No. 20A10

IN THE

Supreme Court of the United States

IN RE: FEDERAL BUREAU OF PRISONS' EXECUTION PROTOCOL CASES

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

Applicants,

v.

WESLEY IRA PURKEY, et al.,

Respondents.

OPPOSITION TO APPLICATION TO STAY OR VACATE THE PRELIMINARY INJUNCTION

This case comes before this Court on the government's third application for a stay of an injunction, this time over a preliminary injunction issued 12 hours ago by the United States District Court for the District of Columbia. In its haste, the government has refused to await proper disposition of these proceedings before the D.C. Circuit which, having heard this case four times prior, has acted with deliberation and appropriate dispatch each time. There is no cause for doubt that it will so act here, too. Should this Court act on the government's application, the Court should refuse to stay or vacate the district court's injunction, which will ensure that Respondents—federal prisoners sentenced to death, including Wesley Purkey, who is scheduled to be executed in less than two hours at 7:00p.m.—will have an opportunity to pursue their claims.

In a thoughtful opinion, the district court concluded that Respondents are likely to succeed on the merits of their claim that the federal execution protocol violates the Food, Drug, and Cosmetic Act (FDCA), the purpose of which is to ensure that drugs are "safe and effective for its intended use." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). The court of appeals has already confirmed that the FDCA applies to drugs the government intends to use for executions, *Cook* v. *FDA*, 733 F.3d 1 (D.C. Cir. 2013)—and for good reason, as these drugs, when they do not function as intended, may "result in conscious suffocation, pain, and cardiac arrest," *Beaty* v. *FDA*, 853 F. Supp. 2d 30, 37 (D.D.C. 2012), *aff'd in relevant part sub nom. Cook* v. *FDA*, 733 F.3d 1 (D.C. Cir. 2013). The government's refusal to obtain a prescription for the drugs they intend to use in Respondents' executions flouts these requirements, in direct contravention of the governing federal statute. When the government conducts an execution—its most solemn responsibility—it should turn square corners. But the government proposes to do just the opposite. For these reasons, the district court correctly concluded that Respondents are likely to succeed on their claim that the Protocol violates the FDCA, and correctly found that Respondents would suffer irreparable harm absent an injunction barring their executions pursuant to the Protocol.

The government asks this Court to grant extraordinary relief and give it a green light to proceed with Respondents' executions anyway—including Wesley Purkey's execution today. It seeks this relief even though it has delayed these executions for over eight years, and even though it cannot explain why it is imperative for them to proceed immediately, when serious legal questions remain unresolved and the ongoing global pandemic injects further uncertainty. The government bemoans the "last minute" nature

of the district court's order (Mot. 4), but as the district court explained, that posture is "no fault of Plaintiffs" and a direct result of "Defendants[']cho[ice] to schedule Plaintiffs' executions knowing that their remaining claims were still pending" (A16).[1]

The government's motion should be denied.

BACKGROUND

A. The Lethal-Injection Protocols

In 2004, Applicants adopted a protocol that detailed procedures for carrying out federal executions. *See In re Fed. Bureau of Prisons' Execution Protocol Cases*, 955 F.3d 106, 109-110 (D.C. Cir. 2020) ("*FBOP*") (per curiam), *cert. denied sub nom. Bourgeois* v. *Barr*, No. 19A1050, 2020 WL 3492763 (U.S. June 29, 2020). In 2008, the Bureau of Prisons issued an addendum announcing that federal executions would be carried out using three drugs. *Id.* at 110. But in 2011, BOP announced that it lacked the drugs necessary to implement the 2008 addendum and that it was in the process of considering revisions to it. *Id.*

On July 25, 2019, after more than eight years of review, the Department of Justice issued what it referred to as an "addendum" to the lethal-injection protocol. *FBOP*, 955 F.3d at 111. This self-styled addendum replaced the three drugs specified by the 2008 addendum with a single drug, pentobarbital sodium, and made other changes to the process. *Id.* At the same time, BOP replaced the 2004 protocol with a 2019 main protocol (together with the 2019 addendum, the "2019 Protocol"). *Id.*

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[1] The Appendix appended to the Applicants' Application shall be cited herein as "App." The Application is cited herein as "Mot."

