered surgical anaesthetic. Although patients typically received a dose of around 300 milligrams of sodium thiopental during surgical procedures, the dose in a lethal injection was anywhere from "seven to sixteen times higher." Mark Dershwitz & Thomas K. Henthorn, *The Pharmacokinetics and Pharmacodynamics of Thiopental as Used in Lethal Injection*, 35 Fordham Urb. L.J. 931, 932 (2008); *see also Glossip v. Gross*, 135 S. Ct. 2726, 2742 (2015) (noting that the dose of midazolam in Oklahoma's more recent execution protocol "is many times higher than a normal therapeutic dose").

In 1980, death-row inmates petitioned FDA to seize lethal-injection substances from several States, arguing that, although the substances were approved for other uses, their use in executions would violate the FDCA's prohibitions against the distribution of unapproved new drugs and misbranded drugs. FDA denied the petition, reasoning that it lacked authority to regulate States' use of FDA-approved drugs in capital punishment. FDA also stated that, even if it had such authority, it would decline to regulate in its enforcement discretion. When the issue reached the Supreme Court, the United States argued more broadly that FDA lacked jurisdiction over articles intended for use in capital punishment. *See Heckler*, 470 U.S. 821; Br. for Pet'r at 13–14, 44–46, *Heckler v. Chaney*, 470 U.S. 821 (1985) (No. 83-1878) ("*Heckler* Pet'r Br."). The Court found it "implausible . . . that the FDA is required to exercise its enforcement power to ensure that States only use drugs that are 'safe and effective' for human execution." 470 U.S. at 827. Rather than "address the thorny question of the FDA's jurisdiction," however, the Court held that FDA's exercise of enforcement discretion is not subject to judicial review. *Id*. at 828.

L.A. Times (Jan. 22, 2011), http://articles.latimes.com/2011/jan/22/local/la-me-execution-drug-20110122 (discussing California's use of sodium thiopental produced in North Carolina); Deborah W. Denno, *Getting to Death: Are Executions Constitutional?*, 82 Iowa L. Rev. 319, 354 & n.207 (1997) (explaining that the sole commercial suppliers of electric-chair equipment were in Massachusetts and Arkansas).

In 2009, the sole American manufacturer of sodium thiopental ceased production. *See Glossip*, 135 S. Ct. at 2733. Since then, several States have imported sodium thiopental from foreign suppliers. *Cook*, 733 F.3d at 4. In 2012, however, the U.S. District Court for the District of Columbia held that, although FDA has unreviewable discretion when enforcing the FDCA's domestic prohibitions, FDA's discretion is more limited with respect to the Act's importation provisions. The court issued a permanent injunction requiring FDA to block the importation of sodium thiopental on the grounds that it was unapproved and misbranded. *See Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff'd*, *Cook*, 733 F.3d 1. Neither the parties nor the district court, however, addressed the government's previous argument in *Heckler* that FDA lacks jurisdiction over articles intended for use in capital punishment. *See Beaty*, 853 F. Supp. 2d at 34. Following the *Beaty* injunction, FDA expressly stated in a letter ruling, apparently for the first time, that it had jurisdiction over a substance intended for that use, though, significantly, the State seeking the ruling had conceded the point. *See* Letter from Todd W. Cato, Director, Southwest Import District Office at 5 (Apr. 20, 2017).

As of December 31, 2016, there were over 2,750 inmates with state death sentences. Elizabeth Davis & Tracy L. Snell, Bureau of Justice Statistics, U.S. Dep't of Justice, *Capital Punishment, 2016*, at 3 tbl.1 (2018). And there are now approximately 62 civilian prisoners with federal death sentences. *See* Federal Bureau of Prisons, *Statistics: Sentences Imposed*, https://www.bop.gov/about/statistics/statistics_inmate_sentences.jsp (last updated Apr. 13, 2019). In response to difficulties in obtaining appropriate substances for lethal injection, some States are considering turning to different methods of execution, including the electric chair and nitrogen gas. Tom Barton, *SC Senators Resurrect Bill to Bring Back the Electric Chair, Add Firing Squad*, The State (Jan. 30, 2019), https://www.thestate.com/news/politics-government/article225312765.html; Denise Grady & Jan Hoffman, *States Turn to an Unproven Method of Execution: Nitrogen Gas*, N.Y. Times (May 7, 2018), https://www.nytimes.com/2018/05/07/health/death-penalty-nitrogen-executions.html.

II.

With this background in mind, we turn to whether FDA may regulate articles intended for use in capital punishment. The Supreme Court recognized some time ago that "Congress fully intended that the [FDCA]'s

coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow." *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969). Nevertheless, in *Brown & Williamson*, the Court recognized one limitation to such coverage in the context of reviewing FDA's authority to regulate tobacco products.

In *Brown & Williamson*, the Court considered whether FDA had properly determined that tobacco products as customarily marketed could be regulated as "drugs" or "devices" under the FDCA. FDA had conducted a rulemaking in which it concluded that the definitional phrase, "intended to affect the structure or any function of the body," is "broad in scope and encompass[es] a range of products wider than those ordinarily thought of as drugs or medical devices." Analysis Regarding the Food and Drug Administration's Jurisdiction over Nicotine-Containing Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453, 41,463 (Aug. 11, 1995); Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619, 44,658 (Aug. 28, 1996). FDA deemed nicotine to be regulable as a "drug" because it was "intended" to have "psychoactive, or mood-altering, effects on the brain" that foster addiction, stimulate and depress the nervous system, and suppress appetite, thus mirroring the effects of tranquilizers, stimulants, weight-loss drugs, and other articles long subject to FDA jurisdiction. 61 Fed. Reg. at 44,631–32.

