No. A-__

In the
Supreme Court of the United States

ORLANDO HALL AND BRANDON BERNARD,
Applicants,
v.
WILLIAM P. BARR, ATTORNEY GENERAL, *et al.*
Respondents.

On Application for Stay

EMERGENCY APPLICATION FOR STAYS OF EXECUTION

Executions Scheduled for November 19 (Hall) and December 10 (Bernard)

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QUESTIONS PRESENTED

1. Whether this Court's precedents, including *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010), require a party seeking injunctive relief to show a certainty of irreparable harm, rather than a likelihood of irreparable harm.

2. Whether a substantial and increased risk of bodily harm satisfies the showing required for irreparable harm.

3. Whether the Government may carry out an execution in a manner that federal courts have authoritatively determined to be unlawful.

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To the Honorable John G. Roberts, Chief Justice of the United States and Circuit Justice for the District of Columbia Circuit:

Applicants Orlando Hall and Brandon Bernard respectfully request a stay of their executions. Mr. Hall is scheduled to be executed on November 19, 2020 at 6 PM local time. Mr. Bernard is scheduled to be executed on December 10, 2020; no time has yet been announced. Applicants ask this Court to stay their executions to preserve the Court's jurisdiction to review their petition for certiorari to the District of Columbia Circuit Court of Appeals pursuant to 28 U.S.C. § 1254(1) and 28 U.S.C. § 2101(f).

INTRODUCTION

Orlando Hall and Brandon Bernard (collectively, "Applicants") are scheduled to be executed on November 19, 2020 and December 10, 2020, respectively. They seek a stay of execution to allow this Court to settle three important questions worthy of review: (1) whether this Court's precedents require a plaintiff seeking injunctive relief to show a certainty of irreparable harm, or whether a likelihood of irreparable harm suffices; (2) whether, particularly under a prophylactic statute like the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*., an increased risk of bodily harm is sufficient to show irreparable harm; and (3) whether the Government may carry out an execution in a manner that federal courts have *authoritatively determined to be unlawful*. Each of these questions is important and, absent intervention and clarification by this Court, will recur. Furthermore, the first two questions are the subject of a circuit conflict, and the third is of extraordinary importance. On each question, Applicants are likely to succeed on the merits of their challenge, and absent a stay from this Court will face irreparable harm—execution before the adjudication of the merits of their case, and in a manner that greatly increases their risk of suffering excruciating pain before death.

Applicants' executions, which would use sodium pentobarbital ("pentobarbital") should they take place, will violate the FDCA. Respondents intend to execute Applicants with pentobarbital even though they have not obtained a prescription for its use, which the district court and the court of appeals properly found violated the FDCA. The district court nonetheless erred by finding that Applicants could not show irreparable harm from Respondents' use of pentobarbital *despite* its continuing concern that under the 2019 Protocol, death-sentenced inmates will suffer excruciating pain during their executions—a finding the D.C. Circuit affirmed.

The district court held that to satisfy their burden of demonstrating that irreparable harm was "likely," plaintiffs in fact had to establish a *virtual certainty* that they would suffer excruciating pain in their executions, and also establish that previous executions in fact inflicted excruciating pain. The court of appeals affirmed the district court's conclusion that plaintiffs had not established that likelihood. Though couched in terms of "likelihood," the legal standard for irreparable harm that the district court applied, and that the court of appeals affirmed, in substance required something closer to certainty. That is inconsistent with this Court's decision in *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010), and the decisions of other courts of appeals. That holding warrants this Court's review. *See* Sup. C. R. 10(a). Had the courts below applied the proper standard, they would have found that Applicants have shown that they will be irreparably harmed by Respondents' FDCA violation.

The court of appeals also erred by rejecting Plaintiffs' argument that in the context of severe bodily harm, a concrete *risk* that Plaintiffs would suffer extraordinary pain and suffering is sufficient to show irreparable harm. In the context of a prophylactic statute like the FDCA, an elevated risk of bodily injury should be sufficient in itself to establish irreparable harm; Plaintiffs should not have to demonstrate that they will in fact suffer from flash pulmonary edema while

sensate during their executions. The courts of appeals are divided on whether such a substantial risk of bodily harm warrants injunctive relief. Some have concluded that a high or growing risk of bodily harm will suffice—a standard Plaintiffs have clearly met even accepting the district court's findings of fact. The district court and the D.C. Circuit, however, concluded that a substantial risk alone is insufficient to warrant injunctive relief. That decision warrants this Court's review.

Finally, the court of appeals held that the government's current execution protocol violates the FDCA because it permits the government to proceed without obtaining a prescription for pentobarbital, and the court accordingly set aside the protocol as "not in accordance with law" to the extent that it allows the government to dispense and administer pentobarbital without a prescription. 5 U.S.C. §706(2); App. 25a. As Judge Pillard explained in dissent, "[t]hat conclusion alone requires a stay of the pending executions until the government complies." App. 29a. The government may not carry out executions in violation of its statutory authority. Respondents have indicated, however, that they intend to proceed to execute Applicants under the protocol regardless of whether it is set aside as contrary to law, unless specifically constrained not to do so by an injunction. That disturbing possibility is extraordinary in itself. The government's determination in this case to *ignore* federal courts' authoritative declarations of unlawfulness, and proceed to execute Applicants under an unlawful protocol, alone more than warrants this Court's review.

This Court should therefore grant the stay of Applicants' executions pending disposition of their writ of certiorari.

JURISDICTION

The D.C. Circuit denied Applicants' motion for a stay of execution on November 18, 2020. This Court has jurisdiction to review Applicants' petition for certiorari under 28 U.S.C. §

1254(1). Under 28 U.S.C. § 2101(f), this Court may grant a stay for a reasonable amount of time to enable Applicants to obtain a writ of certiorari.

RELATED PROCEEDINGS

There are several related proceedings, as defined in Supreme Court Rule 14.1(b)(ii).

The proceedings directly related to this emergency application for a stay are:

In re: Federal Bureau of Prisons' Execution Protocol Cases, No. 20-5329, U.S. Court of Appeals for the District of Columbia Circuit. Judgment entered November 18, 2020.

In re: Federal Bureau of Prisons' Execution Protocol Cases, No. 19-mc-145, U.S. District Court for the District of Columbia. Judgment entered September 20, 2020.

