Nos. 23-235, 23-236

IN THE

Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

ON WRITS OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF OF *AMICI CURIAE* SOUTHEASTERN LEGAL FOUNDATION AND TEXAS PUBLIC POLICY FOUNDATION IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

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The Texas Public Policy Foundation is a nonprofit, nonpartisan research foundation dedicated to promoting and defending liberty, personal responsibility, and free enterprise throughout Texas and the nation. For decades, TPPF has worked to advance these goals through research, policy advocacy, and impact litigation. In pursuit of its broad mission, TPPF has advocated against unconstitutional judicial deference to unelected bureaucrats through its litigation, in cases such as *BST Holdings, L.L.C. v. OSHA*, 17 F.4th 604

[1] Pursuant to this Court's Rule 37.6, counsel for *amici curiae* certify that this brief was not authored in whole or in part by counsel for any party and that no person or entity other than *amici curiae* or its counsel has made a monetary contribution to the preparation or submission of this brief.

(5th Cir. 2021); its public advocacy, both in Texas and across the country; and *amicus* briefs such as this one.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

In 1996, the Population Council—a nonprofit founded to combat alleged "overpopulation"—filed a new drug application with the Food and Drug Administration for mifepristone as "part of a two-drug regimen designed to cause abortion." Pet. App. 6a. In 2000, FDA approved mifepristone under Subpart H, which allows expedited approval of drugs treating "serious or life-threatening illnesses." 21 C.F.R. 314.500. Because of the accelerated approval process, FDA imposed certain post-approval restrictions. Among other things, these restrictions capped the maximum gestation age for drug administration at seven weeks, required three in-office visits to administer the drugs and monitor for complications, and required prescribers to report adverse events.

In 2002, the Alliance for Hippocratic Medicine filed a petition with FDA challenging the 2000 mifepristone approval. The law required FDA to respond to that petition within "180 days of receipt." 21 C.F.R. §10.30(e)(2). But not until 2016—nearly fourteen years later—did it reject the petition. On the same day as that rejection, FDA also loosened many of the original restrictions it had imposed on the chemical abortion regimen.

In March 2019, the Alliance filed a new petition challenging the 2016 loosening of the safety restrictions. Two years later, FDA announced that it would allow mifepristone to be dispensed through the

mail during the COVID pandemic. And later that year, FDA finally denied most of the Alliance's 2019 petition. The Alliance then filed suit seeking to set aside the FDA's actions.

Ruling for the Alliance, the district court stayed the effective dates of FDA's 2000 approval of mifepristone and all subsequent challenged actions related to that approval under section 5 of the APA. 5 U.S.C. §705; Pet. App. 194a-95a. The Fifth Circuit affirmed that relief in part. App. 43a-44a.

Staying the effective date of FDA's unlawful actions under section 705 of the APA was an appropriate remedy. Section 705 expressly authorizes courts to "postpone the effective date of an agency action." 5 U.S.C. §705. It separately authorizes the agency to do the same. *Id.* FDA reads section 705 to "require[] that any postponement be contemporaneous with or predate the effective date of the challenged agency action." FDA Br. at 45. But FDA's myopic focus on the word "postpone" is unpersuasive. Only agencies themselves may not stay already effective agency actions under section 705. For good reason: if agencies could stay already-effective actions, they could evade the notice-and-comment process that would otherwise be required to modify or suspend a regulatory action that is already in force. Unlike agencies, however, courts may and do stay already-effective agency action.

Yet even if this Court accepts FDA's reading of "postpone," it should give effect to section 705's full text. Section 705 "confers a broader authority on reviewing courts" than on agencies. *Ctr. for Biological Diversity v. Regan*, 597 F. Supp. 3d 173, 205 (D.D.C. 2022). It empowers courts "to postpone the effective

date ... *or* to preserve status or rights pending conclusion of the review proceedings." *Id.* And, unlike an agency, a court may "issue *all* necessary and appropriate process" to do so. 5 U.S.C. §705. A stay of an agency action already in effect fits comfortably within that power.

Finally, a stay is the correct remedy because the Alliance ultimately seeks to set aside or vacate the FDA's actions. Just as a district court has authority to enter a preliminary injunction as "the temporary form of a permanent injunction," it may also enter a stay as "the temporary form of vacatur." Pet. App. 70a. Because vacatur is a "less drastic remedy" than an injunction, the lower courts were well within their power to choose it. Pet. App. 70a (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010)).