B. Factual And Procedural History

1. On July 25, 2019, simultaneously with the announcement of the 2019 Protocol, Applicants identified five individuals to be executed under the new protocol: Daniel Lee on December 9, 2019; Lezmond Mitchell on December 11; Wesley Purkey on December 13; Alfred Bourgeois on January 13, 2020; and Dustin Honken on January 15. Respondents Lee, Purkey, Bourgeois, and Honken each challenged the 2019 Protocol and sought preliminary injunctions. They argued that the 2019 Protocol violates the Federal Death Penalty Act (FDPA); the Eighth Amendment; the First, Fifth, and Sixth Amendments; the Food, Drug, and Cosmetic Act (FDCA) and the Controlled Substances Act (CSA); and was arbitrary and capricious, in violation of the Administrative Procedure Act (APA).

2. In November 2019, the district court granted a preliminary injunction, finding that Respondents were likely to succeed on their claim that the 2019 Protocol contravenes the FDPA, and thus found it unnecessary to reach any of the other claims. *In re Fed. Bureau of Prisons' Execution Protocol Cases*, No. 12-CV-0782, 2019 WL 6691814, at *7 (D.D.C. Nov. 20, 2019), *vacated by FBOP*, 955 F.3d 106 (D.C. Cir. 2020). The district court further found that, absent preliminary injunctive relief, Respondents would suffer manifestly "irreparable harm"; that this outweighed "any potential harm to the Defendants"; and that it was "in the public interest to issue a preliminary injunction." *Id.* at *8.

The district court, the court of appeals, and the Supreme Court all denied Applicants' motion to stay the preliminary injunction. Dist. Dkt., Minute Order (Nov. 22, 2019); Order, *In re Federal Bureau of Prisons' Execution Protocol Cases*, No. 19-5322

(D.C. Cir. Dec. 2, 2019) (per curiam); *Barr* v. *Roane*, 140 S.Ct. 353, 353 (2019) (mem). As Justice Alito explained, "in light of what is at stake, it would be preferable for the District Court's decision to be reviewed on the merits by the Court of Appeals for the District of Columbia Circuit before the executions are carried out." *Roane*, 140 S.Ct. at 353 (Alito, J., respecting the denial of stay or vacatur). On appeal, a divided panel of the D.C. Circuit reversed the district court's FDPA holding, but did not disturb the court's holding that Respondents would suffer irreparable harm absent injunctive relief or that the equities favored Respondents. *FBOP*, 955 F.3d at 108.

3. Just days after the court of appeals issued its mandate—and while Respondents' petition for certiorari was still pending before this Court—the government set new execution dates: Lee on July 13, Purkey on July 15, and Honken on July 17. The government also set an execution date for Keith Dwayne Nelson for August 28, 2020.[2] Four days later, Respondents moved for a preliminary injunction based on several of their remaining constitutional and statutory claims.

4. On July 13, the day of the first scheduled execution (Lee), the district court granted a preliminary injunction, finding that Respondents are likely to succeed on their claim that the proposed method of execution violates the Eighth Amendment. The court also found that Respondents would suffer irreparable harm absent injunctive relief, and that the equitable factors favored Respondents. The government sought a stay or vacatur of the injunction, which a panel of the court of appeals denied. At approximately 2:00 a.m. on July 14, this Court vacated the district court's preliminary injunction in a 5-

[2] The government did not set an execution date for Bourgeois.

4 decision, holding that the prisoners were not likely to succeed on the merits of their Eighth Amendment claim. *See Barr* v. *Lee*, No. 20A8, 2020 WL 3964985 (U.S. July 14, 2020) (per curiam). In dissent, Justice Sotomayor (joined by Justice Kagan) noted that this "outcome is hard to square with th[e] Court's denial of a similar request by the Government seven months ago in this very litigation," explaining that "because of the Court's rush to dispose of this litigation in an emergency posture, there will be no meaningful judicial review of the grave, fact-heavy challenges respondents bring to the way in which the Government plans to execute them." *Id.* at *3-4 (Sotomayor, J., dissenting).

At approximately 8 a.m. on July 14—the day after the date noticed for his execution— Applicants executed Lee despite the existence of several outstanding claims still pending before the District Court in a motion to enjoin his execution.

