No. 23-10362

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

v.

DANCO LABORATORIES, L.L.C.,

*Intervenor-Appellant.*

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS
CASE NO. 2:22-cv-00223

## BRIEF OF 240 MEMBERS OF CONGRESS AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS' EMERGENCY MOTION FOR A STAY PENDING APPEAL

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| Sen. Patty Murray | Rep. Katherine Clark |
| Sen. Bernard Sanders | Rep. Frank Pallone, Jr. |
| Sen. Richard J. Durbin | Rep. Jerrold Nadler |
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# CERTIFICATE OF INTERESTED PERSONS

*Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.*

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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## STATEMENT OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 29

All parties have consented to the filing of this brief of up to 5,200 words in length. No counsel for a party authored any part of this brief. No party, party's counsel or any person other than the amicus curiae, its members, or its counsel contributed money that was intended to finance the preparation or submission of this brief.

## INTEREST OF *AMICI CURIAE*

*Amici curiae* are 240 Members of Congress—50 Senators and 190 Members of the House of Representatives. (*See* Appendix for List of *Amici*.) *Amici* have a special interest in both upholding the Constitution's separation of powers—among other things, by ensuring that federal administrative agencies are able to faithfully exercise the authorities Congress delegated to them by statute without undue judicial interference—and protecting the physical health and safety of their constituents.

*Amici* believe that the district court's stay of FDA's September 28, 2000 Approval of mifepristone and other challenged agency actions has no basis in law, threatens the Congressionally mandated drug approval process, and poses a serious health risk to pregnant individuals by making abortion more difficult to access—when access has already been seriously eroded in the aftermath of *Dobbs v. Jackson Women's Health Organization*. Accordingly, *Amici* respectfully urge this Court to grant emergency relief from the district court's stay.

## SUMMARY OF ARGUMENT

For the last century, a statutory scheme designed by Congress has assured the safety and effectiveness of the drugs available in the United States. At its core resides the application of scientific standards by agency experts. In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA"), which established the foundations for the modern regulation of our drug supply. *See* 21 U.S.C. §§ 321(p), 355(a). Congress designated the U.S. Food and Drug Administration ("FDA") as the expert federal agency with authority to review and approve drug applications, including subsequent changes to those applications. While Congress permitted some judicial review of FDA's approval decisions, it did not invite federal courts to substitute their judgment for the expert conclusions of FDA's scientists.

Here, FDA's determination that mifepristone is safe and effective is based on a thorough and comprehensive review process prescribed and overseen by the legislative branch. Since mifepristone's initial approval in 2000, FDA has repeatedly and consistently affirmed that the medication is safe and effective for its approved conditions of use. FDA's process and conclusions have been validated by both Congress and the Government Accountability Office—and by the lived experience of over 5 million patients who have used the drug in the United States.

And, as with all drugs, FDA continued to closely monitor the post-marketing safety data on mifepristone.

By staying FDA's two-decade old approval of mifepristone, the district court has disrupted the longstanding statutory framework and erroneously awarded an extraordinary remedy. Decades after FDA's initial approval—yet somehow in an emergency posture—the district court intruded into FDA's drug approval process, casting a shadow of uncertainty over its decisions. The perils of this unwarranted judicial intervention into science-based determinations can hardly be overstated. Researchers, health care providers, and patients suffering from a range of medical conditions rely on the integrity and stability of the rigorous science-based drug approval process. The specter of precipitous judicial meddling therefore threatens access to life-improving and lifesaving drugs.

More immediately, the district court's misguided stay under Section 705 of the Administrative Procedure Act ("APA") will reduce access to abortion, exacerbating an already significant reproductive health crisis. Although the district court styled its relief as "less drastic," it is not apparent that its consequences are less disruptive than those of a mandatory injunction. Since the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, abortion has become inaccessible in much of the United States. The resulting delays and denials of care have already had baleful effect on the health of pregnant individuals, for some of

whom pregnancy is a life-threatening condition, regardless of their desire to carry their fetus to term. The district court's order would exacerbate these adverse health outcomes by eliminating access to the most common method of early abortion—a two drug regimen of mifepristone and misoprostol. Moreover, eliminating access to mifepristone—also used in combination with misoprostol for the management of early miscarriage[1]—will mean fewer options for treating early pregnancy loss,[2] which includes a spontaneous abortion, missed abortion, incomplete abortion, or inevitable abortion—conditions that can be life-threatening, including posing a risk of sepsis or loss of future pregnancy capacity if not treated quickly.[3]

Therefore, emergency relief from the order is necessary to mitigate the imminent harm facing members of the public, many of whom rely on the availability of mifepristone for reproductive care—and many more of whom rely on the integrity of FDA's drug approval process for continued access to life-

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[1] Jessica Beaman et al., *Medication to Manage Abortion and Miscarriage*, 35 J. Gen. Intern. Med. 2398, 2398 (2020) ("Thus, for both medication abortion and medical management of early miscarriage, the standard of care is to provide oral mifepristone followed by misoprostol tablets.").