The Supreme Court rejected FDA's conclusion, holding that the FDCA's jurisdictional provisions must be read in the context of the entire statute, and of later-enacted laws, to ensure "a symmetrical and coherent regulatory scheme." *Brown & Williamson*, 529 U.S. at 133. "Viewing the FDCA as a whole," the Court concluded that it would "contravene[] the clear intent of Congress" to treat tobacco products as subject to FDA regulation. *Id*. at 132, 133. Were tobacco products regulated as "drugs" or "devices," the FDCA would prohibit their sale, because they could not be "safe" or "effective" for their intended use. *Id*. at 134–37. Yet such "a ban would contradict Congress's clear intent as expressed in its more recent, tobacco-specific legislation," which reflected the "collective premise . . . that cigarettes and smokeless tobacco will continue to be sold in the United States." *Id*. at 137, 139, 143–56. Furthermore, Congress had enacted this tobacco-specific legislation "against the background of the FDA repeatedly and consistently asserting that it lacks jurisdiction under the FDCA to regulate tobacco products as customarily marketed." *Id*. at 155–

56. The Court concluded: "The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit." *Id*. at 143.[5]

Congress subsequently ratified the Court's conclusion in the Tobacco Control Act, 21 U.S.C. § 387 *et seq*., which confirmed that tobacco products as customarily marketed are not regulable as "drugs" or "devices" under the FDCA. *See id*. § 321(rr)(1)–(2). At the same time, Congress granted FDA the authority to impose other regulations on tobacco products. *See id*. § 387a(a) ("Tobacco products . . . shall be regulated . . . under this subchapter and shall not be subject to the [drug-and-device] provisions of subchapter V."); *Sottera, Inc. v. FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010).

Under *Brown & Williamson*, FDA lacks jurisdiction to regulate articles intended for a use not traditionally regulated by FDA, when those articles cannot be safe and effective for such intended use, and Congress has otherwise made clear its expectation that at least some of those articles shall remain lawful and available for that use. *See Sottera*, 627 F.3d at 896 (interpreting *Brown & Williamson*); *see also Massachusetts v. EPA*, 549 U.S. 497, 530–31 (2007) (explaining that *Brown & Williamson* rested on "the unlikel[ihood] that Congress meant to ban tobacco products" and "an unbroken series of congressional enactments that made sense only if adopted against the backdrop of the FDA's consistent and repeated statements" disclaiming jurisdiction (internal quotation marks omitted)); *Verizon v. FCC*, 740 F.3d 623, 638 (D.C. Cir. 2014) (similar).

III.

Applying *Brown & Williamson*, we conclude that the FDCA does not allow FDA to regulate an article intended for use in capital punishment in the United States. The FDCA's regulatory framework for "drugs" and

[5] The *Brown & Williamson* Court declined to give the agency deference under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc*., 467 U.S. 837 (1984), because "Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion." 529 U.S. at 160; *see also King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (similarly concluding that "[w]hether [tax] credits are available on Federal [Health Insurance] Exchanges is . . . a question of deep 'economic and political significance'" that Congress did not implicitly delegate to the agency) (quoting *Brown & Williamson*, 529 U.S. at 160)).

"devices" cannot sensibly be applied to such articles. If the FDCA applied to electric chairs, gallows, gas chambers, firearms used in firing squads, and substances used in lethal-injection protocols, the statute would effectively ban those articles. Yet the Constitution and laws of the United States presuppose the continued availability of capital punishment for the most heinous federal and state crimes. FDA did not expressly assert the authority to regulate articles intended for use in executions at any time before 2017, and we believe that such an assertion cannot be reconciled with the FDCA and other federal law.

A.

Articles used in capital punishment do literally "affect the structure or any function of the body" by causing all bodily functions to cease. 21 U.S.C. § 321(g)(1)(C), (h)(3). Hanging, gas asphyxiation, a firing squad, lethal injection, and electrocution are all intended to achieve the same effect: they cause death. When a prison official seeks to purchase an article essential to one of these methods of execution, the seller will often know that the item will be used in an execution and is thus "intended" to affect the structure or any function of the body. *Id.*; *see* 21 C.F.R. § 201.128 (a drug's "intended use" can "be shown by the circumstances surrounding the distribution of the article"); *id.* § 801.4 (same for devices); *cf. United States v. Kaminski*, 501 F.3d 655, 671 (6th Cir. 2007) (concluding that egg powders were "drugs" because defendants "distributed them to consumers for the express purpose of treating and/or preventing diseases" as evidenced by, among other things, "the methods of sale and distribution").

Nevertheless, *Brown & Williamson* prevents us from interpreting the FDCA in a manner that would depart from its "symmetrical and coherent regulatory scheme," 529 U.S. at 133, and interpreting the FDCA to authorize regulation of articles intended for use in executions would do exactly that. *See also Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.*, 139 S. Ct. 361, 368 (2018) ("[S]tatutory language cannot be construed in a vacuum . . . so we must also consider [the term] in its statutory context." (internal quotation marks and citation omitted)). If such articles were regulated as "drugs" or "devices," the FDCA would effectively ban them and FDA could seek fines or prosecutions against those involved in their sale or distribution. 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 (internal quotation marks omitted). In the case of tobacco products, their short-term physiological effects were greatly outweighed by their demonstrated carcinogenic qualities. *Id*. at 134–35. Thus, if tobacco products had been regulated as "drugs" or "devices," the FDCA would have effectively rendered them unlawful. *Id*. at 135–37.