This case has previously been before this Court on the Government's motion for a stay or vacatur. *See, e.g., Barr v. Lee*, 140 S. Ct. 2590 (2020); *Barr v. Purkey*, No. 20A10, 2020 WL 4006821 (July 16, 2020) (mem.); *Barr v. Roane*, 140 S. Ct. 353 (2019) (mem.). This Court denied the Government's application for a stay in *Roane* but granted the applications to vacate the district court's preliminary injunction in *Purkey* and *Lee*.

There are several related cases in the district court that have been consolidated into the single master case from which this emergency application for a stay originates. *See* Order, *In re Fed. Bureau of Prisons' Execution Protocol Cases*, No. 19-mc-145 (D.D.C. Aug. 20, 2019), Dkt #1 ("Dist. Dkt."). They are as follows: *Roane v. Barr*, No. 05-cv-2337 (D.D.C. filed Dec. 6, 2005); *Robinson v. Barr*, No. 07-cv-2145 (D.D.C. filed Nov. 28, 2007); *Bourgeois v. U.S. Dep't of Justice*, No. 12-cv-782 (D.D.C. filed May 15, 2012); *Fulks v. U.S. Dep't of Justice*, No. 13-cv-938 (D.D.C. filed June 21, 2013); *Lee v. Barr*, 19-cv-2559 (D.D.C. filed Aug. 23, 2019); *Purkey v. Barr*, No. 19-cv-3214 (D.D.C. filed Oct. 25, 2019); *Holder v. Barr*, No. 19-cv-3520 (D.D.C. filed Nov. 22, 2019); *Bernard v. Barr*, No. 20-cv-474 (D.D.C. filed Feb. 19, 2020); *Nelson v. Barr*, No. 20-cv-557 (D.D.C. filed Feb. 25, 2020).

One of these related district court cases previously resulted in two appeals to the D.C. Circuit, which were decided on July 6, 2012, and January 24, 2012. *See Roane v. Leonhart*, 741 F.3d 147 (D.C. Cir. 2014); *Roane v. Tandy*, No. 12-5020, 2012 WL 3068444 (D.C. Cir. July 6, 2012). Neither decision was appealed to this Court.

STATUTES INVOLVED

The relevant statutory provisions are included in the Appendix. See. App. E.

OPINIONS BELOW

The D.C. Circuit denied Applicants' motion for a stay of execution pending appeal. *See* No. 20-5329, Dkt. No. 25. Petitioners' Appendix (App.) A. The D.C. Circuit reversed the district court's dismissal of Applicants' Eighth Amendment claim, and ordered the 2019 Protocol set aside to the extent it permits the use of unprescribed pentobarbital in violation of the FDCA, but it affirmed the denial of a permanent injunction to remedy the FDCA violation. *See* No. 20-5329, Dkt. No. 26. App. B.

The district court held on summary judgment that Defendants violated the FDCA but that Applicants have not shown irreparable harm from that statutory violation sufficient to warrant the grant of permanent injunctive relief. *See* ECF No. 261. App. D. The district court denied Applicants' motions for reconsideration. *See* ECF No. 305. App. C.

STATEMENT

This case concerns whether Respondents' planned use of pentobarbital sodium ("pentobarbital") to execute Applicants under the current federal execution protocol (the "2019 Protocol") violates their statutory rights, thereby entitling them to injunctive relief.

1. On June 1, 2020, Applicants, along with more than two dozen other Plaintiffs sentenced to death pursuant to federal statutes, filed an amended complaint alleging that Respondents' execution protocol violated, as relevant here, the FDCA. Dist. Ct. Dkt. No. 92. On July

15, 2020, the district court preliminarily enjoined the executions of three Plaintiffs with execution dates, concluding that they were likely to succeed on the merits of their claim that the 2019 Protocol violates the FDCA. *See* App. 61a. This Court vacated the injunction. *See Barr v. Purkey*, No. 20A10, 2020 WL 4006821 (U.S. July 16, 2020) (per curiam). This Court did not address the merits of Plaintiffs' FDCA claim. *Id.* Respondents executed two Plaintiffs later that week.

On August 27, 2020, the district court entered a permanent injunction barring Respondents from executing Plaintiff Keith Nelson, holding unlawful the use of pentobarbital for lethal injection without first satisfying the FDCA's premarketing, labeling, and prescription requirements. App. 62a. The D.C. Circuit vacated the injunction and remanded for consideration of irreparable harm. *Id.* at 62a-63a. On remand, the district court denied Mr. Nelson's request for a permanent injunction on his FDCA claim, finding that he had failed to demonstrate irreparable harm. *Id.* at 62a. Respondents subsequently executed Mr. Nelson.

On September 20, 2020, the district court granted summary judgment to Plaintiffs, including Applicants, on their FDCA claim. The district court concluded that "the government's use, under the 2019 Protocol, of pentobarbital . . . has not been prescribed and does not meet other statutory requirements of the FDCA," and therefore the intended executions "constitute[] agency action that is contrary to law in violation of the APA [Administrative Procedure Act]." *Id.* at 88a; *see generally* Dist. Ct. Dkt. No. 213.

The district court, however, denied injunctive relief, finding that although there was a "possibility that inmates will suffer excruciating pain during their executions, Plaintiffs have not established that flash pulmonary edema is 'certain' or even 'likely' to occur before an inmate is rendered insensate." App. 91a. Although the district court expressed skepticism about the con-

clusions of Applicants' experts, it found that Plaintiffs had failed to "completely discredit" their testimony or "completely undermine" their conclusions. *Id.* at 93a-94a. The district court also stated that it could not "weigh the evidence before it in a vacuum" and that the Supreme Court in *Lee* had already addressed "most of the evidence Plaintiffs have presented in this case and found that it was not enough to warrant injunctive relief." *Id.* at 94a-95a. The district court denied Plaintiffs' request for injunctive relief despite its continued concerns "that inmates will suffer excruciating pain during their executions." *Id.* at 91a.

Plaintiffs, including Applicants, filed a Fed. R. Civ. P. 59(e) motion to alter or amend the district court's judgments regarding their FDCA claim. *See* Dist. Ct. Dkt. No. 282.[1] Plaintiffs' motions included new evidence that William LeCroy, whom Respondents executed on September 22, 2020, was observed "heav[ing] uncontrollably" *almost immediately* after pentobarbital was administered into his veins. Dist. Ct. Dkt. No. 282-2; *see* Dist. Ct. Dkt. No. 282-1. Plaintiffs also submitted a supplemental expert declaration from Dr. Gail A. Van Norman, whose statements and credibility Respondents did not challenge at the hearing.