[2] *Id.* at 2400 ("Up to one-third of all pregnancies end in miscarriage.").

[3] Brief of *Amici Curiae* Medical and Public Health Societies in Opposition to Plaintiffs' Motion for a Preliminary Injunction at 5, *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223-Z (N. D. Tex. Feb. 14, 2023), Dkt. No. 109.

improving and lifesaving drugs. Congress intended to—and did—vest authority in FDA to evaluate and ensure the safety and efficacy of drugs in the United States, and *Amici* call on this Court to give due weight to that intent.

## ARGUMENT

### I. CONGRESS CHARGED EXPERTS AT FDA WITH EVALUATING THE SAFETY AND EFFECTIVENESS OF DRUGS—SUBJECT ONLY TO CIRCUMSCRIBED JUDICIAL REVIEW

Congress has designed a system for assuring the safety and effectiveness of the drugs available in the United States—a system that became the envy of the world.[4] At the core of that system is the expert application of scientific standards. In 1938, Congress enacted a landmark statute, the FDCA, which established the foundations for the modern regulation of our drug supply. *See* 21 U.S.C. §§ 321(p), 355(a). Since 1962, Congress has required that drugs be shown to be safe and effective for their approved conditions of use before they can be sold in the United States. *See* 21 U.S.C. § 355; *see also id.* § 393(b)(2)(B).

[4] *See* Jennifer Ko, *What the FDA Can Teach Us About Regulatory Excellence*, Regulatory Rev. (Jan. 16, 2018), https://www.theregreview.org/2018/01/16/fda-teach-regulatory-excellence/; *see also* Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA Consumer: The Centennial Edition (Jan.-Feb. 2006).

FDA is the expert agency charged by Congress with reviewing and approving drug applications and any subsequent changes to those applications.[5] In accordance with congressional design, a team of physicians, statisticians, chemists, pharmacologists, and other scientific experts reviews each New Drug Application ("NDA") submitted to the agency and assesses all relevant data in light of the proposed labeling and intended use of the drug.[6] The agency must approve an application if, among other requirements, it has concluded that the drug is safe and effective under the conditions of use prescribed, recommended or suggested in the proposed labeling.[7]

FDCA's review provisions do not invite the courts to substitute their judgment for the expert assessment of FDA scientists, but to treat their "findings . . . as to the facts, if supported by substantial evidence," as "conclusive." 21 U.S.C. § 355(h); *see also Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir.

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[5] *See* 21 U.S.C. § 371(a) ("The authority to promulgate regulations for the efficient enforcement of this chapter [21 U.S. Code ch. 9 (the FDCA)] . . . is vested in the Secretary [of Health and Human Services]."). The Secretary of Health and Human Services ("the Secretary") has in turn delegated all functions vested in the Secretary under the FDCA to the Commissioner. *See* 2 FDA Staff Medical Guides – Delegations of Authority, SMG 1410.10, para. 1(A)(1) (Feb. 22, 2023) (Delegations of Authority to the Commissioner of Food and Drugs), https://www.fda.gov/media/81983/download.

[6] *See* 21 U.S.C. § 355(b)(1).

[7] *See* 21 U.S.C. § 355(d).

1995) ("[J]udgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of FDA's expertise and merit deference from us."); 5 U.S.C. § 706(2) (limiting scope of review to certain circumscribed grounds); *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) ("When examining [an expert agency's] scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential."); *Nat'l Mining Ass'n v. Sec'y, U.S. Dep't of Lab.*, 812 F.3d 843, 866 (11th Cir. 2016) (it is appropriate for reviewing courts to "'give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise'"; "[t]o do otherwise puts [a] court in the unenviable—and legally untenable—position of making for itself judgments entrusted by Congress to [the expert agency]" (citation omitted)). Indeed, the district court's order appears to be the very first time in FDA's history that a court has stayed the approval of a widely marketed drug over the agency's objection.