5. This morning, the district court again enjoined Respondents' executions, finding that Respondents were likely to succeed on their claim that the Protocol violates the FDCA. The court rejected Applicants' argument 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,'" explaining that "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.'" App.12a. The court further noted that the D.C. Circuit in *Cook* already affirmed "that lethal injection drugs are 'drugs' under the FDCA, and that death-sentenced individuals are permitted to assert violations of the FDCA." *Id.*

Regarding their APA arbitrary and capricious claim, the court noted that "Plaintiffs convincingly show that, in developing the 2019 Protocol, Defendants did not consider the risk of flash pulmonary edema," but found that in light of the Supreme Court's holding that the risk of pulmonary edema does not create an Eighth Amendment violation, Respondents had not established likelihood of success on this claim. App.8a. And although the court recognized that Respondents' arguments regarding access to counsel claims raise "serious concerns," the court found that Respondents "fail to demonstrate a likelihood of success on the merits of showing that these requests are constitutionally mandated" and that the COVID-related problems Respondents identify "are not the result of the 2019 Protocol … but of the pandemic itself." App.14a. The court again found that Respondents would suffer irreparable harm absent injunctive relief, and that the equitable factors favored Respondents. App.15-16a.

ARGUMENT

The standard of review on an application to vacate a stay of execution is highly deferential. A stay of execution is an equitable remedy that lies within a court's discretion. *See Kemp* v. *Smith*, 463 U.S. 1321 (1983) (Powell, J., in chambers). "Only when the lower courts have clearly abused their discretion in granting a stay should [this Court] take the extraordinary step of overturning such a decision." *Dugger* v. *Johnson*, 485 U.S. 945, 947 (1988) (O'Connor, J., joined by Rehnquist, C.J., dissenting); *see also Doe* v. *Gonzales*, 546 U.S. 1301, 1307, 1309 (2005) (Ginsburg, J., in chambers) (denying application to vacate stay entered by court of appeals "[a]lthough there is a question as to the likelihood of … success on the merits" because "the applicants have not shown cause so extraordinary as to justify this Court's intervention in advance of the

expeditious determination of the merits toward which the Second Circuit is swiftly proceeding" (internal quotation marks omitted)).

In considering whether to grant a stay of Mr. Purkey's execution, the district court considered: "(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 the equities, and (4) the public interest." App.6a. (quoting *Winter* v. *Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20, 24 (2008)). The district court did not abuse its discretion in holding that these factors weighed in favor of a temporary stay.

I. THE GOVERNMENT IS NOT LIKELY TO SUCCEED ON THE MERITS

A. The 2019 Protocol Violates The FDCA

The district court correctly held that Respondents are likely to succeed on their claim that the 2019 Protocol violates the FDCA and is therefore "not in accordance with law," 5 U.S.C. §706(2)(A), because the Protocol flouts the statute's prescription requirements as well as the FDCA's restrictions on "outsourcing facilities."

The "core" legislative purpose of the FDCA is to ensure that a "drug" is "safe and effective for its intended use." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). One way the FDCA ensures that a drug is safe and effective for its intended use is to condition the dispensation of controlled substances, including pentobarbital, upon either (a) "a written prescription of a practitioner licensed by law to administer such drug," or (b) "an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist." 21 U.S.C. §353(b)(1). But Applicants have confirmed they have not obtained, and do not intend to obtain, a prescription for the drugs they will use in Respondents' executions.

As the district court recognized, the D.C. Circuit held in *Cook* that the FDCA applies in the context of executions. *Beaty* (which the court of appeals affirmed in *Cook*) explains not only that the FDCA applies to execution drugs, but also that the statute helps to ensure that such drugs accomplish the pain-diminishing purpose for which the executioners have selected them. *Beaty*, 853 F. Supp. 2d at 42. The court in *Beaty* therefore concluded—and the D.C. Circuit affirmed in *Cook*—that death-sentenced individuals are permitted to challenge the use of execution drugs that do not comply with the FDCA. *Beaty*, 853 F. Supp. 2d at 37-43; *see also Cook*, 733 F.3d at 10-11.

Applicants attempt to distinguish *Cook*. Mot. 12-14. But *Beaty* unambiguously held that lethal-injection drugs are properly "considered 'drugs' under the FDCA" because "they are 'intended to affect the structure or any function of the body of man,'" 853 F. Supp. 2d at 34 (quoting 21 U.S.C. §321(g)(1))—a conclusion the D.C. Circuit necessarily adopted in *Cook*. Nor does the May 2019 OLC opinion Applicants cite establish that the FDCA does not apply in the lethal-injection context. Mot. 2. The OLC memo cannot displace binding precedent, and *Beaty* and *Cook* previously rejected the position that OLC adopted.

