NO. 20-

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.

ORLANDO CORDIA HALL,
Respondent,

v.

OPPOSITION TO APPLICATION FOR A STAY OR VACATUR OF THE INJUNCTION ISSUED BY THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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INTRODUCTION AND SUMMARY

The United States District Court for the District of Columbia ("the district court") granted Mr. Hall's request for injunctive relief based on yesterday's decision by the Court of Appeals for the District of Columbia ("D.C. Circuit")—which clarified the meaning of this Court's denial of emergency injunctive relief in *Barr v. Lee*, 140 S. Ct. 2590 (2020), and therefore fundamentally changed the court's view of the evidentiary record it had reviewed it its initial consideration of Mr. Hall's entitlement to injunctive relief. The district court explained that correcting its erroneous interpretation of *Lee* "casts the evidence in a different light such that Plaintiffs have established a significant possibility of showing irreparable harm given Defendants' violation of the FDCA." A6. In trying to overturn the district court in this Court and the Court of Appeals, the Government has presented four arguments in support of its motion to stay or vacate the district court's injunction, each of which lacks merit. The Government further argues that the FDCA does not apply to these circumstances, and that Mr. Hall has no standing to bring the underlying action. These, too, are unavailing.

ARGUMENT

A. The District Court Is Permitted to Reconsider Injunctive Relief

First, the district court was correct that the mandate rule did not bar it from reconsidering the evidence before it under the correct legal standard and issuing a preliminary injunction. The D.C. Circuit, in affirming the district court's denial of a permanent injunction, relied on the fact 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." D.C. Circuit Op. 25. The D.C. Circuit therefore rested its holding on the district court's findings of fact regarding irreparable harm, which it reviewed for abuse of discretion.

But as the district court explained, its "conclusion was premised, in part, on its interpretation of *Lee*." A5. The district court continued that it was only because it believed *Lee* required an "improperly elevated" showing that Plaintiffs "completely undermine" the testimony of Dr. Crowns that it found that Plaintiffs had not made the necessary showing for irreparable harm. A6. It also pointed to new evidence from subsequent executions that, given the D.C. Circuit's clarification that

the district court had misread *Lee*, provided it with additional evidence it did not believe it could consider. A6-7.

The district court is best positioned to weigh the facts based on the applicable law. The D.C. Circuit's opinion clarified the applicable law in a manner that forced the district court to reevaluate the evidence before it under the proper standard, which it has done. In other words, given the intervening change in the law, the district court faced a different application of facts to law than it previously had. *See id.* at 7 ("The Court of Appeals' decision has fundamentally changed the law upon which this court relied in making its factual finding."). The D.C. Circuit and this Court are accordingly reviewing a *different injunction* based on a *different analysis* by the district court, and one which it was thoroughly within its authority to make. Such a situation, where "there has been a substantial change in the evidence or where an intervening decision has changed the law," *Yankee Atomic Elec. Co. v. United States*, 679 F.3d 1354, 1360 (Fed. Cir. 2012), is precisely when the mandate rule gives way.

Moreover, the district court's order falls well within its discretion to revisit the propriety of prospective equitable relief in light of new

circumstances. Plaintiffs obtained a judgment in their favor on their FDCA claim—a judgment that was affirmed by the D.C. Circuit. Although the D.C. Circuit also affirmed the district court's denial of injunctive relief, the mandate rule does not prevent Plaintiffs from returning to the district court, judgment in hand, to ask the district court to revisit its prospective assessment of the need for an injunction in light of changed circumstances. Those circumstances include not only the D.C. Circuit's explication of the relevant legal standard, but also the government's inability before this or any court to point to any harm from a brief delay associated with obtaining a prescription, Op. 9; and the government's bold assertion that it intends to defy the D.C. Circuit's decision—and thus violate the law—in conducting Plaintiffs' executions. Even if the government disagrees with the D.C. Circuit's ruling on the FDCA, it may not disregard it by executing the Plaintiffs in a manner that this D.C. Circuit has held exceeds its statutory authority. Those circumstances establish that the district court was within its discretion to revisit the need for equitable relief.

The mandate rule is limited to issues that were actually or necessarily decided by the Court of Appeals, not those that could have

been considered or decided. *See, e.g.*, *Bayala v. United States Dep't of Homeland Sec.*, 246 F. Supp. 3d 16, 22 (D.D.C. 2017). Here, the D.C. Circuit's decision that the district court did not *abuse* its discretion in its prior opinion did not foreclose the district court from reconsidering the exercise of its discretion in light of that court's clarification of the law and other changed circumstances.