ARGUMENT

I. Staying the effective date of FDA's unlawful actions under section 705 of the APA was an appropriate remedy.

A. Section 705 allows courts to stay already-effective agency actions and courts routinely do so.

The "[c]onventional wisdom is that §705 authorizes a stay." Frank Chang, *The Administrative Procedure Act's Stay Provision: Bypassing Scylla and Charybdis of Preliminary Injunctions*, 85 Geo. Wash. L. Rev. 1529, 1546 (2017). Before the APA, this Court recognized stays of agency action as "part of" the federal courts' "traditional equipment for the administration of justice." *Scripps-Howard Radio, Inc. v. FCC*,

316 U.S. 4, 9-11 (1942). The APA then codified the existing equitable powers of federal courts to stay agency actions. *See Sampson v. Murray*, 415 U.S. 61, 68 & n.15 (1974) (explaining section 705 "was primarily intended to reflect existing law"); Tom C. Clark, *Att'y Gen's Manual on the Administrative Procedure Act* 105 (1947) (noting "the function" of section 705 was "to make judicial review effective").

Section 705 comprises two sentences, each discussing the types of interim relief a specified actor may grant while a challenge to an agency action is pending. The first sentence provides an agency itself with the power to grant interim relief pending judicial review by postponing the effective date of an agency action. *See* 5 U.S.C. §705 ("When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review.").

The second sentence describes the powers of "the reviewing court" to similarly "postpone the effective date of an agency action." *Id.* But it also provides courts the additional power to "issue all necessary and appropriate process" "to preserve status or rights pending conclusion of the review proceedings." *Id.* ("On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.").

As the district court concluded, this language "plainly authorizes" a court to stay an agency action—

even after the effective date. Pet. App. 194a. It "confers upon every 'reviewing court' discretionary authority to stay agency action pending judicial review 'to the extent necessary to prevent irreparable injury.'" Clark, *supra*, 105; *see also In re GTE Serv. Corp.*, 762 F.2d 1024, 1026 (D.C. Cir. 1985) (section 705 provides "statutory authority to stay agency orders pending review"); *Mexichem Specialty Resins, Inc. v. EPA*, 787 F.3d 544, 562 (D.C. Cir. 2015) (Kavanaugh, J., dissenting in part) ("Section 705 of the APA authorizes courts to stay agency rules pending judicial review without any time limit on the duration of the stay.").

Yet FDA argues a stay is the wrong remedy. It contends that a court cannot "postpone" the "effective date of actions that became effective years before the litigation began." FDA Br. at 45. In the government's view, section 705 "requires that any postponement be contemporaneous with or predate the effective date of the challenged agency action; otherwise there would be no way for a court to postpone that effective date." *Id.* But FDA's myopic focus on the word "postpone" is unpersuasive. *See, e.g., Meeker v. Lehigh Valley R. Co.*, 236 U.S. 412, 424-425 (1915) (describing how Congress "postponed" the effective date of a statute after that date had passed). Only agencies themselves may not stay already-effective agency actions under section 705. "[O]nce a rule has taken effect, the *agency* can no longer 'put off' the effective date; it can only rescind or modify it." *Ctr. for Biological Diversity*, 597 F. Supp. 3d at 205 (emphasis added).

That the APA gives courts—but not agencies—the power to stay already-effective agency actions makes sense. First, this "greater limitation on agencies exists

because 'agencies are creatures of statute'" and "'possess only the authority that Congress has provided.'" *Texas v. Biden*, 646 F. Supp. 3d 753, 770 (N.D. Tex. 2022), *appeal dismissed*, No. 23-10143, 2023 WL 5198783 (5th Cir. May 25, 2023) (quoting *Nat'l Fed'n of Indep. Bus. v. OSHA*, 142 S. Ct. 661, 665 (2022)).

Second, if agencies could stay already-effective actions, they could evade the notice-and-comment process that would otherwise be required to make changes to an extant rule or policy. *See, e.g., Ctr. for Biological Diversity*, 597 F. Supp. 3d. at 204 ("[I]t is one thing to permit an agency to stay an administrative decision pending judicial review in order to maintain the status quo, but something altogether different to alter the status quo without providing an opportunity for notice and comment."). Indeed, an agency order "delaying [a] rule's effective date … [is] tantamount to amending or revoking a rule[,]" which must go through notice and comment. *Clean Air Council v. Pruitt,* 862 F.3d 1, 6 (D.C. Cir. 2017).