That Applicants procured the pentobarbital from an "outsourcing facility," AR1084, does not free them from this FDCA prescription requirement, and indeed their non-compliance with important limitations on outsourcing facilities independently violates the statute. The FDCA provides a number of rules that all such facilities must follow when compounding drugs in order to be exempt from the premarketing and labeling requirements found elsewhere in the FDCA, and the "new drug" approval process to demonstrate the product's efficacy. *See Athenex Inc.* v. *Azar*, 397 F. Supp. 3d

56, 59-60 (D.D.C. 2019); 21 U.S.C. §353b. An outsourcing facility is ineligible for that exemption if it produces a drug that is "essentially a copy of one or more approved drugs." 21 U.S.C. §353b(a)(5). "[E]ssentially a copy" means a drug that is "identical or nearly identical to an approved drug" (unless it appears on the FDA's list of drug shortages), or contains a "bulk drug substance that is a component of an approved drug" (unless the drug has been changed in order to make a "clinical difference" for an individual patient). 21 U.S.C. §353b(d)(2)(A)-(B). Here, laboratory tests obtained by Applicants show that their objective is to use an outsourcing facility to produce a compounded product that simulates FDA-approved pentobarbital. *See* AR4-5, 932-933, 970-1015. Accordingly, the compounded pentobarbital Applicants intend to use to execute Respondents must comply with the FDCA's premarketing, labeling, and prescription requirements. 21 U.S.C. §353b. It is undisputed that Applicants have not complied with those important protective requirements.

In addition, outsourcing facilities must compound drugs that either (1) use active pharmaceutical ingredients [APIs] that the FDA has placed on the "503B Bulks list" based on a determination of "clinical need," or (2) appear on the FDA's list of drug shortages (a shortage would justify use of a comparatively risky compounded drug rather than the more thoroughly regulated FDA-approved version). *See* 21 U.S.C. §353b(a)(2)(A). To date, the FDA has not placed any APIs on the "503B Bulks list," and it has not identified a shortage of pentobarbital. Moreover, there is no "clinical need" for a particular API when an "FDA-approved drug that could be used to meet the very [same] patient needs" is "already available on the market," *Athenex*, 397 F. Supp. 3d at

58—as is true here with respect to Applicants' compounded pentobarbital, AR 4-5, 932-33, 970-1015.

Applicants' compounding violations implicate the FDCA's purpose of ensuring that a regulated "drug" is "safe and effective for its intended use." *Brown & Williamson*, 529 U.S. at 133. The Drug Quality and Security Act, which is now part of the FDCA, was enacted out of concern that bulk compounders were marketing and distributing their products outside of the FDA's regulatory framework that requires "premarket review for safety, effectiveness, and quality." *Athenex*, 397 F. Supp. 3d at 59. The now-amended FDCA therefore limits the mass production of such drugs to situations in which society's medical need for a drug outweighs the hazards of compounding it. "Both the 'essentially a copy' provision and FDA's 'clinical need' inquiry are directed at identifying whether the compounded product is one that fills a therapeutic purpose unmet by the approved drug." *Athenex*, 397 F. Supp. 3d at 72. Because the Applicants are violating the FDCA's restrictions on outsourcing facilities, the resulting compounded pentobarbital falls outside of the FDCA's safe harbor for large-scale production of compounded drugs. *See id.* at 66. The execution drug is therefore an unapproved "new drug" under the FDCA. *See* 21 U.S.C. §353b(a) (exempting such compounded drugs from 21 U.S.C. §§352(f)(1), 355, and 360eee-1); *Athenex*, 397 F. Supp. 3d at 66 (describing "bulk compounding as an exception within an exception"). The introduction of that drug into interstate commerce is a federal crime. *See* 21 U.S.C. §331(d).

Applicants next falsely attribute to Respondents a contention that lethal-injection drugs can *never* be prescribed for a legitimate medical purpose, then insist that this view would make all lethal injections illegal. *See* Mot. 9-10, 14. But Respondents have never

made such an argument. Rather, they contend that no such purpose is validly advanced *by the 2019 Protocol*, because no medical practitioner has made a clinical judgment that the particular drug is well suited to execute an individual prisoner in light of that prisoner's medical needs.