Dr. Van Norman stated in her declaration that "the respiratory efforts reported by eyewitnesses during the execution of Mr. LeCroy *were not agonal respirations*"—that is, the deep breaths expected before death from pentobarbital—because "[t]here is no heaving motion of the chest, alone or together with the abdomen" with agonal respiration. Dist. Ct. Dkt. No. 282-4 at 8. The fact that "Mr. LeCroy's eyes were open while he was fighting for breath and closed only later" also indicates that he was aware and experiencing flash pulmonary edema before his death.

[1] They also filed two Fed. R. Civ. P. 59(e) motions regarding the district court's decision to dismiss their Eighth Amendment claim and deny injunctive relief on their Federal Death Penalty Act ("FDPA") claim, *see* Dist. Ct. Dkt. Nos. 238, 298. The D.C. Circuit reversed the district court on the former and affirmed on the latter. Applicants are not seeking a stay before this Court with respect to either of those claims.

Id. at 10. Furthermore, "[f]lash pulmonary edema is accompanied by excruciating symptoms of drowning: shortness of breath, anxiety, terror, and panic." *Id.* at 2. In short, LeCroy likely experienced extraordinary pain and suffering before dying.

On November 3, the district court denied the motion. *See* App. 47a. The court explained that it understood this Court's decision in *Barr v. Lee*, 140 S. Ct. 2590 (2020), to raise the "likelihood" threshold for demonstrating irreparable harm to near-insurmountable heights: even if Plaintiff-Appellants had established that flash pulmonary edema while sensate is "possible," "Plaintiffs would need to supply evidence that casts doubt on the more than 100 executions carried out using pentobarbital." *Id.* at 53a.

2. On November 4, Plaintiffs filed a notice of appeal and motion to expedite. The D.C. Circuit set an expedited briefing schedule.

On November 5, Applicants filed a motion for leave to file a stay of execution in the district court, and after receiving leave, filed their motion for a stay of execution the next day. After the district court set a schedule that would not permit it to rule until November 13, Applicants filed a motion for a stay of execution in the court of appeals on November 10, 2020.

3. The D.C. Circuit held oral argument on November 16 and decided the appeal and the stay motion on November 18.

a. The court of appeals affirmed the district court's holding that the 2019 Protocol violates the FDCA to the extent that it permits the dispensing and administration of pentobarbital without a prescription. App. 25a. The D.C. Circuit explained that, under the APA, "the execution protocol as administered by the Federal Bureau of Prisons is 'not in accordance with law'" to the extent that it does so, "and must be 'set aside' in that respect" under the APA. *Id.* (quoting 5 U.S.C. § 706(2)).

The D.C. Circuit nevertheless affirmed the district court's denial of a permanent injunction on Plaintiffs' FDCA claim, a ruling that also had the effect of denying Applicants a stay of execution on this claim. The court explained that "[t]he district court specifically found ... that "the evidence in the record does not support Plaintiffs' contention that they are likely to suffer flash pulmonary edema while still conscious." App. 25a-26a. The court of appeals did not address Plaintiffs' contention that the district court's finding that flash pulmonary edema while sensate was not "likely" reflected its misunderstanding of *Lee* as elevating the likelihood standard to a virtual certainty. Nor did the court of appeals address Plaintiffs' argument that an elevated *risk* of bodily injury constitutes irreparable harm for purposes of the FDCA.

The D.C. Circuit reversed the district court's dismissal of Plaintiffs' Eighth Amendment claim, and remanded for further proceedings. The circuit court held that Plaintiffs had properly and plausibly pled "that the federal government's execution protocol involves a 'virtual medical certainty' of severe and torturous pain that is unnecessary to the death process and could readily be avoided by administering a widely available analgesic first." App. 18a. Indeed, although not necessary at the pleading stage, Plaintiffs had "plausibly substantiate[d]" those allegations with evidence from expert and percipient witnesses. *Id.* at 16a-17a. The D.C. Circuit held that the district court's dismissal of Plaintiffs' Eighth Amendment claim rested on "critical legal errors" based on misreading this Court's precedents. *Id.* at 18a-22a. The court denied Applicants stays of execution on Plaintiffs' Eighth Amendment claim, however, citing its prior denial of such a stay earlier in this litigation. *Id.* at 21a.

b. Judge Pillard concurred in part but dissented from the denials of an injunction and a stay of execution on Plaintiffs' FDCA claim. Judge Pillard explained that the court's holding that the protocol must be set aside to the extent it permits executions in the absence of a

prescription for pentobarbital "requires a stay of the pending executions until the government complies." *Id.* at 29a (Pillard, J., concurring in part and dissenting in part). Although "[i]t is the government's prerogative to execute the plaintiffs by a method of its choosing," "if it elects a method subject to statutory requirements, the government must then abide by those requirements." *Id.*

Judge Pillard also would have held that, if an injunction were required, "the risk of harm flowing from the FDCA violation in this case readily meets the threshold for irreparable injury." In her view, the record indicated that the district court erroneously conflated the showing of such injury needed to enjoin a violation of the FDCA with that needed to enjoin a violation of the Eighth Amendment. *Id.* at 33a. Moreover, "[o]n this record," Plaintiffs' interest in avoiding "the elevated risks of severe and gratuitous pain from administration of pentobarbital absent the requisite statutory safeguards"—which is aligned with "the public interest in adhering to applicable legal requirements"—outweighed "the government's interest in proceeding with the executions as scheduled without obtaining the required prescriptions." *Id.* at 34a-35a.

c. Judge Rao concurred in part, concurred in the judgment, and dissented in part, agreeing that the district court erred in dismissing Plaintiffs' Eighth Amendment claim but dissenting from the panel majority's holding that the 2019 Protocol should be set aside to the extent it permits the dispensing and administration of pentobarbital without a prescription.

4. The import of the court of appeals' decision is that the 2019 Protocol has been set aside as contrary to law to the extent that it permits respondents to execute Plaintiffs using pentobarbital for which it has obtained no prescription. Nevertheless, the government asserted below that even if the 2019 Protocol were set aside, in the absence of a traditional injunction, it would continue to use the protocol to execute Plaintiffs, without obtaining a prescription. Gov't

C.A. Br. 41.

Respondents plan to execute Hall on November 19, and Bernard on December 10. Respondents presumably intend to follow the 2019 Protocol without obtaining a prescription despite the fact that the protocol has been set aside to the extent that it does not require a prescription. For the reasons set forth below, this Court should issue a stay of execution to allow Applicants to pursue their meritorious claims on certiorari without threat of having those claims mooted by their deaths.

