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.

(CAPITAL CASE)

REPLY IN SUPPORT OF 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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This Court made clear -- yesterday, in this case -- that last-minute stays or injunctions blocking executions are permissible only as an "extreme exception." No. 20A8, at 3 (quoting Bucklew v. Precythe, 139 S. Ct. 1112, 1134 (2019)). The district court disregarded that direction today, issuing another admittedly "last minute" injunction of respondents' executions that has even less support in the law and the equities than the injunction this Court vacated yesterday. Appl. App. 16a. Indeed, respondents make no attempt to explain how allowing today's injunction to remain in place would be consistent with this Court's decision yesterday. They instead rely (Opp. 1, 17) on (1) the D.C. Circuit's prior denials of earlier government applications, one of which this Court

abrogated yesterday; and (2) a Seventh Circuit stay granted in respondent Purkey's case, which this Court vacated this afternoon, see No. 20A4. Respondents again have "not established that they are likely to succeed on the merits of their claim" -- an implausible claim that would mean that hundreds of state executions (and all recent federal executions) were unlawful because they were carried out using drugs that lacked a prescription. No. 20A8, at 1-2. Respondents' suggestion (Opp. 13-16) of potential affirmance on an alternative ground that even the district court was unwilling to adopt as a fourth rationale for enjoining the protocol, see Appl. App. 7a-9a, plainly lacks merit. And the equities supporting today's injunction are far weaker than those that purportedly supported the injunction vacated yesterday, because respondents' claims here involve at most an alleged technical legal violation rather than any alleged risk of pain. For the same reasons that it did so yesterday, this Court should vacate the district court's injunction so that respondents' "executions may proceed as planned." No. 20A8, at 3.

1. On the merits, respondents' position is irreconcilable with this Court's decisions in FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000), and Heckler v. Chaney, 470 U.S. 821 (1985), for the reasons detailed at length in the Office of Legal Counsel (OLC) opinion discussed in the government's stay

application that neither respondents nor the district court attempted to refute. See Appl. App. 19a-44a.

a. At bottom, respondents contend that lethal-injection drugs are within the ambit of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 et seq., because such drugs are (in their view) used for a "specific medical purpose," Opp. 12. This argument confuses the government's responsible decision to choose a lethal substance that minimizes pain with the existence of the "therapeutic purpose" required by the FDCA. Brown & Williamson, 529 U.S. at 143. Drugs intended to cause death have no such purpose, yet Congress' decision nevertheless to enact the Federal Death Penalty Act of 1994 (FDPA), 18 U.S.C. 3591 et seq., at a time when lethal injection was the prevailing execution method in the States and the federal government, see 57 Fed. Reg. 56,536, 56,536 (Nov. 30, 1992), makes clear that lethal-injection drugs "cannot be banned," Brown & Williamson, 529 U.S. at 143. Like the tobacco products in Brown & Williamson, lethal-injection drugs "simply do not fit" under the FDCA. Ibid.

The district court's contrary holding that the FDCA provisions assuring the safety and efficacy of drugs apply to substances intended to implement capital punishment finds no support in the law or common sense. Not only would respondents' position mean that hundreds of state executions (and all recent federal executions) were unlawful because they were carried out

using drugs that lacked a prescription, but it would also lead to the surprising conclusion that articles used in executions such as electric chairs and perhaps even rifles may also be regulated under the FDCA. Simply put, respondents' view, if adopted, would render implementing the death penalty impossible. That cannot be the law. See Appl. App. 19a-44a.

b. In addition, respondents' claim fails for the separate and independent reason that they cannot seek relief under the FDCA because its provisions are not enforceable by private parties. See Appl. 25-27. In particular, 21 U.S.C. 337(a) makes clear that "all" enforcement actions "to restrain violations" of the Act "shall be by and in the name of the United States." Under this Court's precedent, that kind of language squarely forecloses private-party enforcement, whether directly under the statute or through the backdoor of an APA action. See Block v. Community Nutrition Inst., 467 U.S. 340, 351 (1984).

Respondents have no answer to that point, and do not even cite Section 337 or Block. That is also why respondents' heavy reliance (Opp. 9) on Cook v. FDA, 733 F.3d 1 (D.C. Cir. 2013), is misplaced: as the government has explained (Appl. 27-29), the D.C. Circuit in Cook had no occasion to address whether private parties could enforce FDCA against alleged regulated parties, because the plaintiffs there instead sought to require the FDA to

take action against another party. Cook thus provides no support for respondents' unprecedented claim here.