The same conclusion follows here, because the articles used in capital punishment are intended to cause death—for some articles that is their sole purpose. Under the FDCA, a "new drug" may not go to market unless FDA determines, based on "adequate and well-controlled investigations," that the substance is "safe" and "effective[]" for the "use . . . prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d)(1), (5); *see also* 21 C.F.R. § 314.50(d)(5). To approve a substance for use in a lethal-injection protocol, then, FDA would have to find that clinical-trial data established that the substance was "safe" for executions—that is, that the harm inflicted by the product would be "offset by the possibility of therapeutic benefit" to the inmate. *Brown & Williamson*, 529 U.S. at 134. It would not be sufficient to show that the substance is safer or more effective than other means of execution. *Brown & Williamson* dismissed such an interpretation of "safety" as involving a "qualitatively different inquiry" from that required by the FDCA. *Id*. at 140. Instead, FDA must find "that the *product itself* is safe as used by consumers." *Id*. But there is no way products intended to carry out capital punishment could ever satisfy that test, under which "a drug is unsafe if its potential for inflicting death . . . is not offset by the possibility of therapeutic benefit." *United States v. Rutherford*, 442 U.S. 544, 556 (1979).

The same would be true if electric chairs, gallows, or firing squads' firearms were regulated as "devices." Those articles would require premarket approval because they "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II). And FDA could approve them only if the applicant provided "reasonable assurance" that they were "safe" and "effective" for the intended use of carrying out capital punishment, *id*. § 360e(d)(1)(A), (2)(A)–(B), after "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," *id*. § 360c(a)(2)(C). Again, FDA

could not possibly approve "devices" that are intended to effectuate executions as "safe" and "effective."[6]

Nor would it matter whether an article intended for use in capital punishment was designed solely for that purpose or had other, FDA-approved uses.[7] Either way, whenever manufacturers or distributors intended that an article be used in capital punishment, the FDCA would prohibit distributing it for that use. For example, FDA has approved midazolam for use as a sedative and anesthetic in certain procedures. But if a manufacturer or distributor of midazolam sold it to prison officials specifically for use in capital punishment, the drug's "intended use" would be different from any approved use. *See* 21 C.F.R. § 201.128. A drug's labeling must bear adequate directions for use for all of its intended uses; otherwise it is misbranded. *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.128. Accordingly, the manufacturer or distributor would violate the FDCA's new drug prohibition where the product's labeling suggested its use in capital punishment. Drugs intended for use in lethal injection that were FDA-approved only for other uses would also be misbranded because their FDA-approved labeling would, by definition, lack adequate warnings against unsafe dosages or methods of administration for use in capital punishment. *See* 21 U.S.C. § 352(f)(2).[8] In sum, if articles intended for

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[6] Applications to market drugs and devices both require the submission of well-controlled clinical investigations. 21 U.S.C. §§ 355(d), 360c(a)(2), (3)(A)–(B); 21 C.F.R. § 860.7(c). Given that the articles at issue here are intended to cause death during lawful executions, it is difficult to envision how the articles could be studied in clinical investigations involving humans.

[7] The FDCA's practice-of-medicine exception does not extend to articles used in executions. That exception applies only when an article is "prescribe[d] or administer[ed]" to treat a "condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396 (devices); *see* James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 77–78 (1998) (discussing history behind section 396, which shows it was enacted to extend to devices the practice-of-medicine exception that already applied to drugs).

[8] The law-enforcement exception in 21 C.F.R. § 201.125 exempts a drug from the requirement in section 502(f)(1) of the FDCA that labeling include "adequate directions for use." 21 U.S.C. § 352(f)(1). That exception, however, does not extend to section 502(f)(2), which requires "adequate warnings . . . against unsafe dosage or methods or duration of administration." *Id.* § 352(f)(2). Thus, even if executions qualified as an excepted law-enforcement use, substances used in executions would be misbranded under subsection (f)(2).

use in capital punishment were regulated as "drugs" or "devices," then the FDCA would prohibit them altogether.

In the past, FDA has avoided such regulatory consequences by declining to regulate the domestic sale and distribution of articles intended for use in executions as a matter of enforcement discretion. But the D.C. Circuit recently upheld a district court order enjoining FDA from permitting the importation of foreign-manufactured sodium thiopental, on the grounds that it was misbranded and unapproved. *Cook*, 733 F.3d 1. And the question now is whether FDA's regulatory authority encompasses articles intended for use in lethal injection or other methods of capital punishment, not whether FDA may use its enforcement discretion to alleviate the regulatory consequences. FDA equally had discretion not to enforce the FDCA against domestic tobacco sales that, in FDA's view, would have violated the FDCA's prohibitions on misbranding or unapproved new drugs or devices. What mattered in *Brown & Williamson* was that the FDCA would have rendered the sale of tobacco products per se unlawful, not that FDA could have tempered that ban by selectively sparing particular manufacturers from civil and criminal penalties. *See, e.g.*, 529 U.S. at 136 ("[T]he Act admits no remedial discretion once it is evident that the device is misbranded."). The prospect that articles intended for use in capital punishment could be sold or distributed at FDA's sufferance does not alter the fact that the FDCA, by its terms, would effectively require a ban of such articles if they were regulated under the FDCA as "drugs" or "devices."

B.

Even if the FDCA could be interpreted to authorize regulation of articles intended for use in executions without requiring them to be banned, any attempt to do so would create serious tension with other provisions of the Act. We do not conclude that, in order for FDA to have jurisdiction over an article as a "drug" or "device," every drug- or device-related provision of the FDCA must apply neatly to the article's intended use. But the sheer number of FDCA provisions here that would make no sense as applied reinforces the conclusion that FDA lacks jurisdiction over articles intended for use in capital punishment. For example, with respect to articles intended for use in capital punishment, FDA could not assess "[t]he seriousness of the disease or condition that is to be treated with the drug" or "[t]he expected benefit of the drug with respect to such disease

or condition." 21 U.S.C. § 355-1(a)(1)(B)–(C). Execution drugs address no "condition" suffered by, and produce no "benefit" for, the end user; instead, they exclusively inflict harm upon that user. For the same reason, when reviewing a new drug application for an article intended for use in capital punishment, FDA could not provide for review of scientific disputes by a "panel[] of experts" that includes members with "expertise in *the particular disease or condition* for which the drug . . . is proposed to be indicated." *Id.* § 355(n)(1), (3)(D) (emphasis added); *see also id.* § 360bbb-1; 8 C.F.R. § 10.75(b)(2). In the context of an execution, there is no applicable "disease or condition."

