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IN THE SUPREME COURT OF THE UNITED STATES

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IN RE FEDERAL BUREAU OF PRISONS' EXECUTION PROTOCOL CASES

ORLANDO CORDIA HALL AND BRANDON BERNARD, APPLICANTS

v.

WILLIAM P. BARR, ATTORNEY GENERAL, ET AL.

(CAPITAL CASE)

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RESPONSE IN OPPOSITION TO EMERGENCY APPLICATION FOR STAYS OF EXECUTION

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The Acting Solicitor General, on behalf of respondents William P. Barr et al., respectfully submits this response in opposition to applicants' emergency application for a stay of execution. Although the application is styled as a stay request, there is no order in this case that, if stayed, would preclude applicants' executions. The relief applicants appear to seek is instead an injunction under the All Writs Act, 28 U.S.C. 1651, barring respondents from proceeding with his execution. A request for such relief "'demands a significantly higher justification' than a request for a stay." Respect Maine PAC v. McKee, 562 U.S. 996, 996 (2010) (per curiam) (citation omitted). Ultimately, though, applicants cannot meet any applicable standard for emergency equitable relief. Cf. Appl. 11 & n.2.

After all, this Court has <u>already vacated</u> an injunction that barred executions under the federal lethal-injection protocol based on the same alleged violation of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 <u>et seq</u>., that applicants press here. <u>Barr v. Purkey</u>, No. 20A10 (July 16, 2020). Applicants' prospect of success on that claim has only grown <u>weaker</u> since then, because the district court has found as a matter of fact -- and the court of appeals has affirmed -- that applicants are <u>not</u> "likely to suffer" the asserted harm from the violation. Appl. App. 26a (quoting Appl. App. 94a). Given this Court's vacatur of the prior injunction in <u>Purkey</u>, <u>supra</u>, there is no legal, equitable, or logical basis to enjoin applicants' executions now.

Applicants' death sentences were imposed for heinous federal crimes committed more than 20 years ago. In 1994, Orlando Hall and his conspirators kidnapped a 16-year-old girl, held her hostage for two days, repeatedly raped her, beat her over the head with a shovel, and buried her alive. <u>United States v. Hall</u>, 152 F.3d 381, 389-390 (5th Cir. 1998), cert. denied, 529 U.S. 1117 (1999). In 1999, Brandon Bernard and his conspirators (including Christopher Vialva, who was executed on September 24), robbed a young married couple, locked them in the trunk of their own car, shot them both, and set the car on fire with one of the victims trapped inside still alive. <u>United States v. Bernard</u>, 299 F.3d 467, 472-73 (5th Cir. 2002), cert. denied, 539 U.S. 928 (2003).

Applicants challenged their convictions and sentences on appeal and through motions for collateral relief, all of which failed years ago. Both then became parties to civil litigation challenging the federal execution protocol, which has come before this Court multiple times. See <a href="Purkey">Purkey</a>, <a href="Supra">supra</a>; <a href="Barr">Barr</a> v. <a href="Lee">Lee</a>, <a href="Lee">140</a></a></a>S. Ct. 2590 (2020) (per curiam); <a href="Bourgeois">Bourgeois</a> v. <a href="Barr">Barr</a>, <a href="No. 19-1348">No. 19-1348</a></a> (19A1050) (June 29, 2020); <a href="Barr">Barr</a> v. Roane, <a href="Roane">140</a> S. Ct. 353 (2019).

Of central relevance here, applicants allege that the federal lethal-injection protocol violates the FDCA because that statute requires the Bureau of Prisons (BOP) to obtain a prescription for the drug it will use in applicants' executions — sodium pentobarbital. Appl. App. 22a. On July 15, the district court held that the FDCA applies to lethal-injection drugs and that BOP's noncompliance warranted a preliminary injunction. Id. at 9a. The government sought emergency relief, contending that the FDCA does not apply to lethal-injection drugs, that private parties cannot sue to restrain alleged FDCA violations, and that the absence of a prescription does not create irreparable harm warranting injunctive relief. The court of appeals declined to vacate the injunction, but this Court did so the next morning without noted dissent. See Purkey, supra. The government executed two inmates later that week, and four more in the following months.

Notwithstanding that vacatur and the ensuing executions, the district court in September entered partial summary judgment for

applicants on their FDCA claim. Appl. App. 87a-88a. The court then turned to whether applicants had established irreparable harm warranting a permanent injunction. Id. at 88a-96a. Following an evidentiary hearing at which it considered the credibility of expert witnesses for both sides, the court found as a factual matter that applicants were not entitled to permanent injunctive relief because they had not shown that the alleged FDCA violation was likely to produce irreparable harm. Id. at 91a-96a.

Yesterday morning, the court of appeals issued a published opinion affirming the district court's denial of injunctive relief. Appl. App. 22a-26a. Relying on circuit precedent, Judges Millett and Pillard concluded (over a dissent by Judge Rao) that the FDCA applies to lethal-injection drugs and that private parties can sue to restrain FDCA violations via the Administrative Procedure Act (APA). Id. at 22a-25a. But Judges Millett and Rao then concluded (over a dissent by Judge Pillard) that the district court "was correct to deny a permanent injunction" based on its factual finding that "the evidence in the record does not support [applicants'] contention that they are likely to suffer [the asserted pain] while still conscious." Id. at 25a-26a.

The court of appeals' affirmance of the denial of injunctive relief was correct, and there is no significant prospect this Court would conclude otherwise -- particularly given that the Court has already vacated without noted dissent an injunction issued on the

same claim at an earlier stage of this litigation when no factual findings adverse to applicants had been made. See <a href="Purkey">Purkey</a>, <a href="Supra">supra</a>. As the court of appeals concluded, the district court's factual findings are plainly sufficient under "the deferential 'clear error' standard," and this Court "will not 'lightly overturn' the concurrent findings of the two lower courts." <a href="Glossip v. Gross">Glossip v. Gross</a>, 576 U.S. 863, 882 (2015) (citation omitted). The factual findings affirmed here are further supported by common sense and widespread experience, given that pentobarbital has long been used for anesthesia and euthanasia without reports of severe pain; that States have used single-drug pentobarbital protocols of the kind at issue here to "carry out over 100 executions, without incident"; and that <a href="prisoners themselves">prisoners themselves</a> often invoke pentobarbital as "less painful" than alternative methods. Lee, 140 S. Ct. at 2591.