2. Respondents alternatively ask this Court (Opp. 14-18) to maintain the injunction based on grounds that the district court rejected, specifically that the government's adoption of a widely used lethal-injection protocol approved by this Court was arbitrary and capricious. See Appl. App. 7a-9a. As an initial matter, respondents' assertion cannot be squared with this Court's order yesterday vacating an injunction against the protocol that was based on the Eighth Amendment. No. 20A8. There, the Court offered the following facts about the pentobarbital protocol the government adopted, which "has become a mainstay of state executions." Id. at 2. The Court explained that pentobarbital:

- Has been adopted by five of the small number of States that currently implement the death penalty.
- Has been used to carry out over 100 executions, without incident.
- Has been repeatedly invoked by prisoners as a less painful and risky alternative to the lethal injection protocols of other jurisdictions.
- Was upheld by this Court last year, as applied to a prisoner with a unique medical condition that could only have increased any baseline risk of pain associated with pentobarbital as a general matter (citing Bucklew, supra)

- Has been upheld by numerous Courts of Appeals against Eighth Amendment challenges similar to the one presented here. See, e.g., Whitaker v. Collier, 862 F. 3d 490 (CA5 2017); Zink v. Lombardi, 783 F. 3d 1089 (CA8 2015); Gissendaner v. Commissioner, 779 F. 3d 1275 (CA11 2015).

No. 20A8, at 2. Respondents' claim that the government acted arbitrarily and capriciously in adopting this well-vetted, humane protocol blinks reality.

Respondents also recast their now-rejected claims that various aspects of the execution protocol violate the Eighth Amendment as an arbitrary-and-capricious claim, contending that the federal Bureau of Prisons (BOP) failed to consider their particularized grievances, and that this failure renders the protocol unlawful. Compare D. Ct. Doc. 102, at 21-27 (respondents' motion for a preliminary injunction, arguing that the protocol violates the Eighth Amendment because of the possibilities that pentobarbital will cause pain due to pulmonary edema, that complications with IV lines will arise, and that compounded pharmacies will prove unreliable), with id. at 5-20 (contending that BOP unlawfully failed to consider the possibilities that pentobarbital will cause pain due to pulmonary edema, that complications with IV lines will arise, and that compounded pharmacies will prove unreliable). As even the district court correctly recognized, none of these alleged failure-to-consider

arguments "rises to the level of arbitrariness or capriciousness for an APA violation." Appl. App. 8a.

BOP more than satisfied the APA's deferential standard of review by "articulat[ing]" multiple "satisfactory explanation[s] for its action" in adopting the federal protocol. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Because "[n]o federal execution ha[d] occurred since 2003," A.R. 869, the agency began by "[b]enchmarking" against state protocols, A.R. 930, a touchstone that respondents themselves have urged should guide the federal government, see Pet. at 21, Bourgeois v. Barr, No. 19-1348 (June 5, 2020). Next, BOP considered the protocol's legality and confirmed that "pentobarbital is litigation tested." A.R. 932. Further, BOP consulted with medical professionals and reviewed publicly available expert testimony concerning pentobarbital and other lethal agents. See A.R. 401-524, 527-761, 931. And finally, before completing its selection, BOP confirmed the availability of a reliable supply of pentobarbital. See A.R. 871-872 (noting that BOP "disfavored" a three-drug protocol "because of the complications inherent in obtaining multiple drugs").

Despite all this, respondents contend (Opp. 13-16) that BOP's decision falls below the APA's floor of reasoned decision-making, arguing that BOP failed to consider several issues in developing the protocol, all of which pertain to respondents' allegations

regarding the risk of unnecessary pain. As noted, that is a topic the agency assuredly did consider, looking to judicial acceptance of similar protocols, soliciting medical expert opinions, and surveying States' widespread use of similar protocols without incident. BOP did not "entirely failed to consider an important aspect of the problem," State Farm, 463 U.S. at 43, merely because respondents disagree with BOP's balancing of the need to avoid pain during an execution with the many other considerations before it -- such as the feasibility of obtaining various lethal agents, see A.R. 870-872; the need to "minimize[] * * * negative impact[s] on the safety, security, and operational integrity of the correctional institution in which [executions] occur[]," A.R. 1020; and the "privacy interests of those persons for whom the law and BOP policy requires such privacy," A.R. 1020. To the contrary, the fact that BOP struck the same balance as the States that conduct the most executions strongly indicates that BOP acted entirely rationally. See No. 20A8, at 2.