ARGUMENT

"To obtain a stay pending the filing and disposition of a petition for a writ of certiorari, an applicant must show (1) a reasonable probability that four Justices will consider the issue sufficiently meritorious to grant certiorari; (2) a fair prospect that a majority of the Court will vote to reverse the judgment below; and (3) a likelihood that irreparable harm will result from the denial of a stay." *Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010). "'[I]n a close case it may [also] be appropriate to balance the equities,' to assess the relative harms to the parties, 'as well as the interests of the public at large.'" *Indiana State Police Pension Trust v. Chrysler, LLC*, 556 U.S. 960 (2009) (quoting *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers)). Those standards are satisfied here.[2]

[2] In the court of appeals, the Government contended that Applicants "in substance seek an injunction" and therefore must provide a "significantly higher justification"—a clear and indisputable right to relief—than the typical standard for a stay. Govt. C.A. Op. to Stay, at 8 n. 3 (quoting *Respect Maine PAC v. McKee*, 562 U.S. 996, 996 (2010)). But *Respect Maine PAC* relied on the fact that granting the requested relief would be a "judicial alteration of the status quo." 562 U.S. at 996. Applicants have asked for precisely the opposite here: avoiding unalterably changing the status quo by executing them while their claims for relief are pending, thereby mooting their certiorari petition.

Unsurprisingly, this Court has never required such an elevated showing of a clear and indisputable right to relief in the context of a stay of execution pending a challenge to a lethal injection protocol. In this Court's recent execution protocol cases, the Court granted stays pend-

I. THE PETITION WILL PRESENT A COMPELLING CASE FOR CERTIORARI, AND THIS COURT IS LIKELY TO GRANT REVIEW.

A. Granting Certiorari is Necessary to Resolve a Conflict Created by This Court's Decision in *Monsanto* As to the Necessary Showing for Irreparable Harm

This case presents both an issue on which the court of appeals are in conflict, Sup. C. R. 10(a), and an important issue on which lower federal courts have conflicted with relevant decisions of this Court, Sup. C. R. 10(c): the proper standard that a plaintiff must meet to show irreparable harm under this Court's injunction and stay tests. As this Court has held, "a stay pending appeal certainly has some functional overlap with an injunction," *Nken*, 556 U.S. at 418, 428 (2009), and both a stay and an injunction require the moving party to prove the existence of irreparable harm absent equitable relief, *see id.* at 435; *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

Lower courts disagree about whether this Court's decisions require a plaintiff to show that future irreparable harm will *certainly* occur, or is merely *likely* to occur. As the district court noted, *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010), provides support for each of these standards. *Compare id.* at 162 (noting that a permanent injunction "guard[s] against a[] present or imminent risk of *likely* irreparable harm"), *and id.* at 163 ("It is hard to see how . . . [the action] would cause [respondents] *likely* irreparable injury."), *with id.* at 162 (finding no irreparable harm because "respondents cannot show that they *will* suffer irreparable injury if APHIS is allowed to proceed with any partial deregulation"); *see also, e.g. Winter v. NRDC*, 555 U.S. 7, 20, 129 S. Ct. 365, 374, 172 L. Ed. 2d 249 (2008) (requiring only a showing that a

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ing its decisions on the merits, see *Bucklew v. Precythe*, 139 S. Ct. 1112 (2019); *Glossip v. Gross*, 576 U.S. 863 (2015); *Baze v. Rees*, 553 U.S. 35 (2008), and the petitioners ultimately did not prevail in each. The granting of the stays in those cases, in which petitioners did not prevail, suggests the Court does not apply the Government's suggested "significantly higher justification."

plaintiff is "*likely* to suffer irreparable harm in the absence of" injunctive relief) (all emphases added).

This Court's contrary statements have created a conflict in the lower courts. As the district court noted, the D.C. Circuit has interpreted this Court's precedents to require a showing that any irreparable harm must be "certain and great." *League of Women Voters of United States v. Newby*, 838 F.3d 1, 8 (D.C. Cir. 2016); *see also Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (same). Consistent with that view, the district court applied a standard that was in substance a certainty standard: although it stated at times that the question was whether irreparable harm was "likely," the court also made clear that it viewed that standard in substance as requiring a virtual certainty. Purporting to be "constrained" by *Lee*, the district court required Plaintiffs to "completely undermine" Defendants' expert evidence and to "supply evidence that casts doubt on the more than 100 executions carried out using pentobarbital," a standard not found anywhere in the case law or otherwise. App. 53a. The court of appeals affirmed the district court's holding that irreparable harm is not likely, thereby accepting the unduly heightened standard applied by the district court.

Meanwhile, other courts of appeals have found injunctive relief proper where an action "will likely cause irreparable damage." *Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1092 (9th Cir. 2015); *see, also, e.g.*, *Am. Civil Liberties Union v. Clapper*, 785 F.3d 787, 825 (2d Cir. 2015) (requiring a showing of "likely . . . irreparable harm); *Ferring Pharm., Inc. v. Watson Pharm., Inc.*, 765 F.3d 205, 217 (3d Cir. 2014) (a plaintiff must show "she is likely to suffer irreparable harm if an injunction is not granted"), *holding modified by Reilly v. City of Harrisburg*, 858 F.3d 173 (3d Cir. 2017); *Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Engineers*, 826 F.3d 1030, 1037 (8th Cir. 2016) ("[T]he alleged harm need not be

occurring or be certain to occur before a court may grant [injunctive relief]." (quoting *Michigan v. U.S. Army Corps of Engineers*, 667 F.3d 765, 788 (7th Cir. 2011))).

This clear conflict between the courts of appeals, which is the product of this Court's internally contradictory language in *Monsanto*, warrants this Court's review.

B. Granting Certiorari is Necessary to Resolve Whether the Heightened Risk of Bodily Harm Constitutes Irreparable Harm

This case also presents an opportunity for the Court to resolve a conflict among the lower courts as to whether a heightened risk of serious bodily harm constitutes irreparable harm.