Applicants attempt (Appl. 12-24) to impugn the district court's approach to factfinding. But their assertions fare no better in this Court than they did in the court of appeals. Applicants primarily contend (Appl. 15) that the district court erroneously required them to show "certainty," rather than "likelihood," of harm. But the district court expressly stated that applicants had failed to show that their asserted harm "is 'certain' or even 'likely' to occur," and thus that injunctive relief is unavailable "[e]ven under the likelihood of future irreparable harm standard" applicants urge. Appl. App. 90a-91a

(emphasis added). Applicants similarly insist (Appl. 14) that "a heightened risk of serious bodily harm constitutes irreparable harm." But the district court did not disagree; it simply held, after considering the evidence, that the "risks" of harm applicants assert were unlikely to occur. Appl. App. 90a-91a.

Unable to refute the factual findings that they are not likely to be harmed, applicants contend (Appl. 15-16, 24-25) that an FDCA violation suffices to halt their executions. But as the courts below recognized, that position ignores this Court's many precedents holding that a statutory violation alone cannot support injunctive relief. See, e.g., Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20, 32-33 (2008). Rather, "[t]o obtain an injunction, \* \* \* the prevailing party must demonstrate that it actually 'has suffered,' or is 'likely to suffer irreparable harm.'" Appl. App. 26a (quoting Winter, 555 U.S. at 20). And an injunction is necessary for the relief applicants seek, because an order setting aside the execution protocol under the APA would involve only a non-binding rule of procedure -- not the source of the government's substantive authority to carry out executions. See In re Federal Bureau of Prisons' Execution Protocol Cases (Protocol Cases), 955 F.3d 106, 112 (D.C. Cir. 2020).

In any event, the execution protocol does not violate the FDCA. As Judge Rao's opinion explains -- and as the government contended in obtaining vacatur of the prior FDCA injunction in

July -- the FDCA does not apply to lethal-injection drugs. Appl. App. 38a-44a; Gov't Appl. at 21-25, Purkey, supra 20A10); see also App., infra, 1a-26a (Office of Legal Counsel (OLC) opinion). The FDCA requires a drug to be "safe and effective" for its intended use, which means its "therapeutic benefits must outweigh its risk of harm." FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 140 (2000). But a lethal-injection drug could never satisfy that standard, because its intended use is to cause death to effectuate a capital sentence, not provide therapeutic benefits. Applying the FDCA to lethal-injection drugs would thus mean banning lethal injection -- the "humane means of" execution used "by every jurisdiction that imposes the death penalty." Baze v. Rees, 553 U.S. 35, 41 (2008) (plurality opinion). That cannot be what Congress did in the FDCA, because later statutes -including the Federal Death Penalty Act of 1994 (FDPA), 18 U.S.C. 3591 et seq. -- contemplate the use of lethal injection in federal executions. The "inescapable conclusion is" that lethal-injection drugs "do not fit" within the requirements of the FDCA. Williamson, 529 U.S. at 134; see Appl. App. 40a-44a (Rao, J.).

In addition, as Judge Rao also explained and as the government contended in obtaining the prior FDCA-injunction vacatur, applicants' claim fails because Congress barred private parties from suing to prevent alleged FDCA violations by BOP. See Appl. App. 44a-46a; Gov't Appl. at 27-30, Purkey, supra. The statutory

text could not be clearer: "all \* \* \* proceedings for the enforcement, or to restrain violations" of, the FDCA "shall be by and in the name of the United States." 21 U.S.C. 337(a). Applicants cannot circumvent that limitation by invoking the APA, because that cause of action is unavailable where the underlying statute at issue "preclude[s] judicial review." 5 U.S.C. 701(a)(1). Indeed, even an <a href="implicit">implicit</a> preclusion of review may be sufficient to bar APA claims, see, <a href="e.g.">e.g.</a>, <a href="Block">Block</a> v. <a href="Community">Community</a> Nutrition Inst., 467 U.S. 340, 351 (1984), and here the preclusion is <a href="express">express</a>, because Section 337(a)'s terms plainly "foreclose" applicants' APA suit against BOP. Appl. App. 45a (Rao, J.).

Finally, the equities strongly support denying this application. Seven federal inmates have been executed since July under the challenged protocol, and more than 1000 inmates have been executed by lethal injection over the past four decades — all without any requirement to comply with the FDCA. See Lee, 140 S. Ct. at 2591. It is implausible that those executions were all unlawful and inflicted irreparable harm. Delaying applicants' executions would "serve no meaningful purpose and would frustrate the [government's] legitimate interest in carrying out a sentence of death in a timely manner." Baze, 553 U.S. at 61. The Court should accordingly decline to grant "last-minute intervention" and allow applicants' executions to "proceed as planned" on November 19 and December 10, respectively. Lee, 140 S. Ct. at 2591-2592.

#### STATEMENT

#### A. LEGAL BACKGROUND

1. The "Constitution allows capital punishment," and Congress has authorized the death penalty for the most egregious federal crimes since 1790. <u>Bucklew</u> v. <u>Precythe</u>, 139 S. Ct. 1112, 1122 (2019). It "necessarily follows that there must be a" lawful "means of carrying" out executions. <u>Baze</u> v. <u>Rees</u>, 553 U.S. 35, 47 (2008) (plurality opinion).

In the Nation's early years, hanging was the "standard method of execution" for both States and the federal government. Glossip v. Gross, 576 U.S. 863, 867 (2015). Over time, States replaced hanging with new methods of execution such as electrocution and lethal gas, each of which was considered "more humane" than its predecessors. Baze, 553 U.S. at 62 (plurality opinion). In 1937, Congress directed that the federal "manner of inflicting the punishment of death shall be the manner prescribed by the laws of the State within which the sentence is imposed" (or, where that State did not impose the death penalty, a State designated by the court). Act of June 19, 1937 (1937 Act), ch. 367, 50 Stat. 304.

Shortly thereafter, Congress enacted the FDCA. Act of June 25, 1938, ch. 675, 52 Stat. 1040. The statute authorized the Food and Drug Administration (FDA) to regulate drugs and devices, defined in relevant part as non-food articles "intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. 321(g)(1), (h). In the decades that followed, FDA

declined to assert jurisdiction over articles intended for use in capital punishment (e.g., electric chairs, gas chambers, and firing-squad rifles), despite the thousands of executions by the federal government and the States. See App., infra, 22a.