Further, with respect to articles intended for use in capital punishment, "patient experience data"—which includes "information about patients' experiences with a disease or condition," such as "patient preferences with respect to treatment of such disease or condition"—would never be available. 21 U.S.C. § 360bbb-8c(b)(1), (c)(2). Other FDCA provisions treat death as a serious side effect that triggers mandatory reporting and FDA oversight. *See, e.g.*, *id.* § 355(k)(3)(C)(i)(II) (requiring drug manufacturers to "report[] . . . on all serious adverse drug experiences," including death); 21 C.F.R. § 314.80 (detailing exhaustive reporting requirements for each "adverse drug experience," including those resulting in death). These provisions cannot sensibly be read to allow an article's intended use to be the causing of death in an execution.

Other provisions presuppose that an approved device may not be intended to effectuate an execution. A manufacturer's application for FDA approval "shall include" a "description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure," 21 U.S.C. § 360e-1(a)(2)(A), which suggests that a device must be intended to *improve* a patient's circumstances. FDA must also submit any new device to a panel of experts with "adequate expertise . . . to assess . . . the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose." *Id.* § 360c(b)(1), (5)(B)(i)(I). But again, it would make no sense to apply those provisions to articles for use in executions, which are not intended to produce any benefit for the end user.

Congress has treated certain articles intended to cause death as falling outside FDA's jurisdiction. For instance, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") expressly gives the Environmental Protection Agency rather than FDA jurisdiction over "pesticides," which include "any substance . . . intended for preventing, destroying, repelling,

or mitigating any pest" but exclude "any article that is a 'new animal drug' within the meaning" of the FDCA. 7 U.S.C. § 136(u). FIFRA thus suggests that Congress generally views substances intended to harm or kill pests (such as mosquitos and rats, *see id*. § 136(t)) as outside FDA's jurisdiction.

Over the years, FDA has disclaimed jurisdiction over several other articles intended to kill or harm humans or animals. In 1969, for instance, FDA's Chief Counsel testified that even though "pistols and bullets are intended to affect the function or structure of the body in the same way" as mace, the agency "concluded that the products could not properly be classified as drugs under the definition" in the FDCA. *Public Sale of Protective Chemical Sprays: Hearings Before the Consumer Subcomm. of the S. Comm. on Commerce*, 91st Cong. 37 (1969) (statement of William Goodrich). FDA reiterated that position when asserting jurisdiction over tobacco products in 1996, explaining that it "has never construed the structure-function provision to include products such as guns, airbags, and chemical sprays," despite their intended effects on the structure or function of the body. 61 Fed. Reg. at 44,684. That same rationale extends to articles intended for use in executions.[9]

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[9] Since 1977, FDA has asserted jurisdiction over articles intended for animal euthanasia. FDA first asserted jurisdiction over Beuthanasia-D. *See United States v. Articles of Drug Beuthanasia-D Regular*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,265 (D. Neb. Aug. 1, 1979). A district court agreed that FDA had jurisdiction, both because Beuthanasia-D's two active ingredients were listed in the United States Pharmacopoeia (a different component of the FDCA's definition of "drug"), *id*. ¶ 39,129 (citing 21 U.S.C. § 321(g)(1)(A) (1972)), and because "euthanasia—the cessation of all bodily functions— . . . constitute[s] an effect on the function, if not the structure, of the animal's body," *id*. ¶ 39,130 (citing 21 U.S.C. § 321(g)(1)(C) (1972)). In 1980, FDA issued a two-paragraph guidance statement, opining that "products intended for animal euthanasia . . . conform to the definition of a drug" under the FDCA "since they are clearly intended to affect the function of the body by inducing death." FDA, Compliance Policy Guide § 650.100 (Oct. 1, 1980). FDA's guidance in this area predates *Brown & Williamson*, and no court has revisited the matter. Although it may be difficult to view animal-euthanasia articles as "safe" for their intended use (at least where such articles are used on healthy but unwanted animals), FDA has regulated such articles since 1977; it has approved five applications for these articles; its regulation does not raise constitutional concerns; and we are aware of no legislation that suggests FDA's assertion of jurisdiction over articles intended for animal euthanasia is contrary to the intent of Congress. Additionally, animal euthanasia has long been an accepted part of veterinary practice, whereas capital punishment has not been a part of medical practice. Therefore, whether or not animal euthanasia may be distinguishable from executions, we do not view FDA's practice of regulating the former

C.

The FDCA cannot be read as authorizing FDA to effectively ban capital punishment, because that reading would contravene or render moot a host of federal statutes that presuppose the lawfulness of capital punishment. In *Brown & Williamson*, the Court held that FDA was not authorized to prohibit tobacco products because Congress had repeatedly confirmed that such products would remain available. That reasoning applies equally well to articles intended for use in capital punishment. The Constitution and numerous federal statutes presuppose that capital punishment will remain available and that the federal government will defer to States over methods of execution. Interpreting the FDCA to bar the importation, sale, and distribution of articles intended for use in executions would conflict with that settled understanding. By contrast, the conclusion that articles intended for use in executions cannot be regulated under the FDCA would be consistent with how FDA has traditionally exercised its authority; and it would avoid the serious federalism concerns that would arise from a contrary interpretation.