District and circuit courts across the country have repeatedly held that the heightened *risk* of bodily harm, including an elevated risk of contracting illness, is sufficient to justify injunctive relief. *See, e.g.*, *Roman v. Wolf*, 977 F.3d 935, 944 (9th Cir. 2020) ("The district court also correctly concluded that Plaintiffs were likely to suffer irreparable harm absent relief given COVID-19's high mortality rate."); *Edmo v. Corizon, Inc.*, 935 F.3d 757, 797-98 (9th Cir. 2019) ("It is no leap to conclude that . . . the *high risk* of self-castration and suicide she faces absent surgery *constitute irreparable harm*." (emphases added)); *Battista v. Clarke*, 645 F.3d 449, 456 (1st Cir. 2011) (affirming grant of injunctive relief because "while the risk of self-mutilation is unpredictable, it grows as the litigation drags on"); *see also Gayle v. Meade*, No. 20-21553-Civ, 2020 WL 3041326, at *21 (S.D. Fla. June 6, 2020) ("Even in the early days of the pandemic, and with few exceptions, courts did not hesitate to find irreparable harm as a result of *potential* COVID-19 exposure in prison and detention, including in facilities where there had not been a confirmed case." (emphasis added)). Other courts have taken the opposite approach. *See, e.g.*, *Orr v. Shicker*¸ 953 F.3d 490, 502-53 (7th Cir. 2020) (reversing grant of preliminary injunctive relief where the district court found "that waiting . . . could well create a substantial risk to inmates of liver damage, liver cancer, and painful extrahepatic conditions"); *Aslanturk v. Hott*,

459 F. Supp. 3d 681, 700 (E.D. Va. 2020) (concluding petitioner's increased risk of "severe illness or death if he contracts COVID-19" was insufficient to show irreparable harm).

As relevant here, the district court expressly stated that Plaintiffs' evidence left it "concerned at the possibility that inmates will suffer excruciating pain during their executions" by pentobarbital. *See* App. 91a. The court thus recognized that there was a real, substantial, and troubling *risk* that Plaintiffs, including Mr. Hall and Mr. Bernard, will suffer flash pulmonary edema while sensate. Despite this finding, the court concluded that Plaintiffs had failed to show irreparable harm because they had not demonstrated a certainty or likelihood that they absolutely *would,* in fact, experience such suffering—a conclusion the D.C. Circuit did not disturb on appeal. This has only deepened a split between the courts regarding whether significant and elevated risks of suffering are sufficient to show irreparable harm, which warrants this Court's review.

C. Granting Certiorari is Necessary Because the Government Intends to Carry Out Executions in a Manner That Federal Courts Have Authoritatively Determined is Unlawful

This case also presents another issue of extraordinary importance: Whether the government may, absent an injunction, carry out an execution in a manner that federal courts have authoritatively determined to be unlawful.

The court of appeals and the district court in this case both held that the government's current execution protocol violates the FDCA, a statute that imposes certain safety procedures categorically to mitigate risks of bodily harm. App. 25a, 88a. The D.C. Circuit held that, under the APA, the protocol must be set aside to that extent as contrary to law. *Id.* at 25a. Respondents have indicated, however, that they intend to proceed to execute Petitioners under the protocol regardless of whether it has been set aside as contrary to law, unless specifically constrained not to do so by an injunction. That disturbing possibility is extraordinary in itself.

Ordinarily, the government treats a declaration of unlawfulness as equivalent to an injunction, in that it complies. *See, e.g.*, *Texas v. United States*, 945 F.3d 355, 402–03 (5th Cir. 2019) (noting government's representation that a declaratory judgment of statute's invalidity would be "sufficient relief against the Government," because a declaratory judgment would "operate[ ] in a similar manner as an injunction" against the federal government, which would be "presumed to comply with the law" once the court provides "a definitive interpretation of the statute."). The government's extraordinary determination in this case to *defy* federal courts' authoritative declarations of unlawfulness, and proceed to execute Petitioners under an unlawful protocol, alone more than warrants this Court's review.

II. THERE IS A FAIR PROSPECT THAT THIS COURT WILL REVERSE THE COURT OF APPEALS' DECISION.

A. Respondents' Violation of the FDCA Will Cause Applicants Irreparable Harm

The court of appeals affirmed the district court's denial of Applicants' request for a permanent injunction on their FDCA claim on the ground that the district court had found that Plaintiffs were not likely to suffer flash pulmonary edema while sensate. The district court's finding to that effect, however, rested on several legal errors that the court of appeals failed to address: the district court effectively required Plaintiffs to demonstrate a virtual certainty that irreparable harm would occur, and mischaracterized the nature of the harm; erroneously believed that the permissible universe of factual findings was "constrained" by *Lee*; and misconstrued the manner in which enforcing the FDCA would prevent irreparable harm. Applicants are likely to succeed on their claim that the courts below erred in holding that Plaintiffs had not established irreparable harm.

1. The Courts Below Erred By Applying a Heightened Standard for Irreparable Harm to Applicants' Request for Permanent Injunctive Relief

a. Although the district court below credited Applicants' evidence and were "concerned at the possibility that inmates will suffer excruciating pain during their executions," (App. 91a), it ultimately denied Applicants' request for injunctive relief because it found the evidence was insufficient to show that flash pulmonary edema while sensate is "likely, let alone 'certain' or 'imminent,'" *id.* at 95a (alteration in original) (citing *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)). The court confirmed that it sought evidence demonstrating a virtual certainty when it stated that Plaintiffs were required "to supply evidence that casts doubt on the more than 100 executions carried out using pentobarbital." *Id.* at 53a. The court of appeals affirmed without questioning the district court's apparent understanding of the legal standard. *See id.* at 30a (Pillard, J., concurring in part and dissenting in part) (noting that "[a]t one point in the court's order denying Plaintiffs their injunction, it faulted them for failing to show 'that they will suffer irreparable injury'). This was error.

The test for irreparable harm does not demand absolute certainty that the threatened harm will occur. This Court's decisions in *Monsanto* and *Winter* establish that a plaintiff must show that irreparable harm is likely to occur, not that it is certain to occur. See *Monsanto*, 561 U.S. at 16 ("It is hard to see how . . . [the action] would cause [respondents] *likely* irreparable injury."); *Winter*, 555 U.S. at 20 (requiring a showing that plaintiff is "*likely to suffer* irreparable harm in the absence of" injunctive relief) (emphases added).

Indeed, the courts below erred because even the D.C. Circuit's decision in *Wisconsin Gas* makes clear that this is the proper standard. According to that case, in line with this Court's precedents, the test requires two separate but related showings: first, "the injury must be both certain and great; it must be actual and not theoretical"; and second, the injury must be "likely"

to occur. 758 F.2d at 674. By requiring Applicants to prove that pulmonary edema while sensate is *certain* to *occur*, the courts below erroneously conflated the *type* of injury required for injunctive relief (a concrete one) with the *quantum of proof* required (merely "likely," not "certain"), and imposed an unduly heightened burden on Applicants.