Eventually, the "progress toward more humane methods of execution" "culminat[ed] in [a] consensus on lethal injection." Baze, 553 U.S. at 62 (plurality opinion). Thus, after Congress repealed the 1937 law that had incorporated the state manner of execution for federal executions, the federal government in 1993 promulgated a regulation prescribing lethal injection as its method of execution. 58 Fed. Reg. 4898 (Jan. 19, 1993); 28 C.F.R. \$26.3(a)(4). The next year, Congress enacted the FDPA, which restored the requirement to conduct federal executions using the manner prescribed by state law. 18 U.S.C. 3596(a). Because lethal injection was "increasingly \* \* \* the method of execution in the states," however, it remained the presumptive federal method of execution. 57 Fed. Reg. 56,536, 56,536 (1992). Consistent with decades of practice, FDA did not assert -- and indeed disclaimed -- authority to subject the drugs used in lethal injections to the provisions of the FDCA, such as the requirement to obtain a prescription. See App. infra, 6a.1

In 2015, to comply with a district court order and injunction, FDA exerted limited authority over a State's attempt to import a drug for use in capital punishment. See  $\underline{\text{Cook}}$  v.  $\underline{\text{FDA}}$ ,

2. Initially, most States and the federal government conducted lethal injections using a combination of three drugs.

Baze, 553 U.S. at 42-44, 53 (plurality opinion). Although those protocols had been selected to minimize pain, inmates nevertheless claimed that they constituted cruel and unusual punishment. See id. at 41. Seven Justices rejected that claim in Baze. Ibid.; see id. at 71 (Stevens, J., concurring in the judgment); id. at 94 (Thomas, J., concurring in the judgment); id. at 107 (Breyer, J., concurring in the judgment). The Court also rejected claims that States were required to adopt the inmates' proposed alternative single-drug protocol. Id. at 57 (plurality opinion).

Although <u>Baze</u> did not mandate adoption of a single-drug protocol, some States voluntarily did so. Administrative Record (A.R.) 93. Of particular relevance here, a number of States chose to conduct executions using the single drug pentobarbital, a sedative that "can reliably induce and maintain a comalike state that renders a person insensate to pain." <u>Glossip</u>, 576 U.S. at 870-871 (citation omitted). Those States have since used that protocol to carry out more than 100 executions, and this Court and multiple courts of appeals have upheld pentobarbital's use against Eighth Amendment challenges. <u>Barr</u> v. <u>Lee</u>, 140 S. Ct 2590, 2591 (2020) (per curiam) (collecting cases).

<sup>733</sup> F.3d 1, 3 (D.C. Cir. 2013). It is undisputed that the federal government does not import lethal-injection drugs.

3. In July 2019, BOP issued a revised execution protocol adopting a single-drug pentobarbital protocol of the kind used by many States. A.R. 868-875. After careful study, BOP determined that such a protocol is "the most suitable method based on its widespread use by the states and its acceptance by many courts." A.R. 871. BOP also consulted two medical experts, including one credited by this Court in evaluating a challenge to a single-drug pentobarbital protocol in <a href="Bucklew">Bucklew</a>. A.R. 872. Both concluded that a single-drug pentobarbital protocol "would produce a humane death." A.R. 3. Specifically, they explained that an inmate receiving the proposed injection of pentobarbital "will lose consciousness within 10-30 seconds," and "be unaware of any pain or suffering" before death occurs "within minutes." A.R. 525.

#### B. PRIOR PROCEEDINGS

1. After adopting the amended protocol, BOP scheduled execution dates in December 2019 and January 2020 for five federal death-row inmates. In re Federal Bureau of Prisons' Execution Protocol Cases, 955 F.3d 106, 111 (D.C. Cir. 2020). Four of those inmates sought to enjoin their executions on constitutional and statutory grounds in the District of Columbia federal district court. See <a href="mailto:ibid.">ibid.</a> The district court entered a preliminary injunction on the ground that the inmates were likely to succeed on their claim that the protocol was inconsistent with the FDPA. See ibid. This Court denied an emergency motion to stay or vacate

the injunction, but the court of appeals vacated it on appeal, see id. at 108, 111, and this Court denied further review.

After the government rescheduled several executions, the district court issued a second preliminary injunction on the morning of the first rescheduled execution. Lee, 140 S. Ct. at 2591. The court held that the inmates had shown they were likely to suffer excruciating pain, in violation of the Eighth Amendment, because pentobarbital would cause a form of respiratory distress called pulmonary edema while they were still sensate. See ibid. This Court vacated the injunction a few hours later. Ibid. Court noted that pentobarbital "has become a mainstay of state executions" that has been used to "carry out over 100 executions, without incident"; that courts, including this Court in Bucklew, have rejected Eighth Amendment challenges to pentobarbital protocols; and that prisoners themselves have pentobarbital "as a less painful and risky alternative to" other methods. Ibid. Although the inmates had introduced expert evidence in support of their claims, the Court noted, the government had "produced competing expert testimony of its own, indicating that any pulmonary edema occurs only after the prisoner has died or been rendered fully insensate." Ibid. The Court concluded that the inmates "ha[d] not established that they are likely to succeed on the merits of their Eighth Amendment claim," which faces "an exceedingly high bar," and that the district court's "last-minute" injunction should be vacated so that the executions "could proceed as planned." <u>Id.</u> at 2591-2592. BOP carried out the execution of Daniel Lee shortly thereafter.

- 3. The next day, the district court issued a third preliminary injunction, this time on the ground that BOP's protocol was subject to but failed to comply with the FDCA, including its prescription requirement. D. Ct. Doc. 145, at 10-13. A few hours later, this Court again vacated the district court's injunction, this time without noted dissent. Barr v. Purkey, No. 20A10 (July 16, 2020). BOP then carried out the executions of Wesley Purkey and Dustin Honken.
- 4. In the continuing litigation, the district court granted the government's motion to dismiss the inmates' Eighth Amendment claim (as to all but one inmate). See D. Ct. Doc. 193. Shortly before inmate Keith Nelson's August 28 execution, however, the district court granted a fourth injunction, this time a permanent one premised on its earlier holding that the protocol was inconsistent with the FDCA. D. Ct. Doc. 213. The court of appeals vacated the injunction within hours, explaining that it "fail[ed] to comply with Fed. R. Civ. P. 65(d) in that, inter alia, there are insufficient findings and conclusions that irreparable injury will result from the statutory violation found by the district court." C.A. J.A. 916. Nelson was executed later that day.