1.

As the Supreme Court recently observed, the Constitution expressly "allows capital punishment." *Bucklew v. Precythe*, 139 S. Ct. 1112, 1122 (2019). Indeed, "the Fifth Amendment, added to the Constitution at the same time as the Eighth, expressly contemplates that a defendant may be tried for a 'capital' crime and 'deprived of life' as a penalty, so long as proper procedures are followed." *Id*. Federal law, accordingly, has authorized the imposition of the death penalty since 1790, when the First Congress mandated that several federal crimes, including treason and murder on federal land, be punished by death. Act of Apr. 30, 1790, ch. 9, §§ 1, 3, 33, 1 Stat. 112, 112, 113, 119. By 1938, federal statutes authorized the death penalty for dozens of offenses. And, in the decades since the FDCA's enactment, Congress has acted numerous times to make additional federal crimes punishable by death.[10] In providing that the

as sufficient to overcome the force of the arguments against FDA's authority to regulate the latter.

[10] *See, e.g.*, Act of June 8, 1940, ch. 286, 54 Stat. 255, 255–56 (authorizing capital punishment if anyone is killed by the willful derailment of any train in interstate commerce); Uniform Code of Military Justice, Act of May 5, 1950, ch. 169, 64 Stat. 107,

death penalty is an available punishment for dozens of federal crimes, Congress has presupposed there would be a lawful means for carrying out such a sentence.

From 1790 until 1937, federal law prescribed hanging as the method of execution. Act of Apr. 30, 1790, § 33, 1 Stat. at 119; *Andres v. United States*, 333 U.S. 740, 745 n.6 (1948). Congress then mandated that each federal execution be carried out in "the manner prescribed by the laws of the State within which the sentence is imposed," or, if that State did not have the death penalty, in accordance with the laws of another State designated by the sentencing court. Act of June 19, 1937, ch. 367, 50 Stat. 304, 304 (repealed 1984). At the time, nearly 30 States were using cyanide gas or the electric chair, but the States adopted at least six different methods of execution between then and the early 1980s. *See* Deborah A. Denno, *Getting to Death: Are Executions Constitutional?*, 82 Iowa L. Rev. 319, 439–64 (1997). After that provision was repealed in 1984, federal regulations required the government to propose to the sentencing court that any death sentence be carried out by lethal injection. 28 C.F.R. § 26.2(a)(2). Unless the court ordered otherwise, they required the Director of the Federal Bureau of Prisons to "determine[]" which "substance or substances" to use. *Id.* § 26.3(a)(4).

Today, capital sentences imposed under the Federal Death Penalty Act of 1994 are again required to be implemented "in the manner prescribed by" either (i) "the law of the State in which the sentence is imposed," or (ii) if that State does not have the death penalty, the law of another State designated by the sentencing court. 18 U.S.C. § 3596(a). The Army's executions are by "intravenous administration of a lethal substance, or substances, in a quantity sufficient to cause death." Army Regulation 190-55, U.S. Army Corrections System: Procedures for Military Executions § 3-1, -2 (Jan. 17, 2006).

135–40 (articles 85, 90, 94, 99, 100, 101, 102, 104, 106, 110, 113, 118, and 120, establishing 13 military offenses punishable by death); Organized Crime Control Act of 1970, Pub. L. No. 91-452, sec. 1102, § 844(d), 84 Stat. 922, 957 (authorizing capital punishment if death results from the use of explosives to maliciously destroy government property); Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, § 7001(a), 102 Stat. 4181, 4387–88 (codified at 21 U.S.C. § 848(e)) (authorizing capital punishment for intentional killing while engaging in criminal enterprises or drug felonies); Federal Death Penalty Act of 1994, Pub. L. No. 103-322, §§ 60001–60026, 108 Stat. 1796, 1959–82 (codifying procedures for federal death sentences and authorizing capital punishment for 60 offenses under 13 existing and 28 new federal statutes).

This extensive backdrop of legislative and regulatory action precludes any suggestion that the FDCA prohibits the importation, sale, or distribution of articles intended for use in executions; to the contrary, these statutory and regulatory schemes unambiguously assume the continued availability of such articles. Before and after the FDCA's enactment, Congress extended the federal death penalty and required the federal government to adopt States' preferences as to methods of execution. Such provisions would be nonsensical if the FDCA had rendered it a crime to distribute in interstate commerce, including through importation (*see* 21 U.S.C. § 321(b)), the very articles that States and the federal government need to effectuate capital sentences. By expressly recognizing States' discretion to select methods of execution (subject to constitutional limits), Congress precluded any role for FDA in supplanting States' judgments about those methods.

2.

In addition, as in *Brown & Williamson*, "[t]he consistency of the FDA's prior position" concerning the absence of regulatory jurisdiction over methods of execution, coupled with a corresponding history of non-enforcement, "provides important context" for interpreting federal death-penalty legislation postdating the FDCA. 529 U.S. at 157. Just as FDA "asserted authority to regulate tobacco products as customarily marketed" only late in its history, *id*. at 146, FDA does not appear to have asserted jurisdiction to regulate articles intended for use in executions before 2017.

Between 1981 and 1985, FDA directly addressed its jurisdiction in the proceedings associated with *Heckler*, 470 U.S. 821. The challenge in *Heckler* involved state lethal-injection protocols, which required the unapproved use of drugs that were FDA-approved for other purposes. Although the *Heckler* Court found it "implausible . . . that the FDA is required to exercise its enforcement power to ensure that States only use drugs that are 'safe and effective' for human execution," *id*. at 827, the Court ultimately declined to resolve the "thorny question of the FDA's jurisdiction" in that circumstance, *id*. at 828. Instead, the Court held that FDA's decision not to enforce the FDCA was unreviewable. *Id*. at 837–38. Even so, we find instructive FDA's own statements about its jurisdiction in the Supreme Court and in the underlying administrative proceeding.