Unable to demonstrate that BOP did not consider the humaneness of the execution protocol or risk of needless pain thereunder, respondents focus on their more granular pain-related complaints about the protocol that they claim the agency did not consider with sufficient specificity -- namely, (1) the risk of flash pulmonary edema, (2) the risk of faulty IV insertion, and (3) the risks associated with using compounding pharmacies to obtain

pentobarbital. But a party unhappy with an agency's choice may not invalidate it simply by identifying narrower subtopics on a matter the agency considered in making a rational choice. On the contrary, even in a proceeding in which the public has a right to participate -- unlike the adoption of the procedural rule here – "[t]he agency need only state the main reasons for its decision and indicate that it has considered the most important objections." Simpson v. Young, 854 F.2d 1429, 1434-35 (D.C. Cir. 1988) (emphasis added); cf. Public Citizen, Inc. v. FAA, 988 F.2d 186, 197 (D.C. Cir. 1993) (explaining that during notice-and-comment rulemaking, "the agency's response to public comments need only enable us to see what major issues of policy were ventilated * * * and why the agency reacted to them as it did") (citation omitted). Procedural rules governing only the agency's own "internal house-keeping measures" such as the federal protocol, 955 F.3d 106, 145, certainly require no greater level of specificity.

Respondents' proposed level of scrutiny would be particularly anomalous as applied to agency action exempt from notice-and-comment requirements. In such situations, the public does not provide the agency with ex ante notice of the issues it thinks should be considered in making a decision -- rather, the agency must identify and address issues sua sponte. It is thus unsurprising that courts give agencies considerable deference in determining which issues to explicitly take into account. See

Pension Ben. Guar. Corp. v. LTV Corp., 496 U.S. 633, 645-646 (1990) (rejecting courts of appeals' conclusion that an agency's decision in an informal adjudication was arbitrary and capricious because the "record did not reflect thorough and explicit consideration" of three arguably relevant "bodies of law"). Litigants unhappy with the agency's choices will always be able to raise after-the-fact, subsidiary issues the agency did not expressly address in the administrative record. If such objections sufficed to render an agency's decision arbitrary and capricious, it could become virtually impossible to proceed through any form of rulemaking outside the APA's notice-and-comment procedures, contrary to Congress's express authorization, see, e.g., 5 U.S.C. 553(b). See LTV Corp., 496 U.S. at 646 ("If agency action may be disturbed whenever a reviewing court is able to point to an arguably relevant statutory policy that was not explicitly considered, then a very large number of agency decisions might be open to judicial invalidation."). Indeed, Congress made the notice-and-comment requirements inapplicable in certain circumstances precisely because it recognized a need for the agency to be able to act quickly and nimbly with respect to the exempted types of rules. See Batterton v. Marshall, 648 F.2d 694, 707 (D.C. Cir. 1980) (explaining that the procedural-rule "exception was provided to ensure that agencies retain latitude in organizing their internal operations"); Guardian Federal Sav. and Loan Ass'n v. Federal Sav.

and Loan Ins. Corp., 589 F.2d 658, 662 (D.C. Cir. 1978). Respondents' expansive failure-to-consider theory, permitting invalidation by virtue of post hoc identification of narrow issues, defies this congressional design.

Instances where courts have deemed agency action arbitrary and capricious for failure to consider an aspect of a problem involve wholesale failure to consider a highly generalized issue at all. See State Farm, 463 U.S. at 51. Such decisions provide no support for respondents' suggestion that courts can invalidate agency choices by demanding that the agency consider ever more specific subtopics -- a rule that would provide a ready-made route to force delay and reconsideration of virtually any agency action.