- 5. As two September execution dates approached, the district court considered the parties' summary judgment motions on a variety of remaining claims. Of particular relevance here, the court reiterated its view that the FDCA applied to BOP's use of pentobarbital in executions and required, among other things, that BOP obtain a prescription. Appl. App. 88a. After holding a twoday evidentiary hearing, however, the court found that the inmates had "not established that flash pulmonary edema is 'certain' or even 'likely' to occur" after the administration of pentobarbital "before an inmate is rendered insensate." Id. at 91a. added that "it is not apparent how securing a prescription would alleged harm," given eliminate [the inmates'] pentobarbital would have the same physiological effects regardless of whether it is accompanied by a prescription. Id. at 90a. court accordingly granted summary judgment to the inmates on the merits of their FDCA claim, but declined to enter an injunction given the inmates' failure to demonstrate irreparable harm from the FDCA violation. Id. at 96a. William LeCroy and Christopher Vialva were executed on September 22 and 24, respectively.
- 6. After filing a series of reconsideration motions, see Appl. App. 47a-55a, applicants and the other plaintiffs appealed. After expedited briefing and argument, the D.C. Circuit yesterday affirmed the district court's denial of injunctive relief on the FDCA claim. Appl. App. 2a-46a. In a per curiam opinion, the court

of appeals relied on circuit precedent to hold (over Judge Rao's dissent) that the FDCA applies to lethal-injection drugs and that private parties can sue to restrain FDCA violations via the APA. Id. at 22a-25a. The court then held (over Judge Pillard's dissent) that the district court "was correct to deny a permanent injunction" based on its factual finding that "the evidence in the record does not support [applicants'] contention that they are likely to suffer [pain from] flash pulmonary edema while still conscious." Id. at 25a-26a. The court accordingly declined to enjoin respondents from conducting applicants' executions, see ibid., leaving the government free to proceed as planned.<sup>2</sup>

#### ARGUMENT

Applicants' request for emergency relief should be denied. As an initial matter, applicants state that they are seeking a stay of execution, but they cannot obtain that relief in this case. A stay "temporarily divest[s] an order of enforceability," Nken v. Holder, 556 U.S. 418, 428 (2009), but there is no order before this Court that, if divested of enforceability, would bar applicants' executions. The only such orders would be the criminal

The court of appeals vacated the district court's dismissal of applicants' Eighth Amendment claim but declined to enter a stay or injunction of their executions on that ground. See Appl. App. 14a-22a. The court of appeals also affirmed the district court's grant of summary judgment to the government on applicants' FDPA claim. See id. at 26a-28a. Applicants do not seek relief in this Court on those claims. See Appl. 7 n.1.

judgments imposing applicants' death sentences, but those cannot be challenged in this method-of-execution suit. See  $\underline{\text{Hill}}$  v. McDonough, 547 U.S. 573, 579-583 (2006).

What applicants actually appear to seek is an order under the All Writs Act, 28 U.S.C. 1651, barring respondents from proceeding with their executions in a particular way. Such an order would be an injunction -- an "in personam" order "directed at someone, and govern[ing] that party's conduct." Nken, 556 U.S. at 428. An injunction pending further review "'demands a significantly higher justification' than a request for a stay." Respect Maine PAC v. McKee, 562 U.S. 996, 996 (2010) (citation omitted). To obtain such relief, applicants must show "legal rights" that are "indisputably clear." Wisconsin Right to Life, Inc. v. FEC, 542 U.S. 1305, 1306 (2004) (Rehnquist, C.J., in chambers).

Ultimately, though, the precise standard is immaterial, because applicants cannot prevail under any applicable standard

Applicants contend (Appl. 11 n.2) that the higher standard for an injunction pending further review does not apply because they are not seeking to alter the status quo. That claim is difficult to understand. The status quo is that applicants are to be executed under the criminal sentences imposed more than 20 years ago; applicants are trying to change that status quo by enjoining the government from using a particular means of implementing those sentences. Applicants also observe (ibid.) that this Court stayed earlier method-of-execution challenges in which inmates did not ultimately prevail. But the Court did not explain the standard that it was applying in any of those stay orders, and so they provide no precedent for departing from the well-established standards above.

for equitable relief pending further review. The decision by both courts below to deny injunctive relief on their FDCA claim is correct for multiple independent reasons, and there is no reasonable prospect that this Court would grant review to consider applicants' objections, let alone reverse on the merits. Indeed, this Court vacated, without noted dissent, an injunction on this FDCA claim even before the district court made factual findings adverse to applicants. See <a href="Barr">Barr</a> v. <a href="Purkey">Purkey</a>, No. 20A10 (July 16, 2018). The equities, moreover, weigh heavily against an injunction or stay of applicants' executions for horrific federal crimes committed more than two decades ago. Seven federal inmates have been executed since July under the challenged protocol, and applicants cannot come close to showing that they are now entitled to last-minute relief.

I. THE COURTS BELOW CORRECTLY CONCLUDED THAT APPLICANTS ARE NOT ENTITLED TO INJUNCTIVE RELIEF ON THEIR FDCA CLAIM

The decisions of both lower courts to deny injunctive relief on applicants' FDCA claim were correct for three independent reasons. First, as Judge Rao explained in her opinion below and the government contended in its application in <u>Purkey</u>, <u>supra</u>, the FDCA does not apply to lethal-injection drugs. Second, as also demonstrated by Judge Rao and the government's <u>Purkey</u> application, the FDCA precludes private enforcement suits, including under the APA. Third, as the district court found as a matter of fact and

the court of appeals correctly affirmed, applicants have not shown irreparable harm from the purported FDCA violation.

Any of those reasons supports the denial of injunctive relief on applicants' FDCA claim. The courts below have repeatedly declined to engage with the government's first two arguments, however, because those courts believe themselves bound by contrary circuit precedent, Cook v. FDA, 733 F.3d 1 (2013). Although this Court need not explain its reasoning for denying applicants' requested relief, cf. Purkey, supra, the Court may wish to briefly do so to pretermit any efforts to continue to raise this legally meritless claim, cf. Barr v. Lee, 140 S. Ct. 2590 (2020).

#### A. The FDCA Does Not Apply to Lethal-Injection Drugs

To begin, injunctive relief is unwarranted on applicants' FDCA claim because the FDCA does not apply to lethal-injection drugs. See Appl. App. 40a-44a (Rao, J.); App., <u>infra</u>, 1a-26a (OLC opinion); Gov't Appl. at 21-25, Purkey, supra (No. 20A10).