Lastly, Applicants contend that Respondents lack a right of action to enforce either the CSA or the FDCA. Mot. 10-11. The APA, however, provides a cause of action when agency action is "not in accordance with law." 5 U.S.C. §§702, 706(2)(A); *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 316-318 (1979). Importantly, Respondents do not seek to compel enforcement of the CSA or FDCA against a third party, *cf.* 21 U.S.C. § 337(a) (precluding litigation under the FDCA by private parties against other private parties), but rather seek to compel Applicants' compliance with the statutes' substantive requirements in agency decision-making (and avoid the arbitrary and capricious result of enforcing a Protocol that requires others to violate the statutes). The APA provides for such review in 5 U.S.C. §§ 702, 706(2)(A), and nothing in the FDCA (including § 337(a)) cuts off review of the federal government's own statutory violations. *See Banzhaf v. Smith*, 737 F.2d 1167, 1168-1169 (D.C. Cir. 1984) ("[T]he court must heed the APA's basic presumption of judicial review that will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." (quotation marks omitted)).

In sum, Applicants insist that they selected pentobarbital as an execution drug for the medical purpose of preventing pain, and to otherwise ensure a "humane" death. AR1, 3, 525-526, 858, 871-872, 929, 931. Having crafted a protocol to achieve a specific medical purpose, enlisted scientific experts to assist in that purpose, and defended the protocol as "humane" because it allegedly achieves that purpose, Applicants cannot now claim

they are exempt from laws that ensure that a drug is "safe and effective for its intended use." *Brown & Williamson*, 529 U.S. at 133. The FDCA "provide[s] safeguards against improper use of lethal injection chemicals by assuring that medical practitioners are adequately involved in the use of those chemicals." *Ringo* v. *Lombardi*, 706 F. Supp. 2d 952, 958 (W.D. Mo. 2010). "[I]gnoring those safeguards, as Plaintiffs allege Defendants intend to do, places Plaintiffs at risk." *Id.*

B. The 2019 Protocol Is Arbitrary And Capricious

Alternatively, Applicants are unlikely to succeed on the merits of their appeal because the 2019 Protocol is arbitrary and capricious. *See Haynes* v. *D.C. Water & Sewer Auth.*, 924 F.3d 519, 524 (D.C. Cir. 2019) (the court can affirm on any basis supported by the record).[3]

As this Court recently reaffirmed, an agency's decision is arbitrary and capricious when, among other things, the agency has "entirely failed to consider [an] important aspect of the problem." *Department of Homeland Sec.* v. *Regents of the Univ. of Cal.*, 140 S.Ct. 1891, 1913 (2020). The APA provides that an agency decision that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" must be "h[e]ld unlawful and set aside." 5 U.S.C. §706(2)(A). Every agency action is subject to the strictures of arbitrary and capricious review, regardless of whether notice and comment is required. *Perez* v. *Mortgage Bankers Ass'n*, 575 U.S. 92, 105-106 (2015);

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[3] The district court found that Respondents were unlikely to succeed on the merits of this claim, but Respondents have filed a notice of cross-appeal and intend to urge reversal of the district court's decision on that ground. This Court accordingly may consider the likelihood of success on the merits of that claim in considering whether to vacate the preliminary injunction.

Independent Petrol. Ass'n of Am. v. *Babbitt*, 92 F.3d 1248, 1256-58 (D.C. Cir. 1996) (agency letter exempt from notice-and-comment requirement was nevertheless arbitrary and capricious).

Here, the 2019 Protocol is arbitrary and capricious because Applicants failed to consider at least three important issues associated with the procedures outlined in the 2019 Protocol: the risk that pentobarbital will cause flash pulmonary edema, the risks related to IV-insertion, and the risks of procuring pentobarbital from a compounding pharmacy.

First, Applicants never considered the risk that pentobarbital will cause flash pulmonary edema. Flash pulmonary edema is a condition that causes the excruciating feeling of drowning that evidence shows is nearly certain to occur after injection of a single dose of pentobarbital, before prisoners become unconscious (even if they are nonresponsive). *See* Dist. Dkt. #102 ("PI Mot.") at 6-10. Applicants admit that they never considered this risk, instead arguing that they did not need to consider it because pentobarbital will quickly render an inmate unconscious. That explanation is contradicted by the evidence. Regardless, Applicants do not contend that they dismissed the risk of flash pulmonary edema for this reason *at the time they took the action*. *See Regents*, 140 S.Ct. at 1907 ("It is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'"). Instead, Applicants' admission that they never considered flash pulmonary edema at the time, defended only by an after-the-fact and contradicted justification for why they did not *need* to consider it, renders the 2019 Protocol arbitrary and capricious.