In 1981, FDA rejected a petition from death-row inmates asking FDA to adopt a procedure for the seizure and condemnation of drugs destined or held for use in executions. *See* Letter for David E. Kendall, from Arthur Hull Hayes, Commissioner of Food and Drugs at 1 (July 7, 1981) ("*Heckler* Petition Response"). The inmates contended that the States' acquisition of FDA-approved drugs for capital punishment constituted misbranding because the drugs lacked adequate directions or warnings for that use. *Id*. at 1–2. FDA denied the petition in the first instance because "the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction." *Id*. at 2. FDA concluded that the States' off-label use of FDA-approved drugs in lethal-injection protocols was sufficiently analogous to the practice of medicine, including physicians' lawful off-label use of FDA-approved drugs, to fall outside the FDCA's ambit. *Id*. at 3–4. But FDA also emphasized that its lack of jurisdiction flowed from "a consideration of the proper role of the Federal Government with respect to the conduct of State criminal justice systems." *Id*. at 2. FDA further recognized that, "[b]ecause . . . the [FDCA] does not provide us with authority to declare unlawful the use by State governments of drugs for lethal injection," concerns about the safety of lethal-injection protocols would "more appropriately [be] addressed to the State legislatures." *Id*. at 4.[11]

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[11] FDA did contend that, "[u]nder the Supremacy Clause," "a State could not legitimize the unlawful shipment of an unapproved new drug in interstate commerce or prevent its misbranding after shipment in interstate commerce by authorizing its use," including for purposes of execution. *Heckler* Petition Response at 3. But that reflected a general observation that state law cannot trump the FDCA's provisions to the extent they apply to a given drug or device, or effectively immunize prior conduct that violated the FDCA by approving a product's use at a later time. The government's opening brief in the Supreme Court also represented in a footnote that "[t]his case concerns the FDA's authority to regulate the states' *use* of drugs, lawfully in interstate commerce, for the unapproved purpose of causing death, and not the *marketing* of drugs for an unapproved use." *Heckler* Pet'r Br. at 45–46 n.34; *accord* Reply Br. at 8, *Heckler v. Chaney*, 470 U.S. 821 (1985) (No. 83-1878) ("*Heckler* Reply Br.") ("FDA lacks jurisdiction over the use of approved drugs by state authorities for capital punishment purposes."). The brief asserted that an FDCA violation would occur "if a drug were marketed for the purpose of causing death without being approved for that use," but it noted that no one was alleged to have "directly or indirectly promote[d] the use of the drugs at issue" for executions. *Heckler* Pet'r Br. at 45–46 n.34. Those statements did not reserve FDA jurisdiction over unapproved articles used in executions because the government's briefs categorically disclaimed FDA jurisdiction over any method of execution. *See infra* notes 12–13 and accompanying text.

In the resulting litigation, the D.C. Circuit divided over whether FDA had jurisdiction over drugs intended for use in executions. *See Chaney v. Heckler*, 718 F.2d 1174 (D.C. Cir. 1983), *rev'd*, 470 U.S. 821 (1985). The majority rejected FDA's conclusions that administering capital punishment fell within the FDCA's "practice of medicine" exception or, in the alternative, that actions taken by prison officials did not qualify as misbranding under the Act. *See id*. at 1179, 1181. Then-Judge Scalia, in dissent, recognized the incongruity in treating "a law designed to protect consumers against drugs that are unsafe or ineffective for their represented use" as "mandating federal supervision of the manner of state executions." *Id*. at 1192 (Scalia, J., dissenting). He would have held that FDA lacked jurisdiction because the drugs were not "held for sale" in interstate commerce. *Id*. at 1199–1200. Because FDA did not press the point, neither opinion addressed whether "the unapproved use of drugs for lethal injection is outside the general jurisdictional provisions of the Act"—that is, whether drugs intended for use in lethal injection are subject to regulation under the FDCA. *Id*. at 1179.

In the Supreme Court, the government contended that FDA categorically lacked jurisdiction over articles used in capital punishment, and that FDA had denied the inmates' petition because it had concluded "that it lacked authority under the FDCA to regulate the states' use of lethal injections for capital punishment." *Heckler* Pet'r Br. at 13; *see id*. at 4 (similar). The government repeatedly asserted that "Congress did not intend the FDA to regulate capital punishment," *id*. at 45, and emphasized that the assessment of lethal injections would be "far removed from [FDA's] mission of protecting the consuming public from unsafe and improperly labeled drugs," *id*. at 10; *see id*. at 45 (similar).[12] The government concluded that FDA jurisdiction over the unapproved use of FDA-

[12] *See also Heckler* Reply Br. at 8 ("[T]here is not a scintilla of evidence that Congress intended for the FDCA to regulate capital punishment."); *id*. at 11 ("The FDA has no experience or particular expertise in making a comparative assessment of different methods of capital punishment, nor does it have a congressional mandate to venture into this field."); *Heckler* Pet'r Br. at 13 ("[T]here is not a hint in the legislative history that Congress had any intention to regulate the methods used by states in carrying out lawful death sentences."); *id*. at 44 ("Neither the court of appeals nor respondents have produced a shred of evidence that Congress wanted the FDA to regulate the methods of capital punishment used by the states."); *id*. at 46 ("[T]here is absolutely no evidence that Congress intended to regulate the use of drugs or devices, pursuant to a lawful court order, for the purpose of capital punishment.").

approved drugs in executions "would lead to the absurd result of requiring the FDA to regulate such traditional means of capital punishment as the gas chamber, electric chair, and gallows." *Heckler* Reply Br. at 8.[13]

Although *Heckler* did not resolve the question of the agency's jurisdiction, *see* 470 U.S. at 837–38, for more than three decades thereafter, FDA continued to avoid regulating drugs intended for use in capital punishment. In 2011, FDA explained that "[r]eviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA's explicit public health role," and that as a matter of "longstanding policy," FDA would "continue to defer to law enforcement on all matters involving lethal injection." E-mail for Nathan Koppel, from Shelly Burgess, FDA Public Affairs Specialist (Jan. 4, 2011), Doc. 13-3, *Beaty v. FDA*, No. 11-cv-289 (D.D.C. Apr. 20, 2011).