The Government fares no better attacking the district court's finding of irreparable harm. *See* Mot. at 7-10. It miscasts Mr. Hall's primary showing of harm as based on a "bare" statutory violation. *Id.* at 9. But that is not the harm that the district court credited. To the contrary, the court made known its continuing awareness of the risk that an "inmate injected with a high dose of pentobarbital will suffer flash pulmonary edema while sensate." A6. The court observed that "new evidence" after "each execution" tended to "chip away at [Dr.] Crowns' hypothesis" that the prisoner's visible respiratory distress during an execution might reflect agonal breathing instead of flash edema, which was the district court's stated reason for previously finding that Plaintiffs had failed to "completely undermine" the Government's experts. *Id.* (quoting ECF No. 261 at 38). The district court explained that the recent

evidence from William LeCroy's execution and otherwise, considered in tandem with the court's corrected understanding of *Lee*, "undermines the court's basis" for finding no irreparable harm on the FDCA violation. A6-7. And even *before* that evidence, the district court was "concerned at the possibility that inmates will suffer excruciating pain during their executions." ECF No. 261 at 36.

The court-credited risk of excruciating pain from the prisoner's conscious experience of flash edema amplifies its finding of irreparable harm: "[W]ithout injunctive relief, Plaintiff will be executed with a drug administered in violation of a federal law that ensures its safety and efficacy for the intended purpose." A8. The very purpose for which Defendants have chosen to inject pentobarbital is to ensure a humane execution with "the least amount of discomfort as possible." AR 1, 3, 525-526, 858, 871-872, 929, 931; Nov. 15, 2019 Deposition of Rick M. Winter at 281:19-21 (ECF No. 45 Ex 1). That purpose justifies adherence to a statute that ensures that the drug is "safe and effective for its intended use," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000), as the district court itself has recognized:

> 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 enacted to ensure that the drugs operate humanely. ECF Doc. 213 at 8.

The FDCA's prescription requirement ensures the presence of clinical judgment in determining whether and how a prescription-only drug will be administered. *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. 2002). The FDCA's prescription requirement "provides 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.*

The Government's third and fourth arguments are likewise unavailing. The Government claims that Plaintiffs would be unable to secure a permanent injunction under the FDCA even if they do establish irreparable harm, because an FDCA-based injunction is inappropriate in light of the "balance of equities" and "the public interest". Mot. at 10. The Government's argument finds no support. The Plaintiffs' interest in avoiding illegal executions that expose them to risks of grievous bodily

pain and suffering outweighs the Government's claimed interest in carrying out death sentences in a "timely fashion".

It is indisputable that the public has an important interest "in the humane and constitutional application of [a] lethal injection statute." *Nooner v. Norris*, 2006 WL 8445125, at *4 (E.D. Ark. June 26, 2006). This is especially true here, given Plaintiffs' interest in avoiding "elevated risks of severe and gratuitous pain from administration of pentobarbital absent the requisite statutory safeguards . . . outweighs the government's interest in proceeding with the executions as scheduled without obtaining the required prescriptions." (Pillard, J. concurring in part and dissenting in part, at 6-7.) Indeed, the district court emphasized that it "is deeply concerned that the government intends to proceed with a method of execution that this court and the Court of Appeals have found violates federal law." A9.

Although Defendants argue that "last-minute" stays of execution should be treated as an exception, as the district court explained, the timing in this instance could not be avoided, given that the D.C. Circuit issued its decision and mandate only yesterday and the district court promptly issued its order this morning. A10. In so doing, the district

court also emphasized that it "would not issue a stay were it not convinced that the Plaintiff has presented claims that had a substantial possibility of succeeding." (*Id.*) In light of these circumstances, including Defendants' intentions to proceed with executions in clear and proven violation of law, as well as the court's strong expressed belief that Plaintiffs will succeed on their claim, the equities squarely favor enjoining Plaintiff Hall's execution.

These factors also far outweigh any assertion that finality must come in this case right now. For seventeen years, Defendants did not execute or seek to execute any death-sentenced prison-ers, including Plaintiff Hall, who timely intervened in the litigation in 2007. Once Defendants announced their intent to do so, Plaintiffs swiftly moved for relief at all stages of this litigation, as Judge Pillard expressly recognized. (See Pillard, J. concurring in part and dissenting in part, at 6 ("It is difficult to see what more plaintiffs might have done to obtain earlier rulings on the mer-its of their claims. Time that the government and the courts have reasonably required cannot weigh against plaintiffs' entitlement to a permanent injunction."). A relatively short stay to allow Plaintiff Hall to fully and fairly litigate the merits of his claims will not

substantially injure either the public or Defendants where, as here, Defendants' newfound urgency emerged only after nearly two decades of inaction. *See Oscorio-Martinez*, 893 F.3d at 179 ("[T]he fact that the Government has not—until now—sought to remove SIJ applicants, much less designees, undermines any urgency surrounding Petitioners' removal.").