Here, rather than affording any deference to FDA, the district court appears to have second-guessed FDA's expert determinations with cherry-picked anecdotes and studies, and on that basis, imposed a remedy that could significantly upend the status quo. Appellants' Exhibits in Supp. of Mot. for Stay at Add. 44-45, Dkt. No. 27 (hereinafter, "Add.") (asserting that "chemical abortion drugs do not provide a meaningful therapeutic benefit over surgical abortion."); *id.* at 48 (claiming that

surgical abortion is a far safer procedure); *id.* at 52 (relying on "myriad stories and studies brought to the Court's attention"); *id.* at 57-58 (admitting the court does not have exact numbers and is relying on compounding assumptions). The National Academies of Sciences, Engineering and Medicine have concluded that much of the published literature on the supposed negative effects of abortion (such as that relied upon by the district court) "fails to meet scientific standards for rigorous, unbiased research."[8] Numerous courts have rejected the expert testimony of the physicians whose submissions the district court accepted at face value.[9] Even when "conflicting evidence is before the agency"—which was not the case here—"the agency and not the reviewing court has the discretion to accept or reject from the several sources of evidence." *Sabine River Auth. v. U.S. Dep't of Interior*, 951 F.2d 669, 678 (5th Cir. 1992).

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[8] Nat'l Acads. of Scis., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 152 (2018), http://nap.edu/24950.

[9] *See, e.g.*, *MKB Mgmt. Corp. v. Burdick*, 855 N.W.2d 31, 68 (N.D. 2014) (per curiam) (rejecting testimony of Dr. Harrison as lacking "scientific support"); *Planned Parenthood of Sw. & Cent. Fla. v. State*, No. 2022 CA 912, 2022 WL 2436704, at *13 (Fla. Cir. Ct. July 5, 2022) (rejecting testimony of Dr. Skop, who "provided no credible scientific basis for her disagreement with recognized high-level medical organizations in the United States"), *rev'd on other grounds*, 344 So. 3d 637 (Fla. Dist. Ct. App. 2022).

For decades, the federal judiciary has respected Congress's delegation of the drug approval process to FDA's scientists and experts. While courts have, on occasion, held against FDA on issues related to the market exclusivity that is afforded to a drug sponsor by the statute, it is an extraordinary and unprecedented step for the district court to invalidate on substantive grounds—and over FDA's objection—a longstanding approval for a drug with a history of safe and effective use. This Court should stay that aberrant decision pending appellate review.

## II. FDA'S DETERMINATION THAT MIFEPRISTONE IS SAFE AND EFFECTIVE FOLLOWED A THOROUGH AND COMPREHENSIVE PROCESS PRESCRIBED AND OVERSEEN BY THE LEGISLATIVE BRANCH

More than twenty years ago, FDA approved mifepristone, determining that it is safe and effective for the medical termination of intrauterine pregnancy under the conditions set forth in the FDA-approved prescribing information. Add. 181 (Approval of NDA for mifepristone, Sept. 28, 2000); *see also* 21 U.S.C. § 355(b)(1)(A)(i), (c)(1)(A), (d). Since then, FDA has repeatedly and consistently affirmed that mifepristone is safe and effective for its approved conditions of use.[10]

[10] *See Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA: U.S. Food & Drug Admin. (Mar. 23, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

### A. The District Court's Focus On 21 C.F.R. Part 314, Subpart H, Is Misplaced Because FDA's Authority To Authorize Mifepristone Is Derived From Statutory Authority Under the FDCA, And Any Alleged Defect In The 2000 Approval of Mifepristone Has Been Cured By Subsequent Congressional Action

The district court's focus on 21 C.F.R. Part 314, Subpart H, ignores FDA's longstanding interpretation of that regulation. In 1992, FDA lawfully promulgated Subpart H, in accordance with the APA, to help assure the safety and effectiveness of products for use in the United States. *See* 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (promulgating Subpart H). Subpart H applies to federal regulations for certain new drugs "studied for their safety and effectiveness in treating serious or life-threatening illnesses" that "provide meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. § 314.500. This was an entirely appropriate and proper exercise of authority, consistent with Section 701 of the FDCA, 21 U.S.C. § 371, which expressly authorizes FDA to promulgate regulations for the efficient enforcement of the FDCA.[11]

However, FDA's authority to approve mifepristone stemmed from Section 505 of the FDCA, 21 U.S.C. § 355, not from 21 C.F.R. Part 314, Subpart H. Prior to marketing a new drug, a sponsor must file an NDA pursuant to

[11] *See supra* note 5.

Section 505(b) of the FDCA, and must demonstrate that the drug is safe and effective for the proposed indication. 21 U.S.C. § 355(b)(1)(A)(i).

When FDA approved mifepristone in 2000, it reviewed data from two "prospective, open-label, multicenter clinical trials" in the United States involving over two thousand patients,[12] as well as expert advice from members of the FDA Reproductive Health Drugs Advisory Committee.[13] Moreover, the agency's determination was consistent with its long-standing construction of the scope of these regulations and similar regulatory programs to cover drugs designed for "conditions" as well as illnesses and diseases. In the final rule, FDA explained that Subpart H was available for serious or life-threatening "conditions," whether or not they were understood colloquially to be "illnesses." 57 Fed. Reg. 58,942, 58,946 (Dec. 11, 1992) (explaining that "FDA's reference to depression and psychoses" in its preamble to the proposed rule "was intended to give examples of conditions or diseases that can be serious for certain populations or in some or all of their phases"); *see also* 57 Fed. Reg. 13,234, 13,235 (proposed Apr. 15, 1992) (preamble ).[14]

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[12] *See* Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., Application No. 20-687, Medical Reviews 6-20 (1999).