Applicants' evidence amply satisfies both components of this Court's test for irreparable harm, properly understood. There can be no doubt that flash pulmonary edema is a concrete harm; both Drs. Van Norman and Crowns agree that flash pulmonary edema is an acute and painful medical condition that can cause shortness of breath, wheezing, gasping, and coughing. *See* Dist. Ct. Dkt. No. 246-1 at 4-5 (Declaration of Dr. Crowns); Dist. Ct. Dkt. No. 249-1 at 5 (Additional Supplemental Report of Dr. Van Norman).

Applicants demonstrated that they are *likely* to experience flash pulmonary edema while sensate. Dr. Van Norman stated that *all* prisoners who have been executed by lethal injection with pentobarbital and who have been autopsied showed signs of flash pulmonary edema. *See* Dist. Ct. Dkt. No. 249-1 at 4. In addition, flash pulmonary edema "occurs virtually immediately during and after high-dose barbiturate injection," and it is "extremely likely" all of the aforementioned prisoners "were aware and experienced sensations of drowning and suffocation as they died." Dist. Ct. Dkt. No. 24 at 36. Indeed, when LeCroy was executed, his eyes remained open as his torso "began to jerk and contract uncontrollably" and he "grasp[ed] for air"—"classic motion[s] of chest-abdomen paradox" associated with flash pulmonary edema. Dist. Ct. Dkt. Nos. 282-1, 282-2, 282-4 at 10. Against this evidence, the district court found only that Dr. Crowns was not "completely undermined" and that Dr. Antognini was not "unqualified," though his "testimony did not carry much weight." App. 93a-94a. The district court's acceptance of Applicants' experts' testimony and the lack of credit it gave to Defendants-

Respondents' experts together show that, if the proper standard from *Wisconsin Gas* is applied, flash pulmonary edema while sensate is "likely."

b. Indeed, there is no question that the lack of a prescription subjects Plaintiffs to an increased risk of severe bodily suffering, which in itself constitutes irreparable harm. Courts repeatedly have held that a heightened risk of bodily harm—like the risk of pain and suffering at issue here—will justify injunctive relief. *See, e.g.*, *Ingraham v. Wright*, 430 U.S. 651, 695 (1977) ("The infliction of physical pain is final and irreparable."); *Edmo v. Corizon, Inc.*, 935 F.3d 757, 798 (9th Cir. 2019); *Al-Joudi v. Bush*, 406 F. Supp. 2d 13, 20 (D.D.C. 2005). As Judge Pillard noted, "'[i]n the context of safety regulations [like the FDCA], risk is itself the harm prohibited by law. Exposure to that harm thus is irreparable injury.'" App. 31a (quoting *Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 614 & n. 39 (D.C. Cir. 1980)). Thus, if there were "an official agency policy of sending truck drivers out onto the roads without seatbelts, or of serving meats to employees stored at a temperature below what federal regulations require . . . the agency would be subject to an injunction without a further evidentiary showing of how likely it was that the drivers or diners were to be injured." *Id.* That is because "[w]here a legal mandate protecting bodily health and safety is concerned, the law itself reflects the regulatory or legislative judgment that the [subjects of the law] are likely to suffer harm if that mandate is ignored." *Id.*

The FDCA safeguards that Respondents are flouting were intended to protect against the very risks of harm that Applicants face. For the reasons stated above, there is no question that Applicants have demonstrated a concrete, elevated risk of suffering based on Respondents' continuing violations. That alone should be sufficient to merit injunctive relief. *Mays v. Dart*, 456 F. Supp. 3d 966, 1015 (N.D. Ill. 2020) (granting injunction based on elevated, "grave risks

to health [that] are not an insignificant possibility"); *see supra p.* 14 (collecting additional cases in which the possibility of grave health risk is enough to make the necessary showing of irreparable harm). .

2. The District Court Erred by Concluding that its Factfindings were "Constrained" by *Lee*, Leading it to Partially Abdicate its Duty to Find the Facts

In addition to applying the wrong standard for irreparable harm, the district court committed two additional legal errors. First, the district court misread this Court's decisions in *Bucklew v. Precythe*, 139 S. Ct. 1112 (2019), and *Lee* to foreclose the possibility that Respondents' evidence was sufficient to show irreparable harm. Second, and as a result, the district court improperly required Applicants to "completely undermine" Dr. Crowns' conclusions to demonstrate irreparable harm.

"[F]actfinding is the basic responsibility of district courts." *DeMarco v. United States*, 415 U.S. 449, 450 n.* (1974) (per curiam). "The trial judge is the most important agency of the judicial branch of the government precisely because on it rests the responsibility of ascertaining the facts. . . . For that very reason every effort should be made to render it as adequate as it humanly can be." *United States v. Forness*, 125 F.2d 928, 943 (2d Cir. 1942). A district court is generally not free to delegate its factfinding responsibilities by substituting another court or party's factual findings for its own. *See* Fed. R. Civ. P. 52(a)(1) ("In an action tried on the facts without a jury or with an advisory jury, the court *must* find the facts specially.").

Here, however, the district court partially abdicated its factfinding responsibilities out of a mistaken belief that this Court's decisions in *Bucklew* and *Lee* dictated certain factual and credibility findings. The district court even stated that it was "constrained by the[] findings" as to pentobarbital in *Lee*. App. 53a.

Thus, despite the district court's concern that Dr. Antognini's research was "rather old" and dealt primarily with animals, the district court gave his reports and testimony weight simply because *Bucklew* had relied on his testimony. *Id.* at 94a. But *Bucklew* was a different case involving a different set of facts. Indeed, this Court stressed in *Bucklew* that the plaintiff's expert, in contrast to Dr. Antognini, "was evasive" and "crossed up the numbers" in his testimony. 139 S. Ct. at 1132. No such issues have arisen in this case with respect to Dr. Van Norman's many declarations, and Respondents did not even question Dr. Van Norman.

The district court also erred when it denied Applicants' claims based on the mistaken notion that "[t]he Supreme Court . . . already addressed most of the evidence Plaintiffs have presented in this case and found that it was not enough to warrant injunctive relief." App. 94a-95a (citing *Lee*, 140 S. Ct. at 2592). This misreads *Lee*, which was a summary per curiam opinion that held only that the applicant had not demonstrated a likelihood of success on his Eighth Amendment claim based on pentobarbital and which did not have before it any of Plaintiffs' evidence concerning LeCroy's execution or Applicants' cross-examinations of Drs. Crowns and Antognini. *Id.* at 93a. By giving *Bucklew* and *Lee* controlling weight on the question of irreparable harm in *this* case, the district court failed to conduct an independent analysis of the facts and evidence before it as required by Federal Rule of Civil Procedure 52(a).