1. The FDCA creates a complex set of requirements to ensure that every "drug or device" subject to the statute is "safe and effective" for its intended use. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 142 (2000). As relevant here, the FDCA defines "drugs" and "devices" to include "articles \* \* \* intended to affect the structure or any function of the body." 21 U.S.C. 321(g)(1)(C), (h)(3). Lethal-injection drugs are in a sense "intended to affect \* \* \* [a] function of the body." Ibid. But

williamson, the fact that a drug or device arguably falls within that definitional provision does not necessarily mean that it is subject to the FDCA. 529 U.S. at 132-133. After all, the tobacco products at issue in <a href="mailto:Brown & Williamson">Brown & Williamson</a> were arguably intended to affect a function of the body, <a href="mailto:ibid.">ibid.</a>, but the Court nevertheless held that they were not subject to the FDCA, see id. at 126.

The crux of Brown & Williamson's reasoning was that the FDCA must be construed to create a "coherent regulatory scheme." 529 U.S. at 133 (citation omitted). The Court concluded that applying the FDCA's requirements to tobacco products would produce an incoherent scheme, because it would require banning tobacco products even though Congress had plainly foreclosed that result. See id. at 143. Specifically, the Court explained that tobacco products could not be "safe and effective" for FDCA purposes because their "'potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." Id. at 134 (quoting United States v. Rutherford, 442 U.S. 544, 556 (1979)). Tobacco products would accordingly have to be "remove[d] \* \* \* from the market entirely." Ibid. But, the Court explained, such "a ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation." Ibid. the "inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme." Ibid.

The same reasoning applies to lethal-injection drugs. As with tobacco products, lethal-injection drugs' "potential for inflicting death or physical injury" is "not offset by the possibility of therapeutic benefit." Brown & Williamson, 529 U.S. at 134 (citation omitted). If anything, this is an a fortioricase, because the very purpose of lethal-injection drugs (unlike tobacco products) is to "inflict[] death" on capital inmates. Ibid. (citation omitted). Lethal-injection drugs, like tobacco products, would accordingly have to be "remove[d] \* \* \* from the market" if they were subject to the FDCA. Ibid.

Yet just as Congress made clear that tobacco products could not be banned, Congress has made clear that lethal-injection drugs cannot be banned. See <a href="Brown & Williamson">Brown & Williamson</a>, 529 U.S. at 134. Over the past four decades, the federal government and the States have collectively carried out <a href="more than a thousand">more than a thousand</a> executions by lethal injection. Gov't C.A. Br. 5; see, <a href="e.g.">e.g.</a>, <a href="Bucklew">Bucklew</a> v. <a href="Precythe">Precythe</a>, 139 S. Ct. 1112, 1129 (2019). None of those executions has been conducted on the premise that the FDCA applies to lethal-injection drugs, and Congress has never suggested such executions are unlawful. Quite the opposite, Congress in the 1994 FDPA directed the federal government to carry out executions using the manner "prescribed by the law of the State in which the [federal] sentence is imposed," which at the time required the federal government to use lethal injection for inmates convicted in most States. 18

U.S.C. 3596(a); see 57 Fed. Reg. 56,536, 56,536 (Nov. 30, 1992); A.R. 879. Those enactments cannot be reconciled with the premise that Congress precluded the use of lethal-injection drugs under the FDCA. As with tobacco products, the "inescapable conclusion is that there is no room for" lethal-injection drugs "within the FDCA's regulatory scheme." Brown & Williamson, 529 U.S. at 134.

Other provisions of the FDCA confirm that subjecting lethalinjection drugs to the statute's coverage would fail to produce a "coherent regulatory scheme." Brown & Williamson, 529 U.S. at 133 (citation omitted). For example, drug approval under the FDCA requires analysis of "[t]he expected benefit of the drug with respect to [the] disease or condition" for which it is indicated. 21 U.S.C. 355-1(a)(1)(B),(C). But lethal-injection drugs are not designed to bring about an "expected benefit" with respect to any "disease or condition"; they are designed to induce the death of a capital inmate. Ibid. Likewise, the FDCA requires review of "patient experience data." 21 U.S.C. 360bbb-8c(b)(1). condemned inmates facing lethal injection are not patients, and lethal-injection drugs could not ethically be tested in clinical Reading the FDCA as a whole, lethal-injection drugs trials. "simply do not fit." Brown & Williamson, 529 U.S. at 143.

Moreover, the reading of the FDCA embraced by applicants would appear to extend not only to lethal-injection drugs, but also to other articles traditionally used in executions such as electric

chairs, lethal gas, and perhaps even firing-squad rifles. Such articles seemingly fall within the statutory definition of "device" -- an "instrument, apparatus, implement, [or] machine" that is "intended to affect the structure or any function of the body of man." 21 U.S.C. 321(h). And like lethal-injection drugs, such execution articles could not be regarded as "safe and effective," because their "'potential for inflicting death or physical injury" is "not offset by the possibility of therapeutic benefit.'" Brown & Williamson, 529 U.S. at 134 (citation omitted). If the FDCA applied to such articles, then, they would be banned. Yet there is no indication that Congress outlawed the most common execution methods used by the federal government and the States when it enacted the FDCA in 1938. Cf. id. at 137.

Indeed, under this understanding of the FDCA, it is unclear how any drug or device used in an execution could ever escape the statute's reach or be approved as "safe and effective." Brown & Williamson, 529 U.S. at 134. The upshot would be that Congress effectively abolished capital punishment when it enacted the FDCA. But that cannot be correct, given that Congress has continued to authorize the death penalty in many subsequently enacted statutes, including the 1994 FDPA. See App., infra, 16a & n.10.

Finally, the view that the FDCA applies to lethal-injection drugs and other articles used to effectuate capital punishment contradicts the longstanding position of FDA. In the more than 80

years that the FDCA has been in force, FDA has not sought to enforce the FDCA against any of the nearly 4,000 executions that have occurred in the United States. App., infra, 22a. And shortly after the advent of lethal injection, the government argued to this Court in Heckler v. Chaney, 470 U.S. 821 (1985), that "Congress did not intend the FDA to regulate capital punishment." Gov't Br. at 45, Chaney, supra (No. 83-1878); see Chaney v. Heckler, 718 F.2d 1174, 1192 (D.C. Cir. 1983) (Scalia, J., dissenting). The FDA's "consistent" position on the question underscores the difficulty of concluding that the FDCA applies to lethal-injection drugs. Brown & Williamson, 529 U.S. at 146.

2. The courts below did not seriously engage with those arguments, instead relying almost entirely on the D.C. Circuit's prior decision in Cook, supra. See Appl. App. 24a; D. Ct. Doc. 145, at 10-13. But Cook is neither binding on this Court nor in conflict with the government's interpretation of the FDCA.