[13] *See id.* at 21.

[14] *See also* Ctr. for Drug Evaluation & Rsch. (CDER), *Drug and Biologic Restricted Distribution Approvals as of June 30, 2018*, FDA: U.S. Food & Drug *(cont'd)*

Moreover, any alleged defect in the original approval of mifepristone in 2000 was cured in 2007, when Congress gave FDA the authority to require a risk evaluation and mitigation strategy ("REMS") in circumstances when FDA determined that such a strategy is "necessary to ensure that the benefits of the drug outweigh the risks."[15] 21 U.S.C. § 355-1(a)(1). When Congress codified the restricted use and distribution provisions of Subpart H in 2007 through the REMS program, it applied the new REMS framework to drugs for a "disease or *condition*."[16] When Congress enacted this REMS provision, it "deemed" drugs with restrictions of distribution under Subpart H, including mifepristone, to have an effective REMS. Pub. L. No. 110-85, § 909(b)(1)(A). Congress was well

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Admin, https://www.fda.gov/media/115040/download (last visited Apr. 11, 2023) (listing drugs which treat, *inter alia*, pulmonary hypertension and Irritable Bowel Syndrome (IBS)). Both hypertension and IBS are colloquially known as "conditions." *See Irritable Bowel Syndrome (IBS)*, NHS Inform, https://www.nhsinform.scot/illnesses-and-conditions/stomach-liver-and-gastrointestinal-tract/irritable-bowel-syndrome-ibs (last visited Apr. 11, 2023); *Hypertension*, World Health Org., https://www.who.int/health-topics/hypertension#tab=tab_1 (last visited Apr. 11, 2023).

[15] Where FDA has determined that a REMS is necessary, the sponsor must submit an application along with a proposed REMS. In making a determination of whether the benefits of the drug outweigh its risks with REMS, FDA shall consider factors including the "seriousness of the disease or condition" to be treated and the "seriousness of any known or potential adverse events that may be related to the drug." 21 U.S.C. § 355-1(a)(1)(B), (E). Through this process, mifepristone has been subjected to exacting scrutiny and review.

[16] 21 U.S.C. § 355-1(a)(1)(B), (C) (emphasis added).

aware that mifepristone would be included under that provision when it took this action, and it made no exception for it.[17]

In 2011, FDA took the step of implementing the REMS for mifepristone under express statutory authority in section 505-1 of the FDCA, 21 U.S.C. § 355-1. FDA had announced several years earlier that mifepristone would require submission of a REMS application. *See* Identification of Drug and Biological Products, 73 Fed. Reg. 16,313, 16,314 tbl. 1 (Mar. 27, 2008). Subsequently, a REMS application for mifepristone was submitted on September 17, 2008, and FDA approved the application on June 8, 2011. Add. 769. By virtue of FDA's approval of REMS for mifepristone under its express statutory authority, any alleged defect in the prior approval process for mifepristone was affirmatively cured.[18]

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[17] *See* 153 Cong. Rec. 11668 (May 9, 2007) (statement of Sen. Coburn); 153 Cong. Rec. 10940 (May 2, 2007) (statement of Sen. DeMint).

[18] The district court also misapplied the Comstock Act, 18 U.S.C. § 1461, erroneously ignoring the Department of Justice's well-reasoned opinion. *See generally* U.S. Dep't of Just., Off. of Legal Counsel, *Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions* 46 Op. O.L.C.___ (Dec. 23, 2022) (concluding that Congress's repeated actions ratified the well-established judicial construction that the statute did not prohibit the mailing of items designed to produce abortion unless the sender intended them to be used unlawfully). That opinion correctly notes that, in enacting the REMS provision in 2007, Congress acted "in a manner consistent with the understanding that the Comstock Act does not categorically prohibit" the distribution of drugs intended to induce abortions by mail or common carrier. *Id*. at 14.