Finally, Defendants' argument that "more than 1000 inmates have been executed by lethal injection" in violation of the FDCA (Br. 11-12) is no answer at all. The D.C. Circuit has now ruled definitively that Defendants' use of pentobarbital to carry out executions without obtaining a valid medical prescription is unlawful. The Government's blatant disregard for that ruling and the statutory requirements to which it must comply should not be countenanced. *See League of Women Voters*, 838 F.3d at 12 ("There is generally no public interest in the perpetuation of unlawful agency action."); *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").

B. The Unresolved Issues of the FDCA's Applicability to Lethal Injection Drugs and Cognizability under the Administrative Procedure Act Do Not Justify Summary Vacatur

The government also seeks vacatur based upon an issue on which Mr. Hall and his fellow plaintiffs prevailed in the D.C. Circuit: that the Federal Food, Drug and Cosmetics Act (FDCA) applies to drugs used for lethal injection and that private parties may sue under the APA to prevent violations of the APA. *See In re Federal Bureau of Prisons Execution Protocol Cases*, No. 20-5329, 2020 WL 6750375, at *10 (D.C. Cir. Nov. 18, 2020). As the court below noted, Applicants prevailed on both of these issues due to established and longstanding D.C. Circuit precedent. *See id.* (citing *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013); *Chaney v. Heckler*, 718 F.2d 1174, 1179-1182 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985)). The government's Application shows that the question of the proper interpretation of the FDCA is an important issue of statutory interpretation that has implications beyond the precise circumstances here—including implications for the FDCA's importation provisions, as well as (in the government's view) other means of execution. App'n at 5-6. Comprehensive statutory schemes such as the FDCA are applied across myriad contexts. Any

decision about the application of the FDCA that could have broad consequences, including outside the lethal injection context, should not be made absent a decision by this Court that plenary review is warranted, and after the opportunity for that plenary review.

In the context of the FDCA's application to drugs used for lethal injection, the government's Application again makes clear the appropriateness of plenary Supreme Court review. While the D.C. Circuit has long held that drugs used for lethal injection are subject to the FDCA, *see Cook* 733 F.3d at 10-11, Applicants note that Judge Rao took the opposite position below (and that the OLC did so earlier this year), *see* App'n at 5-6, 19. And as the court below stated, this Court "has never resolved 'the thorny question of the FDA's jurisdiction" over the drugs used in lethal injections.'" *Heckler v. Chaney*, 470 U.S. 821, 828 (1985) (citation omitted). The Government recently made clear that it believes that plenary review on this issue is warranted: "This Court may wish to clarify that denial of injunctive relief on applicants' FDCA claim is appropriate . . . because there is no FDCA violation here at all." No. 20-A99 Op. 38. Mr. Hall agrees that this important and unresolved issue is worthy of this Court's attention, but certainly not in

a per curiam decision reached without the benefit of this Court's typical determination regarding whether plenary review is warranted and then the deliberate consideration such plenary review makes possible. The Application thus demonstrates that the proper course is to uphold the District Court's injunction in order to permit the orderly litigation of Mr. Hall's claims, including the possibility of this Court's full review.

Finally, the government asks this Court, without full briefing or argument, to vacate the district court's injunction on the sweeping ground that private individuals lack a cause of action under the APA to challenge a violation of the FDCA. App'n at 6-7, 19. Mr. Hall prevailed on this issue, too, in the D.C. Circuit. Moreover, the government's argument would have broad implications outside the context of challenges to a lethal injection protocol, and the D.C. Circuit was disturbed enough by those arguments to request a supplemental letter from the government explaining the reach of its contentions. *See* No. 20-5329, (D.C. Cir.), 11/17/2020 letter from U.S. But as this Court has made clear, the bar is exceptionally high for determining that a statutory scheme has precluded review, and the Court instead applies a

"presumption favoring judicial review of administrative action." *Sackett v. EPA*, 566 U.S. 120, 128 (2012). At minimum, the Court should consider whether plenary review is warranted before preemptively holding, as the government urges, that no private party can *ever* bring suit to challenge an action that violates the FDCA.

CONCLUSION

For the foregoing reasons, the Court should deny the emergency motion to stay or immediately vacate the District Court's injunction barring the execution of Mr. Hall.

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Respectfully submitted,

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