The question in <u>Cook</u> was whether FDA was required to enforce an FDCA provision concerning imports of drugs destined for lethal-injection use in state correctional facilities. 733 F.3d at 11. The government contended that FDA's decision not to enforce the FDCA against such imported drugs was unreviewable under <u>Chaney</u>. See <u>ibid</u>. The D.C. Circuit rejected that view based on the distinctive text of the imported-drug provision, 21 U.S.C. 381(a), which provides that FDA "shall" take certain actions with respect

to certain imported drugs. 733 F.3d at 8-10. But the parties did not press, and Cook did not resolve, the antecedent question whether the FDCA applies to lethal-injection drugs. The decision accordingly has no binding force on that matter, either as a precedent in the D.C. Circuit or as persuasive authority in this Court. See, e.g., United States v. L.A. Tucker Truck Lines, Inc., 344 U.S. 33, 38 (1952) (explaining that a prior decision is not binding on an issue that "was not questioned and \* \* \* passed [upon] sub silentio").

Applicants and the district court have also suggested that lethal-injection drugs can be considered "safe and effective" for FDCA purposes because they are intended to cause death in a humane See D. Ct. Doc. 145, at 10-13. But that position is way. irreconcilable with both the ordinary meaning of "safe and effective" and this Court's decision in Brown & Williamson. ordinary English speaker would say that a drug is "safe" if it is virtually certain to -- indeed, intended to -- kill its user to effectuate a death sentence. And nothing about the FDCA context requires a different understanding. To the contrary, this Court explained in Brown & Williamson that a drug is "safe and effective" for FDCA purposes if its "potential for inflicting death or physical injury" is "offset by the possibility of therapeutic benefit." 529 U.S. at 134 (citation omitted). If the tobacco products at issue in Brown & Williamson could not meet that standard given their serious health risks and limited therapeutic benefits, there is no way lethal-injection drugs can meet that standard given that their very purpose is to "inflict[] death" on capital inmates. Id. at 134 (citation omitted).

### B. <u>Private Parties May Not Sue To Prevent Alleged</u> Violations Of The FDCA, Including Under The APA

Even if drugs intended for use in executions were subject to the FDCA, applicants' claim for injunctive relief still fails at the threshold for the alternative reason that Congress barred private parties like applicants here from bringing suit to compel compliance with the FDCA. See Appl. App. 44a-46a (Rao, J.); Gov't Appl. at 27-30, <u>Purkey</u>, <u>supra</u> (No. 20A10).

1. The FDCA provides, subject to exceptions inapplicable here, that "all \* \* \* proceedings for the enforcement, or to restrain violations," of its provisions "shall be by and in the name of the United States." 21 U.S.C. 337(a); see <u>Buckman Co. v. Plaintiff's Legal Comm.</u>, 531 U.S. 341, 349 (2001) (discussing FDA's authority to enforce the FDCA). Congress thus left "no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA. <u>Buckman</u>, 531 U.S. at 349. Recognizing that express textual limitation, the inmates here do not attempt to sue BOP directly under the FDCA. They instead bring their claims against BOP under the APA, and the courts below approved that course. See Appl. App. 24a-25a. But that approach is mistaken for multiple reasons.

As an initial matter, an APA suit claiming that BOP action is "not in accordance with law" for failure to comply with the FDCA's prescription requirements, 5 U.S.C. 706(2)(A), is still seeking to "enforce[]" the FDCA, and to "restrain" an alleged "violation[]" of that statute, 21 U.S.C. 337(a). Applicants' suit thus falls squarely within Section 337(a)'s bar on private-party suits, notwithstanding that it was brought under the APA. See ibid.

Moreover, this Court has emphasized that an APA action is precluded by federal statutes even where they <a href="implicitly">implicitly</a> foreclose private-party enforcement. See, <a href="e.g.">e.g.</a>, <a href="Block">Block</a> v. <a href="Community">Community</a> <a href="Nutrition Inst.">Nutrition Inst.</a>, 467 U.S. 340, 351 (1984); see also 5 U.S.C. 701(a)(1) (withdrawing the APA's cause of action where "statutes preclude judicial review"). By <a href="explicitly">explicitly</a> reserving FDCA enforcement discretion to the government in Section 337, Congress plainly manifested its intent to preclude private-party enforcement, even against federal agencies.

Finally, the flaw in allowing applicants to sue BOP for FDCA violations under the APA is especially clear in light of this Court's holding in <u>Chaney</u> that "[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." 470 U.S. at 837-838; see 5 U.S.C. 701(a)(2) (withdrawing the APA's cause of action where "agency action is committed to agency discretion by law"). The district court in

this case properly rejected applicants' APA claims against FDA\_for failure to enforce the FDCA against BOP. See D. Ct. Doc. 213, at 10-11. But it would make little sense for Congress to have barred suits against FDA -- the agency charged with administering the FDCA -- for failure to enforce the FDCA as to lethal-injection drugs, while allowing suits against other agencies based on the same ground. It is similarly unlikely that Congress allowed federal executions to be enjoined based on purported FDCA violations, while rejecting as "implausible" the prospect that state executions could be enjoined based on the same purported FDCA violations. Chaney, 470 U.S. at 827. That is particularly true given that States carry out far more executions by lethal injection than does the federal government.

2. The courts below provided little response to those arguments, instead relying again on the D.C. Circuit's decision in Cook. See Appl. App. 24a-25a. But Cook is even more inapposite on this issue than on the scope of the FDCA's coverage, because it involved a suit against FDA for failure to enforce, under a specific FDCA provision that was found to constrain FDA's otherwise-unreviewable enforcement discretion. 733 F.3d at 7-10 (analyzing 21 U.S.C. 381(a)). The court of appeals in Cook thus had no reason there to address Section 337's bar on private enforcement, and it has provided no valid reason here why private parties like applicants should be allowed to sue BOP given this

"Court's acknowledgement that an APA action is precluded by federal statutory schemes that foreclose private party enforcement." Appl. App. at 45a (Rao, J.).

# C. The Absence Of Irreparable Harm From The FDCA Violation That Applicants Allege Forecloses Injunctive Relief

In all events, the courts below correctly denied injunctive relief because applicants failed to show irreparable harm arising from their alleged legal violation -- an essential component in obtaining an injunction. See, e.g., Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20, 32-33 (2008). That holding was based on a factual finding by the district court, made after an evidentiary hearing at which the court assessed the credibility of the parties' experts, and affirmed on appeal. Appl. App. 25a-26a, "Where an intermediate court reviews, and affirms, a trial court's factual findings, this Court will not 'lightly overturn' the concurrent findings of the two lower courts." Glossip v. Gross, 576 U.S. 863, 882 (2015) (citation omitted). The decision below readily satisfies that "deferential" standard. Ibid. Applicants' objections are largely based on misreadings of the district court's opinion or misunderstandings of this Court's standard for injunctive relief. Applicants fall far short of showing error or any likelihood that this Court will grant review and reverse, particularly when this Court vacated an FDCA-based injunction without noted dissent even before such adverse factual findings had been made and affirmed.