3. Finally, the equities overwhelmingly favor a stay or vacatur of the injunction. Respondents were convicted of horrific crimes more than 15 years ago, and their executions have already been delayed once for six months by a legally unwarranted injunction. Declining to stay or vacate the injunction issued today -- the district court's third in this case, following this Court's vacatur of its second yesterday -- would likely produce many more months of delay for no valid reason. Respondents have received extensive review of their convictions and sentences, which they do not challenge here. They received thorough appellate proceedings on the statutory claim that was the district court's first choice for an injunction. And the FDCA claim at issue here,

which involves at best an asserted technical legal violation, is so unmeritorious that further review would not serve any meaningful purpose. At this point, "no more delay is warranted." United States v. Lee, No. 97-cr-24 (E.D. Ark. July 10, 2020), slip op. 9. The government is prepared to implement the sentence in a humane and dignified way. The father and other loved ones of Jennifer Long, the teenage girl raped and murdered by respondent Purkey more than 20 years ago, are now in Terre Haute waiting to witness the implementation of the sentence imposed long ago. They have waited long enough.

Although respondent Purkey had previously suggested that federal regulations or the protocol posed an obstacle to executing him after midnight today, he now appears to concede (Opp. 20) that nothing in the "letter" of the regulations, or even the nonbinding protocol, actually prevents the government from designating tomorrow as his execution date if the last-minute injunctions entered by the district court are vacated by this Court late in the evening. That concession is well founded. As explained in the government's application (at 36-38), the regulations plainly allow the BOP Director to designate a new execution date -- including the next day -- if the initially scheduled date passes by reason of a stay. 28 C.F.R. 26.3(a). The protocol does not contain any contrary direction. And in all events, the protocol both specifically permits "deviation or adjustment" when

"required, as determined by the Director of the BOP or Warden," and further provides that it "explains internal government procedures and does not create any legally enforceable rights or obligations." A.R. 1019; see 955 F.3d at 129 (Rao, J., concurring) (explaining that the protocol is "non-binding"); see also id. at 125-126 (Katsas, J., concurring) (likewise explaining that the protocol permits deviation).

Respondents' ambiguous suggestion (Opp. 20) that "the spirit" of the regulations or the protocol might be violated by rescheduling his execution for tomorrow if necessary is both irrelevant and mistaken. Respondents' executions were scheduled a month or more ago, and they have had more than adequate time to "designate witnesses and contact spiritual leaders." Ibid. Those individuals may or may not have chosen to attend Purkey's execution this evening, and if there, they may or may not choose to wait for it to occur after midnight. But the purpose of the notice regulations -- and, more important, their actual requirements -- poses no obstacle to executing respondent Purkey tomorrow if this Court does not vacate the relevant injunctions until after midnight. Particularly given that the family members of Purkey's victim are waiting in Terre Haute, the government will follow that course if necessary.*

* In describing Daniel Lee's execution, respondents falsely state (Opp. 20) that the government "strap[ped] [Lee] to a gurney notwithstanding that there were multiple court orders prohibiting his execution." That is flatly untrue. After this

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For the foregoing reasons and those stated in the government's application for a stay or vacatur, the district court's injunction should be stayed or vacated effective immediately.

Respectfully submitted.

JEFFREY B. WALL
Acting Solicitor General

JULY 2020

Court allowed Lee's execution to proceed and BOP initiated execution proceedings, Lee's counsel asserted in the wee hours of the morning for the first time that a stay from the District Court for the Eastern District of Arkansas was still in place. But that stay had been vacated by the Eighth Circuit on June 1, 2020. See United States v. Lee, No. 19-3618. The stay order was therefore no longer operative as of that date, and once this Court vacated the preliminary injunction entered July 13 by the district court in this case, see No. 20A8, no impediments prevented Lee's execution. Indeed, until the early hours of July 14, that was the parties' shared understanding, as demonstrated by Lee's representations to this Court on July 13 that granting the government's requested relief would permit his and other "executions to proceed" as scheduled that day. Opposition at 1, No. 20A8. Lee's counsel nevertheless asserted -- after execution proceedings had commenced -- that the vacated stay remained in effect because the Eighth Circuit's mandate was not scheduled to issue until July 16, 2020. The government continues to dispute that untimely and mistaken premise: the Eighth Circuit's vacatur, no less than this Court's July 14 vacatur, was immediately effective. The government, however, awaited the Eighth Circuit's issuance of the mandate before it carried out Lee's execution. That caution only underscores the government's commitment to carrying out its solemn responsibility to implement capital sentences in an orderly, lawful, and dignified way.