### B. The Integrity of FDA's Approval Process Of Mifepristone Has Been Examined and Validated

The integrity of FDA's approval process for mifepristone has been examined before—and found to be sound. In 2008, the U.S. Government Accountability Office (GAO), an independent, non-partisan agency, conducted an extensive audit of mifepristone's 2000 approval, concluding it was "generally consistent with the approval processes for the other . . . Subpart H restricted drugs." GAO-08-751, *Approval and Oversight of the Drug Mifeprex* at 6 (2008).[19] The GAO also noted that, when it came to post-market oversight of mifepristone, "FDA has routinely reviewed the available information on reported adverse events" from a range of sources and then, "working with the drug's sponsor, has taken a variety of steps . . . . to address safety concerns."[20] Notably, in conducting its study, the GAO "interviewed FDA officials and external stakeholders who had access to technical information or had conducted analyses" concerning the drug.[21] The GAO report considered many of the same concerns raised by plaintiffs in this case fifteen years later.

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[19] The report was prepared at the request of three Republican members of Congress during the Bush administration: Senator Enzi, Senator DeMint and Representative Bartlett. *See* GAO-08-751, *supra*, at 1.

[20] *Id.* at 38, 41.

[21] *Id.* at 4.

In 2016, after approving a REMS for mifepristone, FDA approved a supplemental NDA. Add. 768-75. In 2018, the GAO reviewed this 2016 approval, and after evaluating 62 studies and articles that supported the efficacy of the proposed changes as well as adverse event data, concluded FDA "followed its standard review process when it approved the [2016 supplemental new drug application]."[22]

FDA has repeatedly demonstrated that its approval of mifepristone is based on a rigorous review of scientific data and literature supporting the safety and efficacy of the drug, which has been validated by the decades of experience of many Americans who, in consultation with their health care providers, have chosen to use mifepristone for a medication abortion.[23]

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[22] U.S. Gov't Accountability Off., GAO-18-292, *Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* cover pg. (2018); *see id.* at 11-16.

[23] *See Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022* at 1, U.S. Food & Drug Admin., https://www.fda.gov/media/164331/download (last visited Apr. 11, 2023) ("The estimated number of women who have used mifepristone in the U.S. for medical termination of pregnancy through the end of June 2022 is approximately 5.6 million women.").

## III. A JUDICIAL STAY OF APPROVAL OF MIFEPRISTONE WOULD PROFOUNDLY DISRUPT THE SCIENCE-BASED, EXPERT-DRIVEN PROCESS THAT CONGRESS DESIGNED FOR DETERMINING WHETHER DRUGS ARE SAFE AND EFFECTIVE

The consequences of the district court's remedy could extend far beyond mifepristone, for it undermines the science-based, expert-driven process that Congress designed for determining whether drugs are safe and effective. By disrupting FDA's two-decade old approval of mifepristone, the district court has interfered with the longstanding statutory framework and erroneously awarded an extraordinary remedy by substituting its judgment for FDA's scientific determination.

As a result, the district court's order undermines the well-established statutory and regulatory framework for the approval of new drugs and the due process generally accorded to drug marketing application holders by statute.[24] Its perilous consequences reach far beyond mifepristone. Providers and patients rely on the availability of thousands of FDA-approved drugs to treat or manage a range of medical conditions, including asthma, HIV, infertility, heart disease, diabetes,

[24] Section 505(e) of the FDCA allows for withdrawal of approval of an application with respect to any drug under the section only "after due notice and opportunity for hearing to the applicant." 21 U.S.C. § 355(e).

and more.[25] Moreover, the prospect of courts second-guessing FDA's rigorous drug safety and effectiveness determinations will disrupt industry expectations and could chill pharmaceutical research and development. "Developing new drugs is a costly and uncertain process," and only about 12 percent of drugs entering clinical trials are approved by FDA.[26] Were each court to take the "legally untenable . . . position of making for itself judgments entrusted by Congress to" FDA, *Nat'l Mining Ass'n*, 812 F.3d at 866, the unpredictability of piecemeal judicial intervention will upend industry expectations, dampening incentives for companies to incur the research and development costs necessary to develop new drugs. Consequently, patient access to life-improving and potentially lifesaving new drugs will suffer, and public interest strongly favors preserving the integrity of FDA's drug-approval process.

## IV. INVALIDATING FDA'S APPROVAL WOULD REDUCE ACCESS TO ABORTION, EXACERBATING AN ALREADY SIGNIFICANT REPRODUCTIVE HEALTH CRISIS

In the aftermath of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, abortion has become inaccessible in much of the

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[25] *See generally* U.S. Dep't of Health & Hum. Servs., *Approved Drug Products with Therapeutic Equivalence Evaluations* (43rd ed. 2023), https://www.fda.gov/media/71474/download.

[26] Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* at 2 (2021).