1. For starters, applicants fail to show any irreparable harm "due to" the FDCA violation they allege: "unprescribed use of pentobarbital." Appl. App. 26a. As the district court explained, "[e]ven if a doctor were to write a prescription, [applicants] will still be executed using pentobarbital." Id. at 91a. "Thus, the prescription requirement does not in and of itself" cause the harm applicants allege. Ibid. After all, pentobarbital either will or will not cause pain; the drug's pharmacological properties are not changed by the presence or absence of a prescription. See ibid. Failure to comply with the FDCA prescription requirement therefore does not provide the showing of irreparable harm required to support an injunction.

Applicants largely disregard that basis for the district court's denial of injunctive relief. See Appl. App. 51a (district court explaining that applicants "ignore [this] key language"). Applicants briefly hypothesize (Appl. 23) that, if a prescription were necessary, a physician "may well prescribe opioids or a similar analgesic \* \* \* as a condition of prescribing pentobarbital for use in an execution." But that speculation is based on nothing more than what the inmates and their selected experts proclaim a doctor who shares their view of pentobarbital's effects would "have recommended." Ibid. Applicants do not suggest that the FDCA requires the prescription of other drugs alongside pentobarbital (it plainly does not) or that all doctors have the

same concerns about pentobarbital (they do not). Applicants accordingly fall far short of meeting their burden to show that the harm they assert is "likely" to result from any FDCA violation or be remedied by compliance with the statute. Winter, 555 U.S. at 20. That failure alone forecloses injunctive relief.

2. Regardless, the district court further found as a factual matter -- and the court of appeals correctly affirmed -- that "the evidence in the record does not support [applicants'] contention that they are likely to suffer" the pain they fear from a lethal injection of pentobarbital. Appl. App. 26a, 94a.

Applicants do not acknowledge the highly deferential standard that applies to that factual finding, see Glossip, 576 U.S. at 882, let alone demonstrate any clear error. Applicants instead largely recite (Appl. 7-8, 18-19, 22, 26-27) evidence offered by their selected experts. But after reviewing the parties' competing expert evidence, the district court concluded that the key dispute — "whether an inmate will suffer flash pulmonary edema before becoming insensate" — was "one upon which reasonable minds could differ." Appl. App. 92a. The court accordingly held an evidentiary hearing over two days in order to make "credibility assessments." Ibid. As a result of that hearing, the court found that applicants "have not established that flash pulmonary edema is 'certain' or even 'likely' to occur" after the administration of pentobarbital under the federal protocol "before an inmate is

rendered insensate." <u>Id.</u> at 91a. The court recounted some of the ample evidence presented by the government "suggesting that an inmate would not experience the effects of flash pulmonary edema before becoming insensate." <u>Id.</u> at 92a. And the court observed that the government's expert witness had explained that evidence on which the inmates relied on below -- and continue to rely on here -- did not bear on the central point in dispute. <u>Id.</u> at 93a-95a. Indeed, the court found that the government's refutation of applicants' evidence was so persuasive that the court would have reached the same findings regarding applicants' failure to establish a likelihood of harm even if it <u>entirely disregarded</u> one of the government's experts. Id. at 94a.

After its own review, the court of appeals affirmed the district court's factual findings, reiterating the conclusion that applicants' evidence had failed to establish a likelihood of irreparable harm. Appl. App. 26a. The position of both courts is strongly reinforced by the widespread consensus that the use of pentobarbital does not cause the excruciating pain the inmates assert. This Court has expressly stated that that pentobarbital "can 'reliably induce and maintain a comalike state that renders a person insensate to pain.'" Glossip, 576 U.S. at 870-871 (citation omitted); see, e.g., Zagorski v. Parker, 139 S. Ct. 11, 11-12 (2018) (Sotomayor, J., dissenting from denial of application for a stay and denial of certiorari) (explaining that

"pentobarbital \* \* \* is widely conceded to be able to render a person fully insensate"). That is why pentobarbital is "commonly used to euthanize terminally ill patients who seek death with dignity in states such as Oregon and Washington." Beaty v. Brewer, 649 F.3d 1071, 1075 (9th Cir. 2011) (Tallman, J., concurring in the denial of rehearing en banc). And as the government's expert noted, barbiturates like pentobarbital have been used for decades as anesthesia on "millions upon millions of patients," without apparent reports of terrible pain. Dkt. 122-2, at 3 & n.2.

- 3. Rather than making any effort to show clear error, applicants devote much of their application to questioning the district court's factfinding approach. In addition to being highly case-specific and unworthy of this Court's review, their objections plainly lack merit.
- a. Applicants' lead argument in this Court (Appl. 12-14, 17-20) is that the district court improperly required them to show that irreparable harm will certainly, rather than likely, occur. But that contention is belied by the plain language of the district court's opinion, which expressly states that applicants failed to show that their asserted harm "is 'certain' or even 'likely' to occur before an inmate is rendered insensate." Appl. App. 91a (emphasis added); see id. at 95a ("[Applicants] cannot meet their burden of showing that the harm of flash pulmonary edema is likely, let alone 'certain'.") (emphases added).

Applicants relatedly urge (Appl. 12) the Court to clarify purported ambiguity about the standard for injunctive relief that they contend arises from Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139 (2010). But the district court directly refuted that objection too, stating that any such ambiguity has no import here because "even assuming Monsanto means a 'likelihood' standard of irreparable harm is distinct from a 'certainty' standard, it does not matter which standard the court applies in this case." Appl. App. 90a (emphasis added). That is because, "[e]ven under the likelihood of future irreparable harm standard" that applicants urge, they "do not meet their burden to warrant the extraordinary relief of an injunction." Ibid. (emphasis added).

b. Applicants similarly contend (Appl. 14-15, 19) that the district court failed to consider whether the purported FDCA violation subjected them to an "increased risk of severe bodily suffering," which they seek to distinguish from the court's consideration of the "likelihood" that they would "experience such suffering." To the extent those formulations are meaningfully different, the court repeatedly considered the "risks" of bodily harm that applicants raised and concluded that applicants had not adequately established them. Appl. App. 90a-91a, 95a. Applicants do not contend that those findings were clearly erroneous, nor (as noted above) do they connect any "risk of severe bodily suffering" to the absence of a prescription. See id. at 26a, 91a.

