No. 23-10362

In The
United States Court of Appeals for the Fifth Circuit

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,

Plaintiffs-Appellees,

v.

FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, Commissioner of Food and Drugs; JANET WOODCOCK, M.D., in her official capacity as Principal Deputy

(Caption continued on inside cover)

On Appeal from the United States District Court
for the Northern District of Texas (No. 2:22-cv-00223-Z)

BRIEF OF THE STATE OF WEST VIRGINIA AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES' OPPOSITION TO A STAY PENDING APPEAL

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April 11, 2023

Commissioner, U.S. Food and Drug Administration; PATRIZIA CAVAZZONI, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services,

Defendants-Appellants,

&

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellant.

CERTIFICATE OF INTERESTED PERSONS

Under this Court's Rule 28.2.1, governmental parties need not furnish a certificate of interested persons.

/s/ Peter D. Lepiscopo
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April 11, 2023

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INTRODUCTION AND INTERESTS OF AMICUS CURIAE

The *amicus* State of West Virginia submits this brief to highlight the constitutional scope of and limits upon power granted to the Food and Drug Administration ("FDA"), an issue of particular relevance to West Virginia's sovereignty. Similarly, other *amici* States have explained numerous issues relating to their particular sovereignty issues and concerns attending the relevant actions of the Food and Drug Administration. Finally, in this brief, the *amicus* State of West Virginia further addresses the limits of FDA's authority vis-à-vis abortion medications and their use.

No counsel for a party authored this brief in whole or in part. No person other than amicus curiae and its counsel made any monetary contribution intended to fund the preparation or submission of this brief.

ARGUMENT

FDA does not have the authority to set national abortion policy.

It is blackletter law that FDA—like any other federal agency—has only the power given it by Congress. Thus, one must always confront a fundamental question of agency power: "whether Congress in fact meant to confer the power the agency has asserted." *West Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587, 2607–08 (2022). Nothing in the text of the Federal Food Drug and Cosmetics Act ("FDCA") suggests that Congress accorded FDA the unilateral power to set national abortion policy. *See* 21 U.S.C. § 301 *et seq.* Under ordinary principles of statutory interpretation, such a contention fails; the FDCA's text does not so much as mentions abortion. Nor does it direct FDA to consider the legitimate and important state interests in

protecting unborn life, maternal health, and the integrity of the medical profession—interests that the Supreme Court in *Dobbs* returned to elected representatives. *See Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022). This conclusion is reinforced by separation-of-powers principles, which compel reviewing courts to find "clear congressional authorization" for expansive assertions of agency authority. *Id.*

Under the major questions doctrine, "courts expect Congress to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance." *Util. Air Regul. Grp. v. Env't Prot. Agency*, 573 U.S. 302, 324 (2014) (cleaned up) ("*UARG*"); *see also West Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587, 2609 (2022) (courts must "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies"). Terminating a pregnancy is an issue with "profound moral and spiritual implications … even [at] its earliest stage." *Planned Parenthood of Southeaster Pennsylvania v. Casey*, 505 U.S. 833, 850 (1992). Given the subject matter at the core of the actions at issue here, "this is a major questions case." *West Virginia*, 142 S. Ct. at 2610. Accordingly, there would need to be more than a "plausible textual basis" for the suggestion that Congress yielded nationwide abortion policy to the FDA cloaked in the guise of evaluating the safety and efficacy of a drug. *Id.* at 2609. Yet there is no such "clear congressional authorization." *Id.*

The Risk Evaluation and Mitigation Strategy (REMS) provision, 21 U.S.C. § 355-1, may seem a possibility as statutory support, but this notion is readily dispelled. That provision merely requires FDA to ensure that the additional safety

requirements that FDA itself imposes on drugs with known serious risks associated with adverse reactions are not "unduly burdensome on patient access to the drug." *Id.* § 355-1(f)(2)(C). In no way does that provision give "clear congressional authorization" for FDA's actions thereunder to serve as national policy directives or that such actions are superior to and displace the policy judgment of states on a different question: whether they will allow abortions and, if so, when, and how. It would be strange indeed for such an "extraordinary grant of regulatory authority" to be accomplished through such a "subtle device" like the REMS requirement. *See West Virginia*, 142 S. Ct. at 2609.

Finally, the FDCA has long been understood not to be a vehicle for national health care policy but rather to set a federal floor on the approval of drugs, allowing complementary state regulations. *See Wyeth v. Levine*, 555 U.S. 555, 555 (2009). The idea that FDA actions regarding a particular drug mandate unfettered access nationally would effectively "claim to discover in a long-extant statute an unheralded power" representing a "transformative expansion in [FDA's] regulatory authority." *UARG*, 573 U. S. at 324. This "newfound power" to regulate abortion, hidden "in the vague language of an ancillary provision" of the FDCA, would allow FDA "to adopt a regulatory program that Congress ha[s] conspicuously and repeatedly declined to enact itself," *West Virginia*, 142 S. Ct. at 2610; *see* Women's Health Protection Act of 2021, H.R.3755, 117th Cong. (2021) (failed to pass). As the Supreme Court said in another FDA case, "Congress could not have intended to delegate" such a sweeping and consequential authority "in so cryptic a fashion."

Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 160 (2000). Such is the case here, as well.

CONCLUSION

The Court should reject the request for emergency stay relief from the District Court's ruling against the FDA's actions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 12, 2023, the foregoing Brief of the State of West Virginia as Amicus Curiae in Support of Plaintiffs-Appellees' Opposition to a Stay Pending Appeal has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record and has been transmitted to the Clerk of the Court.

/s/ Peter D. Lepiscopo
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April 12, 2023

CERTIFICATE OF COMPLIANCE

This brief complies with the word limitations of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because, excluding the parts of the document exempted by Fed. R. App. P. 32, it contains 852 words. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in proportionally spaced typeface, including serifs, using Microsoft Word 2016, in New Times Roman 14-point font.

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April 11, 2023