The district court declined to grant a preliminary injunction on this ground only because it thought itself "bound by the Supreme Court's holding [in *Lee*] that, given Applicants' contention that pulmonary edema occurs post-mortem or after the inmate has been rendered insensate, this risk does not justify last-minute judicial intervention." App. 8a. But *Lee* held only that, given the conflicting evidence about pulmonary edema, Applicants had not made the showing required for a preliminary injunction on Eighth Amendment grounds. That holding has no bearing on whether Applicants were obligated to consider the risk of flash pulmonary edema when they made the decision to adopt pentobarbital (which they admit they overlooked).

Second, Applicants failed to consider the risks associated with IV-insertion. Setting an IV line is a delicate, complicated, and invasive procedure that, when done improperly, can lead to significant pain—from protracted IV access attempts, from injection of lethal-injection drugs into tissue not veins, or from a prolonged execution process due to incomplete drug delivery—as it has in many recent executions. *See* PI Mot. 10-11. Yet Applicants barely considered IV-insertion at all when issuing the 2019 Protocol, overlooking several critical aspects of the problem, including the manner of insertion, the preferred insertion site, any time or attempt limits, monitoring the prisoner, responding to malfunctions, and qualifications, training, and expertise of relevant personnel. *See id.* at 13-14. The District Court declined to grant a preliminary injunction because of the AR's sporadic mention of IV-insertion issues, App. 8a-9a, but the AR barely scratches the surface of the important aspects of IV placement.

Third, Applicants failed to consider the risks of obtaining pentobarbital from a compounding pharmacy. Compounding pharmacies face far less regulation and oversight

than manufacturers of FDA-approved drugs and are routinely found to have engaged in prohibited conduct, thereby producing lethal-injection drugs that pose a higher risk of subpotent drugs that do not work as expected and cause significant pain—a risk that has come to pass in recent executions with compounded pentobarbital. *See* PI Mot. 14-17. Yet the AR shows that Applicants did not consider the risks associated with compounded pharmacies at all. Indeed, Applicants exposed this deficiency by supplementing the AR with a two-page non-binding memorandum dated March 2020—seven months after the 2019 Protocol was announced—that asserts that they will use a compounding pharmacy that complies with some, but not all, FDA requirements. The district court found Applicants' reliance on this nonbinding memorandum "troubling," but denied a preliminary injunction on this ground "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.'" A9. It is true that this Court has "recognized" that "[t]here are … many legitimate reasons why a State might choose, consistent with the Eighth Amendment, not to adopt a prisoner's preferred method of execution," *Bucklew* v. *Precythe*, 139 S.Ct. 1112, 1125 (2019), one of which is inability to obtain alternative legal-injection drugs, *Glossip* v. *Gross*, 135 S.Ct. 2726, 2737-2738 (2015). But these cases do not excuse Applicants, in an APA challenge, from considering important aspects of the method of execution that they *do* choose—here, compounded pentobarbital. So those Eighth Amendment cases simply have no bearing on this question of administrative law.

II. THE GOVERNMENT WILL NOT BE IRREPARABLY HARMED BY THE PRELIMINARY INJUNCTION

The government has not shown that it would be harmed—much less irreparably so—absent a stay.

The government contends that it has a "strong interest" in timely implementing Respondents' death sentences. Mot. 17. But the "eight years [that the government] waited … to establish a new protocol … undermines its arguments regarding the urgency and weight of [its] interest." A16; *see also Purkey* v. *United States*, No. 19-3318, 2020 WL 3603779, at *11 (7th Cir. July 2, 2020) ("A brief stay … will not substantially harm the government, which has waited at least seven years to move forward on Purkey's case."). Indeed, the government has not attempted to explain its sudden urgency to execute these prisoners, and "the fact that the Government has not—until now—sought to" execute Respondents "undermines any urgency" to do so now. *Osorio-Martinez* v. *Attorney Gen. of the U.S.*, 893 F.3d 153, 179 (3d Cir. 2018).

III. RESPONDENTS WILL BE IRREPARABLY HARMED BY A STAY OF THE PRELIMINARY INJUNCTION

Respondents, in contrast, would suffer irreparable harm of the highest order if the preliminary injunction is stayed. The district court has already found on multiple occasions that the harm to Respondents would be "manifestly irreparable" if Respondents were "unable to pursue their remaining claims" and were "executed under a procedure likely to be" unlawful, A15—a conclusion that the D.C. Circuit and this Court have not questioned in prior appeals. There is no basis for reaching a different conclusion now.