Applicants cite (Appl. 14-15) a string of cases that they suggest exhibits a conflict in authority about "whether a heightened risk of serious bodily injury constitutes irreparable harm." But the cases -- most of which appear to arise from the distinctive context of the COVID-19 pandemic -- do not illustrate the conflict applicants suggest. Whether formulated in terms of "risk" of irreparable bodily harm or "likelihood" thereof, the cited cases ultimately all focus on whether the party seeking injunctive relief has established a sufficient probability to warrant the exercise of a court's equitable discretion. exercises are necessarily context-dependent, affording courts considerable flexibility "within the broad boundaries traditional equitable relief." Grupo Mexicano de Desarrollo S.A. v. Alliance Bond Fund, Inc., 527 U.S. 308, 322 (1999). And even if applicants had established that the varying formulations amount to some substantive disagreement, they fail to point to any meaningful conflict with the decision below.

c. Finally, applicants contend (Appl. 15-16, 24-25) that the finding of an FDCA violation alone should preclude the government from conducting executions using unprescribed pentobarbital. But that position contradicts the well-established principle that courts are "not mechanically obligated to grant an injunction for every violation of law." Weinberger v. Romero-Barcelo, 456 U.S. 305, 313 (1982). Rather, as this Court has often

explained, injunctive relief also requires showing that the movant has suffered "irreparable harm," that "the balance of equities tips in \* \* \* favor" of injunctive relief, and that "an injunction is in the public interest." Winter, 555 U.S. at 20; see id. at 32-33 (explaining that the "standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success") (citation omitted).<sup>4</sup>

Applicants contend (Appl. 24-25) that the APA's provision stating that a reviewing court "shall \* \* \* hold unlawful and set aside agency action" found to be "not in accordance with law," 5 U.S.C. 706(2), displaces the four-factor injunction test and categorically disables the government from acting contrary to an APA court's legal determination. But as the court of appeals correctly explained, "[s]uccess on an APA claim does not automatically entitle the prevailing party to a permanent injunction." Appl. App. 25a. Section 706(2) was enacted against a background rule that statutory remedies should be construed in accordance with "traditions of equity practice," Hecht Co. v.

To be sure, the government sometimes argues that coercive injunctive relief is <u>unnecessary</u> because it will comply with a non-coercive declaratory judgment. See Appl. 15-16 (citing <u>Texas</u> v. <u>United States</u>, 945 F.3d 355 (5th Cir. 2019)). But that in no way suggests that the government must comply with a non-coercive declaratory judgment even where the equitable requirements for coercive injunctive relief are not satisfied.

Bowles, 321 U.S. 321, 329 (1944), and courts do "not lightly assume that Congress has intended to depart from established [equity] principles," Weinberger, 456 U.S. at 313. Indeed, the APA itself expressly provides that, absent a special statutory review scheme, the "form of proceeding" shall be a traditional "action" for an "injunction" or "declaratory judgment[]." 5 U.S.C. 703. And the APA expressly preserves "other limitations on judicial review," as well as "the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground." 5 U.S.C. 702; see also Abbott Labs. v. Gardner, 387 U.S. 136, 155 (1967) (stating that the APA incorporates "equitable defenses").

Moreover, applicants' contentions about the APA's "set aside" provision are largely beside the point in this case, because setting aside the execution protocol would not bar the government from executing applicants or other inmates. As the court of appeals previously held — and applicants do not here dispute — the protocol is a nonbinding procedural rule. Protocol Cases, 955 F.3d at 112. That "internal house-keeping measure" is not the substantive source of the government's authority to carry out capital sentences, which comes from the FDPA and the underlying criminal statutes themselves. Id. at 145 (Rao, J., concurring) (citation omitted). As the decision below clearly and correctly recognized, setting aside the protocol based on a purported FDCA

violation thus does not preclude the government from implementing lawful capital sentences. See Appl. App. 25a-26a.

Finally, applicants mistake the lower courts' role in the judicial hierarchy when insisting (Appl. 1) that the government is carrying out executions "in a manner that federal courts have authoritatively determined to be unlawful." The courts below reached that erroneous determination based on circuit precedent that does not bind this Court, and the government is acting lawfully in adhering to its position in the absence of an injunction from the lower courts or an authoritative determination by this Court. That said, applicants' misguided rhetoric underscores why this Court may wish to clarify that denial of injunctive relief on applicants' FDCA claim is appropriate first and foremost because there is no FDCA violation here at all.

## II. THE EQUITIES WEIGH HEAVILY AGAINST A STAY OR INJUNCTION OF APPLICANTS' EXECUTIONS PENDING FURTHER REVIEW

In addition to applicants' unlikely prospect of success on the merits, the equities strongly counsel against delaying these executions to allow further litigation. Applicants were convicted more than 20 years ago of staggeringly brutal federal crimes. They have long since exhausted all permissible appeals and collateral challenges. They have been litigating the civil claims in this case for nearly a year and a half, and those claims have received an exceptional amount of judicial review, including many trips to the D.C. Circuit and this Court.

This Court has emphasized in this litigation that "last-minute intervention" of the kind applicants request "should be the extreme exception, not the norm." Lee, 140 S. Ct. at 2591 (quoting Bucklew, 139 S. Ct. at 1134). There is no good reason for such an exception here. As noted, seven other federal other inmates have been executed under the protocol that applicants challenge, six of them after this Court vacated an injunction on the same claim that applicants assert as the basis for an injunction here. See Purkey, supra. Neither law nor equity supports a different result now, particularly given the adverse factual findings that the district court made and the court of appeals affirmed. Appl. App. 26a.

Further delay would also undermine the public's "powerful and legitimate interest in punishing the guilty" by carrying out the lawfully imposed capital sentences. <u>Calderon</u> v. <u>Thompson</u>, 523 U.S. 538, 556 (1998) (citation omitted). The family members of Hall's 16-year-old victim -- who have waited a quarter century for implementation of sentence imposed for the rape and murder of their loved one -- are now in Terre Haute waiting to witness the execution. Equity now strongly supports the administration of the justice. As the Fifth Circuit recently explained, "It is time -- indeed, long past time -- for these proceedings to end." <u>In re</u> Hall, No. 19-10345, 2020 WL 6375718, at \*7 (Oct. 30, 2020).

## 40 CONCLUSION

The application for stays of execution should be denied. Respectfully submitted.

JEFFREY B. WALL
Acting Solicitor General

NOVEMBER 2020