In 2012, a group of death-row inmates sued FDA, alleging that it had violated the FDCA by allowing shipments of a misbranded and unapproved new drug from an unregistered foreign establishment to enter the United States. The U.S. District Court for the District of Columbia held that, unlike in the domestic context where FDA has unreviewable discretion when enforcing violations, the statutory scheme for imports under 21 U.S.C. § 381(a) is different, and the court enjoined FDA from permitting entry of foreign-manufactured sodium thiopental, on the grounds that it was unapproved and misbranded. *Beaty*, 853 F. Supp. 2d at 37–41. The D.C. Circuit affirmed the injunction. *Beaty* and *Cook*, however, turned solely on whether FDA could exercise enforcement discretion over the imported sodium thiopental. Although the district court assumed that "thiopental is both 'misbranded' and an unapproved 'new drug' under the FDCA," *id*. at 34 n.2, neither the district court, nor the D.C. Circuit, addressed the broader question of FDA's jurisdiction.

Following the *Beaty* injunction, in 2015, FDA blocked Texas's attempt to import sodium thiopental for use in capital punishment. FDA's Southwest Import District Office detained and then refused the shipment on the

[13] *See also Heckler* Pet'r Br. at 13–14 (if FDA had jurisdiction over FDA-approved lethal-injection drugs, then the FDCA would also "encompass many of the paraphernalia traditionally used for executions, such as the gallows and the electric chair," and would presumably oblige FDA "to regulate the use of these devices as well"); *id*. at 44 ("the state and federal governments regularly used" the electric chair and gallows in 1938, and "there is no indication that any member of Congress even considered the possibility that enactment of the FDCA might affect these practices").

grounds that the drug was misbranded and unapproved. *See* Letter from Todd W. Cato, Director, Southwest Import District Office at 1–2 (Apr. 20, 2017). FDA's 2017 notice of final action appears to be the first instance in which FDA expressly asserted jurisdiction over a substance intended for use in capital punishment. Even then, Texas conceded that sodium thiopental "is a drug within the meaning of the [FDCA]," *id*. at 5, and FDA's decision was based upon the premise that "FDA is bound by the terms of the order issued by the District Court" in *Beaty*, *id*. at 2; *see also id*. at 6–7, 23, 24.

An agency may, of course, change its interpretation of an ambiguous statute when the new interpretation falls within the permissible scope of the agency's discretion and the agency shows "that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009); *see Brown & Williamson*, 529 U.S. at 156–57. But for nearly 80 years after the FDCA's enactment, FDA had never asserted jurisdiction over articles intended for use in capital punishment, notwithstanding thousands of cases that would have implicated FDA's enforcement discretion under such a theory. During that period, States carried out approximately 3,700 executions, and the federal government carried out approximately 192 civilian or military executions, employing a range of methods (hanging, the electric chair, firing squads, gas chambers, and lethal injections).[14] FDA did not regulate the method of execution in any of those instances or assert the authority to do so.

3.

Even if there were genuine ambiguity about whether FDA has jurisdiction over articles intended for use in capital punishment, serious constitutional concerns would arise if FDA could regulate and take enforcement action against (including seizing and destroying) such articles. *See Jennings v. Rodriguez*, 138 S. Ct. 830, 842 (2018) ("When a serious doubt is raised about the constitutionality of an Act of Congress, it is a cardinal principle that this Court will first ascertain whether a construction of the

[14] *See Glossip*, 135 S. Ct. at 2732; Bureau of Justice Statistics, U.S. Dep't of Justice, *Publications & Products: Executions*, https://www.bjs.gov/index.cfm?ty=pbtp&tid=182&iid=1 (last visited Apr. 29, 2019); M. Watt Espy & John Ortiz Smykla, *Executions in the United States, 1608-2002: The ESPY File*, Inter-university Consortium for Political and Social Research (July 20, 2016), https://www.icpsr.umich.edu/icpsrweb/NACJD/studies/8451.

statute is fairly possible by which the question may be avoided." (internal quotation marks omitted)). As the Supreme Court recently explained, "because it is settled that capital punishment is constitutional, [i]t necessarily follows that there must be a [constitutional] means of carrying it out." *Glossip*, 135 S. Ct. at 2732–33 (internal quotation marks omitted); *see Bucklew*, 139 S. Ct. at 1122–23 (similar). It would present a serious intrusion on state sovereignty if Congress sought, under the guise of drug-safety regulation, to bar States from effectuating otherwise-lawful death sentences.

The Supreme Court requires an unambiguous statement of congressional intent before it will construe a federal statute as effecting a significant intrusion into an area of traditional state responsibility. Courts must "be certain of Congress' intent before finding that federal law overrides the usual constitutional balance of federal and state powers." *Bond v. United States*, 572 U.S. 844, 858 (2014) (internal quotation marks omitted). When States choose to impose and effectuate death sentences, they are engaged in "the punishment of local criminal activity," which is the "clearest example of traditional state authority." *Id.*[15]

So long as a State employs a method of execution that comports with the Fourteenth Amendment's incorporation of the Eighth Amendment's Cruel and Unusual Punishments Clause, "the Constitution affords a 'measure of deference to a State's choice of execution procedures.'" *Bucklew*, 139 S. Ct. at 1125 (quoting *Baze*, 553 U.S. at 51 n.2). Thus, *In re Kemmler*, 136 U.S. 436 (1890), held that the New York statute requiring execution by electrocution was "within the legitimate sphere of the legislative power of the State." *Id.* at 449. And the plurality opinion in *Baze v. Rees*, 553 U.S. 35 (2008), explained that "[o]ur society has . . .