Unlike agencies, courts may—and routinely do—stay already-effective agency actions. *See, e.g.*, *West Virginia v. EPA*, 577 U.S. 1126 (2016) (staying EPA's Clean Power Plan after 29 states moved for a stay under section 705); *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1135 (5th Cir. 2021); *Texas v. EPA*, 829 F.3d 405, 410-11 (5th Cir. 2016); *Texas v. Biden*, 646 F. Supp. 3d at 771; *Cath. Legal Immigr. Network, Inc. v. Exec. Office for Immigr. Rev.*, No. 21-00094, 2021 WL 3609986 at *4 (D.D.C. Apr. 4, 2021). And even when courts do not explicitly cite section 705, they may use their equitable powers to issue a stay. *See Nken v. Holder*, 556 U.S. 418, 421 (2009); *see*

also Holland v. Florida, 560 U.S. 631, 646 (2010) (noting courts do "not construe a statute to displace courts' traditional equitable authority absent the clearest command.") (cleaned up). Indeed, the All Writs Act "'preserves' courts' authority to issue such stays." *Texas*, 646 F. Supp. 3d at 771; 28 U.S.C. §1651(a).

Even if this Court accepts FDA's reading of "postpone," it should give effect to section 705's full text. *See U.S. Dep't of Energy v. Ohio*, 503 U.S. 607, 630 (1992) (White, J., concurring in part) ("It is axiomatic that a statute should be read as a whole."). Section 705 "confers a broader authority on reviewing courts" than on agencies. *Ctr. for Biological Diversity*, 597 F. Supp. 3d at 205. It empowers courts "to postpone the effective date ... *or* to preserve status or rights pending conclusion of the review proceedings." *Id.* And, unlike an agency, a court may "issue *all* necessary and appropriate process" to do so. 5 U.S.C. §705. Because "Congress use[d] different language in the very same section" of the statute to give courts broader powers, this Court "should assume that it intended that difference to have some meaning." *Ctr. for Biological Diversity*, 597 F. Supp. 3d at 205. A stay of an agency action already in effect fits comfortably within that power.

B. Because the Alliance ultimately seeks vacatur, a stay was an appropriate remedy.

A stay is the correct remedy because the Alliance ultimately seeks to set aside or vacate the FDA's actions. Just as a district court has authority to enter a preliminary injunction as "the temporary form of a permanent injunction," it may also enter a stay as "the temporary form of vacatur." Pet. App. 70a.

Stays and preliminary injunctions are not "one and the same." *Nken*, 556 U.S. at 434. Indeed, they differ in a crucial way: "stays act on the *proceeding*" while "preliminary injunctions act on the *person*." Chang, *supra*, at 1546; *see also Nken*, 556 U.S. at 428 ("[A]n injunction is a judicial process or mandate operating *in personam*" (quoting 1 H. Joyce, *A Treatise on the Law Relating to Inunctions* §1 (1909)); *Nken*, 556 U.S. at 428 (an injunction "tells someone what to do or not to do … [,] directs the conduct of a party, and does so with the backing of [the court's] full coercive powers"); *id.* at 428 (a stay "halt[s] or postpone[s] some portion of the proceeding" or "temporarily divest[s] an order of enforceability" (citing *Stay*, Black's Law Dictionary 1413 (6th ed. 1990)). So while both an injunction and a stay can prevent "some action before the legality of that action has been conclusively determined[,]" an injunction "direct[s] an actor's conduct" but a stay "temporarily suspend[s] the source of authority to act." *Nken*, 556 U.S. at 428-29.

Suspending FDA's authority to act is the Alliance's goal here. "[U]nsupported agency action normally warrants vacatur." *Advocs. for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151 (D.C. Cir. 2005). And the "ordinary practice" is to "vacate unlawful agency action." *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019). Vacatur "does not order the defendant to do anything; it only removes the source of the defendant's authority." Pet. App. 70a (citing *Nken*, 556 U.S. at 428-29). Indeed, "[w]hen a court holds on the merits that a rule is unlawful and should be 'set aside,' the rule is vacated, and thereafter cannot be applied to anyone." Mila Sohoni, *The Power to Vacate*

a Rule, 88 Geo. Wash. L. Rev. 1121, 1131 (2020) (citing *Action on Smoking & Health v. Civil Aeronautics Bd.*, 713 F.2d 795, 797 (D.C. Cir. 1983) ("To 'vacate,' as the parties should well know, means 'to annul; to cancel or rescind; to declare, to make, or to render, void; to defeat; to deprive of force; to make of no authority or validity; to set aside.'")). Because vacatur is a "less drastic remedy" than an injunction, the lower courts were well within their power to choose it. Pet. App. 70a (quoting *Monsanto Co.*, 561 U.S. 139 at 165 (2010)).

CONCLUSION

For these reasons, the Court should affirm the decision below.

Respectfully submitted,

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