

No. 20A99

**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

REPLY IN SUPPORT OF STAYS OF EXECUTION

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

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For the benefit of the Court, and in the interest of time, Applicants address only Respondents’ arguments in Sections I.A (Opp. 19-26) and I.B (Opp. 26-29) of their stay opposition, which urge this Court to deny the requested stays on alternate grounds—grounds on which the court of appeals ruled against Respondents. With respect to the issues addressed in Applicants’ Stay Application, Applicants rest on the arguments made therein.

Applicants prevailed in the D.C. Circuit on their arguments 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* App. 23a-25a. As the court below noted, Applicants prevailed on both of these issues due to established and longstanding D.C. Circuit precedent. *See* App. 24a (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)). As respondents themselves note in their opposition (at 19), the FDCA creates a “complex set of requirements to ensure that every ‘drug or device’ subject to the statute is ‘safe and effective’ for its intended use.” Respondents’ opposition 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. Opp. 21-23. 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 opportunity for that plenary review.

In the context of the FDCA’s application to drugs used for lethal injection, Respondents’ opposition again makes clear the necessity of 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, Respondents note that OLC has taken the opposite position, *see Resp. App.* 1a-26a. 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). Respondents made clear in their Opposition that they believe that 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.” Op. 38. Applicants agree 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. Respondents’ opposition thus demonstrates that the proper course is to grant the stay motion to permit Applicants to file a petition for a writ of certiorari— at which point the Government will be free to raise its FDCA issues in a cross-petition.

Similarly, the government asks this Court, without full briefing or argument, to reverse the D.C. Circuit and provide a sweeping ruling that private individuals lack a cause of action under the APA to challenge a violation of the FDCA. Opp. 26-29. 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 presumptively holding, as the government urges, that no private party can *ever* bring suit to challenge an action that violates the FDCA.

As Respondents' Opposition makes clear, both Applicants and Respondents believe that the D.C. Circuit made errors that warrant this Court's intervention. For that reason, the Court should grant Applicants' Stay Application and allow all parties to seek certiorari on the weighty issues presented by the decision below.

CONCLUSION

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

Dated: November 19, 2020

Respectfully submitted,

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