In any event, to the extent the district court independently assessed the credibility of Drs. Crowns and Van Norman, it erred by requiring Applicants to "*completely* undermine" Dr. Crowns' testimony to prevail on their request for injunctive relief. App. 93a (emphasis added). As the district court acknowledged in its opinion, Plaintiffs identified a serious flaw in Dr. Crowns' testimony, namely that "he was unaware of more recent news reports from the executions of Lee, Honken, Purkey, and Mitchell describing the inmates as showing labored breathing,

gasping for breath, or heaving," which contradicted the news reports on which Dr. Crowns relied to conclude that executed inmates were insensate when they experienced pulmonary edema. *Id.* Notwithstanding this problem, and other evidence Plaintiffs introduced showing flaws in his conclusions, the district court appeared to have considered Dr. Crowns' testimony to be *as* credible as Dr. Van Norman's simply because Plaintiffs did not "completely undermine" Dr. Crowns' conclusions. *Id.*

This was error. Plaintiffs were not required to completely undermine Respondents' evidence to prevail on their request for injunctive relief. As discussed earlier, *see* Part II.A, a plaintiff need only show that he is *likely* to suffer irreparable harm. *See Monsanto*, 561 U.S. 139 at 162. Plaintiffs were therefore entitled to injunctive relief as long as they could show that Dr. Van Norman's conclusions regarding flash pulmonary edema were *generally* more credible than Dr. Crowns' conclusions regarding agonal breathing. That is precisely what Plaintiffs did. Plaintiffs introduced evidence that Dr. Crowns was a pathologist and therefore his opinions about the effects of pentobarbital on the brain were entitled to minimal weight. *See* Dist. Ct. Dkt. No. 282-4 at 10-11; Dist. Ct. Dkt. No. 282-5 at 3. Plaintiffs also introduced evidence that many inmates who were executed exhibited physical responses before dying that were not consistent with the "slow, periodic, deep agonal respiration of cardiac arrest," Dist. Ct. Dkt. No. 282-4 at 10—evidence Dr. Crowns admitted he did not consider when advancing his hypothesis of agonal breathing, *see* App. 93a. Plaintiffs thus met their burden of showing that injecting them with pentobarbital will substantially increase their risk of suffering excruciating pain, thereby causing them to suffer irreparable harm.

3. The Courts Below Failed to Appreciate that Requiring Respondents to Comply With the FDCA Would Decrease the Likelihood that Applicants Will Suffer Before Dying

The district court also concluded that it was "not apparent how securing a prescription [in conformance with the FDCA] would eliminate this alleged harm [of flash pulmonary edema]." *Id.* at 91a. Because "the prescription requirement does not in and of itself ensure that Plaintiffs will . . . be protected from flash pulmonary edema during their executions," the district court concluded that an injunction was unwarranted. *Id.* Again, the court of appeals did not question that conclusion. This, too, was error.

The question is not whether unprescribed pentobarbital is more likely than prescribed pentobarbital to induce flash pulmonary edema. Instead, the question is whether the need for a prescription from a licensed medical professional will require Respondents to include a pain-relieving drug along with pentobarbital, as Plaintiffs and their experts have recommended. *See* Dist. Ct. Dkt. No. 236 at 13; Dist. Ct. Dkt. No. 248 at 3-4. Currently, Respondents can bypass consulting medical professionals altogether when executing death-sentenced individuals such as Applicants—a practice the district court correctly concluded violates the FDCA. Should this Court require compliance with the FDCA, however, Respondents will be required to consult first with a licensed professional who will assess how best to mitigate the risk that executed persons will experience extreme pain before dying. Medical professionals may well prescribe opioids or a similar analgesic—which Applicants established were widely available, needed, and appropriate, and which Respondents have never suggested a clinician would have a reason *not* to prescribe—as a condition of prescribing pentobarbital for use in an execution. *See* Dist. Ct. Dkt. No. 92 at 31-32; Dist. Ct. Dkt. No. 25 at 2-7. In denying a causal link between a prescription and irreparable harm, Respondents misapprehend the purpose of the FDCA's prescription requirement, which is to condition the dispensing of regulated drugs upon the sound exercise of clinical

judgment by a medical doctor. *United States v. Smith*, 573 F.3d 639, 652-53 (8th Cir. 2009); *United States v. Nazir*, 211 F. Supp. 2d 1372, 1375 (S.D. Fla. 1998).

Applicants are therefore likely to succeed on their claims on appeal that the district court erred in denying them injunctive relief on their FDCA claim.

B. The District Court Erred by Failing to Apply the Plain Language of the APA

Although Plaintiffs have demonstrated entitlement to an injunction for the reasons stated above, the court of appeals should be reversed for an independent reason based on the plain text of the APA. The statute states in no uncertain terms 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)(A) (emphases added). Recognizing the mandatory nature of this language, the D.C. Circuit correctly "set aside" the 2019 Protocol in relevant part after concluding it violated the FDCA. App. 25a. However, the D.C. Circuit erred in suggesting that there is no practical consequence to setting aside unlawful agency action and that the government can continue to take precisely the action that the court has found to be contrary to law: executing Plaintiffs with pentobarbital, without obtaining a prescription.

The APA does not permit agencies to continue giving effect to a policy that has been set aside as unlawful. *See United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019) (concluding the agency's failure to offer a reasoned explanation for its 2018 amendment rendered the amendment "*ultra vires* and unenforceable"); *Hughes Air Corp. v. C.A.B.*, 482 F.2d 143, 145-46 (9th Cir. 1973) (explaining that because the agency's orders should be set aside, "they are unenforceable"). And yet, that is precisely what the D.C. Circuit opinion does. Although it purports to "set aside" the 2019 Protocol, the opinion goes on to *permit* the Government to carry out its executions of Applicants Hall and Bernard with pentobarbital absent a prescription—the very action the court deemed violative of the FDCA's requirements. Such an

outcome, left undisturbed, would render the APA's remedy provision illusory: agencies that have established protocols contrary to the law could simply assert, as the government does here, that they never needed those protocols to begin with and thus, that a court's decision to set aside the protocol does not prevent them from carrying out the unlawful action.