[15] *See also Danforth v. Minnesota*, 552 U.S. 264, 280 (2008) (referring to "[t]he fundamental interest in federalism that allows individual States to define crimes, punishments, rules of evidence, and rules of criminal and civil procedure in a variety of different ways—so long as they do not violate the Federal Constitution"); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) ("A basic principle of federalism is that . . . each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction."); *Ewing v. California*, 538 U.S. 11, 24 (2003) (plurality opinion) ("Though three strikes laws may be relatively new, our tradition of deferring to state legislatures in making and implementing such important policy decisions is longstanding."); *Patterson v. New York*, 432 U.S. 197, 201 (1977) ("[W]e should not lightly construe the Constitution so as to intrude upon the administration of justice by the individual States.").

steadily moved to more humane methods of carrying out capital punishment" because state legislatures have taken "the steps they deem appropriate, in light of new developments, to ensure humane capital punishment." *Id*. at 62 (opinion of Roberts, C.J.); *accord Glossip*, 135 S. Ct. at 2731–32 (similar). The Court has never endorsed an Eighth Amendment standard that would "transform [federal] courts into boards of inquiry charged with determining 'best practices' for executions," because that "would substantially intrude on the role of state legislatures in implementing their execution procedures." *Baze*, 553 U.S. at 51 (opinion of Roberts, C.J.).

The FDCA does not reflect any clear statement of congressional intent to regulate the States' administration of capital punishment. Had Congress sought to enable FDA to prohibit articles that States have chosen to use for executions, it would have said so explicitly. But Congress did no such thing. The FDCA's definitions of "drug" and "device" are broad, but breadth alone fails to manifest the intent needed to alter federal-state relations so dramatically with respect to capital punishment. *See, e.g.*, *Bond*, 572 U.S. at 860 ("insist[ing] on a clear indication that Congress meant to reach purely local crimes [in a statute implementing a chemical-weapons treaty] before interpreting the statute's expansive language in a way that intrudes on [States'] police power"). This principle of federalism provides further support for the conclusion that the FDCA should not be read to regulate—and therefore, effectively prohibit—the States' administration of capital punishment.

D.

We emphasize the narrowness of our conclusion that articles intended for use in capital punishment may not be regulated under the FDCA. We are not concluding that the FDCA covers only "drugs" or "devices" that have a medical or therapeutic purpose. For example, FDA has consistently regulated other products that affect the structure or function of the human body for an aesthetic, rather than medical or therapeutic, purpose (e.g., implants to augment breasts, dermal fillers to correct wrinkles, and silicone injections to augment buttocks and breasts). Likewise, FDA has long regulated drugs with non-therapeutic or recreational uses, including narcotics, street drugs, and their alternatives. *See, e.g.*, FDA, *Guidance for Industry: Street Drug Alternatives* (Mar. 2000), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/

ucm070343.pdf. Unlike with tobacco products or articles intended for use in capital punishment, however, federal statutes evince no "collective premise" that drugs intended to be used in achieving a recreational high "will continue to be sold in the United States." *Brown & Williamson*, 529 U.S. at 139. To the contrary, the manufacture and distribution of recreational drugs is already highly restricted by other federal statutes, such as the Controlled Substances Act. *See* 21 U.S.C. § 812.

Nor do we address whether FDA has jurisdiction over drugs intended for use in physician-assisted suicide. In marked contrast with capital punishment and tobacco products, at the time of the FDCA's enactment, there was not—so far as we are aware—any history of federal or state laws authorizing human euthanasia. As with recreational drugs, there is no congressional determination that human-euthanasia drugs remain lawfully on the market, nor has FDA historically disclaimed jurisdiction over them. *Cf. Brown & Williamson*, 529 U.S. at 137–53. Accordingly, human-euthanasia drugs lack the historical backdrop that weighs heavily against FDA jurisdiction over capital punishment.

We further note that a contrary conclusion regarding articles intended for use in capital punishment could sweep well beyond execution-related articles. If FDA had jurisdiction over such articles simply because they are "intended to affect the structure or any function of the body," 21 U.S.C. § 321(g)(1)(C), (h)(3), such reasoning would likely mean that FDA also had jurisdiction in a host of other areas that have long been considered well beyond its purview. Any type of firearm, when used for hunting or by the military or law enforcement, is intended to affect the structure or function of the body by killing or disabling a person or animal. But FDA has never sought to regulate firearms when they are intended to be used for hunting, police operations, or military purposes, and such an implausible interpretation of the FDCA would raise serious constitutional questions of its own.

Finally, there is nothing unusual about our conclusion that articles intended for use in capital punishment fall outside FDA's jurisdiction, even though the same articles could be subject to regulation when intended for other uses. For example, as noted above, FDA has classified articles such as hot tubs, saunas, and treadmills as devices for some purposes, but not for others. *See supra* pp. 3–4. Therefore, finding that substances fall outside FDA's jurisdiction when they are intended for use in capital punishment does not bear upon FDA's potential jurisdiction over other intended uses of the same substances.

IV.

We conclude that articles intended for use in capital punishment by a State or the federal government cannot be regulated as "drugs" or "devices" under the FDCA. FDA accordingly lacks jurisdiction to regulate such articles for that intended use.

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