United States. Abortion is banned, with extremely limited exceptions for life-endangerment, in 12 states, and access is severely restricted in an additional 12 states.[27] Approximately 22 million women of childbearing age, representing almost one third of the total population of women ages 15 to 49—in addition to other people who may not identify as women but are capable of becoming pregnant and may need an abortion—now live in states where abortion is entirely unavailable or severely restricted.[28] At least 66 clinics across 15 states have stopped offering abortion care.[29] (Prior to June 24, 2022, those same 15 states had a total of 79 clinics that offered abortion care; now, there are only 13 such clinics, all located in Georgia.[30]) Travel time and wait time to obtain abortion care have increased significantly across the United States. The shortage of providers has also stretched the capacity of clinics in states where abortion remains legal.[31]

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[27] *See After Roe Fell: Abortion Laws by State*, Ctr. for Reprod. Rts., https://reproductiverights.org/maps/abortion-laws-by-state/ (last visited Mar. 13, 2023).

[28] Marielle Kirstein et al., *100 Days Post-Roe: At Least 66 Clinics Across 15 US States Have Stopped Offering Abortion Care*, Guttmacher Inst. (Oct. 6, 2022), https://www.guttmacher.org/2022/10/100-days-post-roe-least-66-clinics-across-15-us-states-have-stopped-offering-abortion-care.

[29] *Id.*

[30] *Id.*

[31] *Id.*

The resulting delays and denials of care have already dangerously affected health outcomes for pregnant individuals. Some individuals report being forced to forgo cancer treatment,[32] while others report developing sepsis,[33] being left bleeding for days after an incomplete miscarriage,[34] enduring the risk of rupture due to ectopic pregnancy or being forced to continue carrying a fetus diagnosed with a lethal fetal anomaly such as anencephaly.[35] For some individuals, pregnancy is a life-threatening condition, regardless of their desire to carry their fetus to term.[36] Since *Dobbs*, numerous individuals have been left struggling to

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[32] Affidavit of Dr. Sharon Liner in Support of Plaintiffs' Motion at 4-5, *Preterm-Cleveland v. Yost*, No. A2203203 (Ohio Ct. Com. Pl. filed Sept. 2, 2022).

[33] Complaint ¶¶ 17-25, *Zurawski v. Texas*, No. D-1-GN-23-000968 (Tex. Dist. Ct. filed Mar. 6, 2023); *see also id.* at 1 (plaintiffs were denied necessary and potentially lifesaving obstetrical care because medical professionals throughout the state feared liability under Texas's abortion bans).

[34] Frances Stead Sellers & Fenit Nirappil, *Confusion Post-Roe Spurs Delays, Denials for Some Lifesaving Pregnancy Care*, Wash. Post (July 16, 2022), https://www.washingtonpost.com/health/2022/07/16/abortion-miscarriage-ectopic-pregnancy-care/.

[35] *See* Complaint ¶¶ 82-94, *Zurawski*, *supra* note 33.

[36] *See, e.g.*, Ioannis T. Farmakis et al., *Maternal Mortality Related to Pulmonary Embolism in the United States, 2003-2020*, 5 Am. J. Obstetrics & Gynecology Maternal-Fetal Med. 100754 (2023); *What Are the Risks of Preeclampsia & Eclampsia to the Mother?*, Nat'l Insts. of Health, https://www.nichd.nih.gov/health/topics/preeclampsia/conditioninfo/risk-mother (last updated Nov. 19, 2018).

access the essential health care they need.[37] Reports from doctors and journalists highlight the increasing importance of mifepristone for reproductive health care in *Dobbs*' wake:

- One doctor who had "to stop providing abortion care to patients in Wisconsin for the past six months" observes "further difficulties for patients in rural settings." Rural patients "are now being forced to birth, so the risks of bleeding and poor fetal and maternal outcomes have significantly risen. Mifepristone is vital to providing safe care for early pregnancy loss."[38]

- Another doctor recounts a patient who was raped when she was actively planning for pregnancy. The soonest a paternity test could be conducted was at 7 weeks gestation, while Texas, where the patient lived, had banned abortion after 6 weeks. The patient could not afford to travel out of state for termination, and had to seek a medication abortion before her sixth week.[39]

- A woman residing in Louisiana, where all abortion (including in cases of rape and incest) has been banned after *Dobbs*, was refused treatment for her miscarriage when she was between 10 and 11 weeks pregnant. When asked whether treatment was available to alleviate her pain and speed up the process, the doctor replied: "We're not doing that now."[40]

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[37] *See* Jessica Valenti, *I Write About Post-Roe America Every Day. It's Worse Than You Think*, N.Y. Times (Nov. 5, 2022), https://www.nytimes.com/2022/11/05/opinion/election-abortion-roe-women.html.

[38] Brief of *Amicus Curiae* Doctors for America at 6-7, *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223-Z (N. D. Tex. Feb. 13, 2023), Dkt. No. 99.

[39] *Id*. at 9-10.