The law does not sanction such an outcome. As Judge Pillard correctly observed in her dissent, when the government "elects a method subject to statutory requirements, the government must then abide by those requirements." App. 29a. Because the D.C. Circuit was required to set aside the 2019 Protocol—which it properly did—"[t]hat conclusion alone requires a stay of the pending executions until the government complies." *Id.*

III. ABSENT A STAY, APPLICANTS WILL SUFFER IRREPARABLE HARM

This Court recognized in *Nken* that "a stay pending appeal certainly has some functional overlap with an injunction." 556 U.S. at 428. Both require the moving party to prove the existence of irreparable harm absent equitable relief. *See id.* at 435; *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). Thus, for many of the reasons Plaintiffs-Appellants are likely to succeed on the merits of their appeal, *see* Part II, *supra*, they have also shown a likelihood of irreparable harm absent a stay.

Courts have repeatedly held that a plaintiff suffers irreparable harm if he will be executed before his meritorious challenges to the method of execution can be fully litigated. *See, e.g.*, *Nooner v. Norris*, No. 5:06cv00110 SWW, 2006 WL 8445125, at *3 (E.D. Ark. June 26, 2006); *Cooey v. Taft*, 430 F. Supp. 2d 702, 708 (S.D. Ohio 2006); *Brown v. Beck*, No. 5:06CT3018 H, 2006 WL 3914717, at *7 (E.D.N.C. Apr. 7, 2006). The evidence in this case shows that the risk of irreparable harm is just as great, if not greater, than in those cases.

Indeed, because of Respondents' refusal to comply with the FDCA, Plaintiffs are subject to a concrete, elevated risk of severe bodily harm, which in itself constitutes irreparable injury.

See Part II.A.1, *supra*. As explained above, Plaintiffs introduced evidence from Dr. Van Norman, a cardiovascular and perioperative expert whose credibility Respondents did not challenge, who explained that there is a "virtual medical certainty that most, if not all prisoners"—including Applicants—"will experience excruciating suffering, including sensations of drowning and suffocation," upon being injected with 5 grams of pentobarbital. *See* Dist. Ct. Dkt. No. 24 at 7, 31-34, 36. Dr. Van Norman drew upon her wealth of clinical knowledge as well as numerous studies to opine that "a single dose of barbiturate is insufficient to ablate awareness, including the sensations of pain and the extreme suffering of suffocation and asphyxiation that will occur" during the injection. *Id.* at 31.

Most recently, Plaintiffs introduced evidence from LeCroy's execution indicating that he was sensate and responsive when his airway was obstructed and his lungs filled with fluid. *See* Dist. Ct. Dkt. No. 282-4 at 10-11. This evidence—which included first-hand accounts from LeCroy's execution that he heaved for breath and gasped for air almost immediately upon being injected—was wholly consistent with Dr. Van Norman's explanation that flash pulmonary edema tends to occur when the injected individual is *still aware and capable of processing pain*. *Id.* at 9-11. Indeed, even Dr. Crowns admitted that if inmates "were reacting to the effects of pulmonary edema, they would be observed to have shortness of breath (dyspnea), increased respiration (tachypnea), wheezing, gasping, coughing, noisy labored breathing." Dist. Ct. Dkt. No. 246-1 at 4. But as Dr. Van Norman made clear, outward signs of distress are not required to confirm suffering from flash pulmonary edema while conscious. Dist. Ct. Dkt. No. 24 at 24. Past autopsies of executed inmates consistently show the presence of pulmonary congestion and pulmonary edema. *Id.* at 35-36. Critically, "[e]xperience in humans and animal models indicate that flash pulmonary edema occurs virtually immediately during and after high-dose barbiturate

injection, and well within a time frame *before* peak drug effects on the brain have occurred"—i.e., before an individual is rendered insensate. *Id.* at 36.

To constitute irreparable harm, a plaintiff must make a "showing of a[] real or immediate threat that the plaintiff will be wronged … a 'likelihood of substantial and immediate irreparable injury.'" *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983) (quoting *O'Shea v. Littleton*, 414 U.S. 488, 502 (1974)); *see also Connecticut v. Massachusetts*, 282 U.S. 660, 673 (1931) (holding that an injunction will issue only if there is "actual or presently threatened" harm). Applicants' evidence, which has only grown stronger with each additional execution, amply demonstrates irreparable harm. Absent this Court's intervention, Applicants will be executed by a method that is likely to cause them to endure "one of the most powerful, excruciating feelings known to man"—prolonged suffocation. Dist. Ct. Dkt. No. 24 at 34. And there is no way to undo that harm once inflicted. This is the very definition of irreparable harm. *See, e.g.*, *Banks v. Booth*, 459 F. Supp. 3d 143, 159 (D.D.C. 2020) ("The Court concludes that Plaintiffs' risk of contracting COVID-19 and the resulting complications, including the possibility of death, is the prototypical irreparable harm."); *Dean v. Coughlin*, 623 F. Supp. 392, 405 (S.D.N.Y. 1985) (describing pain as a "form[] of irreparable harm").

IV. THE BALANCE OF THE EQUITIES AND PUBLIC INTEREST FAVOR A STAY

The balance of equities and public interest likewise favor a stay. "There is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters*, 838 F.3d at 12; *see, e.g. Gordon v. Holder*, 721 F.3d 638, 653 (D.C. Cir. 2013) ("Enforcement of an unconstitutional law is always contrary to the public interest."); *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994) (noting the substantial "public interest in having governmental agencies abide by the federal laws that govern their existence and operations"). In addition, there is an "important public interest in the humane and constitutional application of [a] lethal

injection statute." *Nooner*, 2006 WL 8445125, at *4; *Cooey*, 430 F. Supp. 2d at 708. This is especially true here, where there is powerful evidence that Respondents' chosen method of execution will cause Applicants to endure extraordinary pain and suffering, and the denial of a stay threatens to permanently extinguish their meritorious claims.

That interest is not outweighed by Respondents' general interest in ensuring the finality of capital proceedings. For seventeen years, Respondents did not execute or seek to execute any death-sentenced prisoners, including Applicants. Once Respondents announced their intent to do so, Plaintiffs swiftly moved for injunctive relief. A stay of a few weeks or months to fully and fairly litigate the merits of Applicants' appeal will not substantially injure either the public or the Government where, as here, the Government's newfound urgency emerged only after nearly two decades of inaction. *See, e.g.*, *Oscorio-Martinez v. Att'y Gen. U.S. of Am.*, 893 F.3d 153, 179 (3d Cir. 2018) ("[T]he fact that the Government has not—until now—sought to remove SIJ applicants, much less designees, undermines any urgency surrounding Petitioners' removal.").

CONCLUSION

For the foregoing reasons, this Court should stay Applicants' executions pending disposition of their petition for certiorari.

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Respectfully submitted,

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