In particular, Respondents would suffer the harm of being executed pursuant to a Protocol that, as the district court found, violates the FDCA, the end result of Congress's efforts to ensure that a drug is "safe and effective for its intended use." *Brown & Williamson*, 529 U.S. at 133. Violations of the FDCA carry "the risk that the drug[s] will not function as intended," which, in the lethal-injection context, may "result in conscious suffocation, pain, and cardiac arrest." *Beaty*, 853 F. Supp. 2d at 37. "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." App.12a. If Applicants cannot obtain a prescription, because it cannot find a physician to attest that the lethal-injection drugs Applicants intend to use are "safe and effective" for their intended use, that only adds heft to the argument that Respondents are likely to suffer irreparable harm if their executions go forward.

The government faults Respondents and the district court for delay, but neither is correct. Respondents acted with all possible speed in bringing their claims and the district court adjudicated the multiple serious legal claims before it as quickly and expeditiously as possible. If anything, the fact that "this order comes at the last minute" is a problem of the government's own making: "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." App.16a. Respondents have acted promptly and diligently and

should not be punished for the ordinary and unavoidable delays associated with efficient litigation.

IV. A STAY IS NOT IN THE PUBLIC INTEREST

Finally, "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." App. 17a. The public interest lies in ensuring that agencies act in accordance with the Constitution and federal law. *League of Women Voters of U.S.* v. *Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016). This interest is only heightened in the context of executions. The public would be ill-served if Respondents were executed pursuant to an unlawful protocol, or before being given a full opportunity to test the protocol's legality. For this very reason, this Court, the D.C. Circuit, and sister circuits have all confirmed that brief injunctions—to permit potentially meritorious claims to be adjudicated before Respondents are executed—are warranted under these circumstances. *See Roane*, 140 S. Ct. at 353 (Alito, J., respecting the denial of stay or vacatur) ("[I]n light of what is at stake, it would be preferable for the District Court's decision to be reviewed on the merits by the Court of Appeals for the District of Columbia Circuit before the executions are carried out."); *Purkey*, 2020 WL 3603779, at *11 ("the public interest is surely served by treating this case with the same time for consideration and deliberation that we would give any case" and "because the death penalty is involved is no reason to take shortcuts—indeed, it is a reason not to do so"); Order, No. 19-5322 (D.C. Cir. Dec. 2, 2019) (per curiam).

The government nonetheless claims that a preliminary injunction is inappropriate given the public's interest in "finality." Mot. 17. A preliminary injunction, however, does

not undermine the finality of Respondents' convictions, as Respondents do not challenge their convictions or their sentences here.

Lastly, the government contends (at 36-38) that, if the multiple stays preventing Mr. Purkey's execution are lifted, it can proceed with the execution at any time, notwithstanding that Mr. Purkey's designated execution date is July 15. The idea that the government can dispense with the notice requirement in order to execute Mr. Purkey at any point after his designated execution date contradicts the spirit if not the letter of the governing regulations and the Protocol, which not only require the government to provide the prisoner of his new execution date, but also require that the prisoner be given time to designate witnesses and contact spiritual leaders. These are important restrictions that are designed to respect the dignity of the person the government proposes to execute. Although the government claims (at 37) that these requirements are merely "hortatory," what it really means is that it reserves the right to do to Mr. Purkey what it did to Mr. Lee just yesterday—strap him to a gurney notwithstanding that there were multiple court orders prohibiting his execution; make him wait with an IV in his arm for hours on end, without being able to contact his counsel, in the hopes that this Court will lift the stay at some point; then, when the Court does lift the stay, begin the execution immediately, in the middle of the night, without notifying his counsel. This Court cannot permit the government to proceed in this manner.

CONCLUSION

The government's request to vacate or stay the preliminary injunction entered by the district court should be denied.

Respectfully submitted.

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July 2020

CERTIFICATE OF SERVICE

I, Alan E. Schoenfeld, a member of the bar of this Court, hereby certify that on this 15th day of July, 2020, I caused all parties requiring service in this matter to be served with the accompanying Opposition to the Application to Stay or Vacate the Preliminary Injunction by email to the address below:

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I further certify that paper copies will be submitted to the Court and served on all parties requiring service by overnight courier on July 16, 2020, per discussion with the Clerk's Office.

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