[40] Rosemary Westwood, *Bleeding and in Pain, She Couldn't Get 2 Louisiana ERs to Answer: Is It a Miscarriage?*, WGCU (Dec. 29, 2022), https://news.wgcu.org/2022-12-29/bleeding-and-in-pain-she-couldnt-get-2-louisiana-ers-to-answer-is-it-a-miscarriage.

> Mifepristone is part of standard treatment to manage early pregnancy loss.[41]

These examples bespeak a broader public health crisis aggravated by providers denying care for fear that their treatment will contravene state criminal law and lead to prosecution.[42] No other practice of medicine bears witness to these types of denials of care based on state restrictions and ideological interference.

The district court's order would exacerbate these adverse health outcomes by eliminating the most common method of early abortion.[43] As a result, childbearing individuals would have to turn to procedural abortion, which is more invasive, may require extensive travel to obtain, has longer wait times, and is often much more expensive. Alternatively, affected individuals would have to seek other methods of medication abortion, even though the FDA-approved regimen using mifepristone is by far the most common and available method of medication abortion in the United States and is a method that FDA has long determined provides a "meaningful therapeutic benefit" over existing treatments. 21 C.F.R. § 314.500.

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41 *See supra* note 1.

42 *See, e.g.*, Westwood, *supra* note 40.

43 Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Inst. (Feb. 24, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

These health risks, as well as financial and logistical challenges, would disproportionately affect individuals already facing systemic barriers to health care, who could be forced to choose between a more costly procedural abortion and an unwanted pregnancy.[44] These particularly vulnerable groups may include low-income individuals, people of color, young people and those residing in rural areas.[45] Medication abortion using mifepristone is an important means for vulnerable groups to access medical care without having to bear the cost of long-distance travel to find access to procedural abortion and the difficulties associated with getting time off or finding child care.[46] By curtailing access to the most

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[44] *See* Katherine O'Connell White, *POV: Overturning Roe v. Wade Will Worsen Health Inequities in All Reproductive Care*, BU Today (June 24, 2022), https://www.bu.edu/articles/2022/overturning-roe-v-wade-will-worsen-health-inequities/.

[45] *See generally* Eugene Declercq et al., *The U.S. Maternal Health Divide: The Limited Maternal Health Services and Worse Outcomes of States Proposing New Abortion Restrictions*, Commonwealth Fund (Dec. 14, 2022), https://www.commonwealthfund.org/publications/issue-briefs/2022/dec/us-maternal-health-divide-limited-services-worse-outcomes; *see also* Rosalyn Schroeder et al., *Trends in Abortion Care in the United States, 2017-2021*, Advancing New Standards in Reprod. Health, U.C.S.F. (2022).

[46] *See* Karen Brooks Harper, *Wealth Will Now Largely Determine Which Texans Can Access Abortion*, Tex. Trib. (June 24, 2022), https://www.texastribune.org/2022/06/24/texas-abortion-costs/ ("About 73% of the people who call Fund Texas Choice for help with travel expenses are Black, Indigenous, Hispanic and Asian . . . ."); *id.* ("[T]hose working in wage-based jobs with no paid time off . . . ."); Chantel Boyens et al., *Access to Paid Leave Is Lowest Among Workers with the Greatest Needs* 2, Urban Inst. (July 2022).

common method of medication abortion, the district court's stay erects additional barriers to health care for vulnerable populations.

Reduced abortion access is also associated with higher rates of poverty, and lower educational attainment for both children and parents.[47] *The Turnaway Study* conducted at the University of California, San Francisco found that being denied an abortion was associated with increased economic insecurity and household poverty for both the mother and children born as a result of abortion denial.[48]

The unavailability of mifepristone will have an especially acute impact on Black maternal health. In 2021, the overall maternal mortality rate shot up by nearly 40 percent,[49] and the maternal mortality rate for Black women was especially high, at 69.9 deaths per 100,000 live births—1.3 times higher than it was in 2020, and 2.6 times higher than the rate for white women.[50] In 2020, maternal

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[47] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 Am. J. Pub. Health 407, 412 (2018).

[48] *See* Diana Greene Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2020).

[49] Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, CDC (Mar. 16, 2023), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm.

[50] *Id.*; Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2020*, CDC (Feb. 23, 2022), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm.

death rates were 62 percent higher in abortion-restriction states than in abortion-access states.[51] From 2018 to 2020, the maternal mortality rate increased nearly twice as fast in states with abortion restrictions than in states without them.[52] Additional restrictions on access to medication abortion threaten to further increase the maternal mortality rate—an issue disproportionately affecting Black women—and exacerbate an already grave Black maternal health crisis.[53]

The district court's order will further restrict abortion access, exacerbating the harmful effects from existing limitations. Just as *Dobbs* upended abortion access and led to chaos following the decision, eliminating access to mifepristone will further narrow options for care.

## CONCLUSION

For the foregoing reasons, *Amici* Members of Congress respectfully request that the Court grant defendant-appellants' emergency motion to extend the seven-day administrative stay pending resolution of stay proceedings in this court, and for a stay of the district court's order pending appeal.

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[51] Declercq et al., *supra* note 45, at Exhibit 4.

[52] *Id.*

[53] *See id.* at Conclusion.

Dated: April 11, 2023
New York, New York

Respectfully submitted,

s/ Boris Bershteyn

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**CERTIFICATE OF ELECTRONIC COMPLIANCE**

I certify that on April 11, 2023, this motion was transmitted to Mr. Lyle W. Cayce, Clerk of the U.S. Court of Appeals for the Fifth Circuit, through the court's CM/ECF document-filing system, https://efc.ca5.uscourts.govt.

I further certify that: (1) required privacy redactions have been made, 5th Cir. R. 25.2.13; (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 25.2.1; and (3) the document has been scanned with the most recent version of a commercial virus scanning program and is free of viruses.

Dated: April 11, 2023
New York, New York

s/ Boris Bershteyn
Boris Bershteyn
*Counsel for Amici Curiae*

**CERTIFICATE OF COMPLIANCE**

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font. The brief contains 5192 words, excluding the parts of the brief exempt by Federal Rule of Appellate Procedure 32(f).

Dated: April 11, 2023
New York, New York

s/ Boris Bershteyn
Boris Bershteyn
*Counsel for Amici Curiae*

**CERTIFICATE OF SERVICE**

I hereby certify that I e-filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system on April 11, 2023. I further certify that the participants in the case are CM/ECF users and that service will be accomplished by using the appellate CM/ECF system.

Dated: April 11, 2023
New York, New York

s/ Boris Bershteyn
Boris Bershteyn
*Counsel for Amici Curiae*

# APPENDIX

## List of *Amici Curiae*

### MEMBERS OF CONGRESS

### 50 United States Senators

Majority Leader Charles E. Schumer

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Sen. Bernard Sanders

Sen. Richard J. Durbin

Sen. Richard Blumenthal

Sen. Tammy Baldwin

Sen. Michael F. Bennet

Sen. Cory A. Booker

Sen. Sherrod Brown

Sen. Maria Cantwell

Sen. Benjamin L. Cardin

Sen. Thomas R. Carper

Sen. Robert P. Casey, Jr.

Sen. Christopher A. Coons

Sen. Catherine Cortez Masto

Sen. Tammy Duckworth

Sen. Dianne Feinstein

Sen. John Fetterman

Sen. Kirsten Gillibrand

Sen. Margaret Wood Hassan

Sen. Martin Heinrich

Sen. John W. Hickenlooper

Sen. Mazie K. Hirono

Sen. Tim Kaine

Sen. Mark Kelly

Sen. Angus S. King, Jr.

Sen. Amy Klobuchar

Sen. Ben Ray Luján

Sen. Edward J. Markey

Sen. Robert Menendez

Sen. Jeffrey A. Merkley

Sen. Christopher S. Murphy

Sen. Jon Ossoff

Sen. Alex Padilla

Sen. Gary C. Peters

Sen. Jack Reed

Sen. Jacky Rosen

Sen. Brian Schatz

Sen. Jeanne Shaheen

Sen. Kyrsten Sinema

Sen. Tina Smith

Sen. Debbie Stabenow

Sen. Jon Tester

Sen. Chris Van Hollen

Sen. Mark Warner

Sen. Raphael Warnock

Sen. Elizabeth Warren

Sen. Peter Welch

Sen. Sheldon Whitehouse

Sen. Ron Wyden

**190 Members of the**
**United States House of Representatives**

Minority Leader Hakeem Jeffries

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Rep. Frank Pallone, Jr.

Rep. Jerrold Nadler

Rep. Diana DeGette

Rep. Barbara Lee

Rep. Alma S. Adams, Ph.D.

Rep. Pete Aguilar

Rep. Colin Allred

Rep. Jake Auchincloss

Rep. Becca Balint

Rep. Nanette Diaz Barragán

Rep. Joyce Beatty

Rep. Ami Bera, M.D.

Rep. Donald S. Beyer Jr.

Rep. Sanford Bishop

Rep. Earl Blumenauer

Rep. Lisa Blunt Rochester

Rep. Suzanne Bonamici

Rep. Jamaal Bowman, Ed.D.

Rep. Brendan Boyle

Rep. Shontel Brown

Rep. Julia Brownley

Rep. Nikki Budzinski

Rep. Cori Bush

Rep. Yadira Caraveo, M.D.

Rep. Salud Carbajal

Rep. Tony Cárdenas

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Rep. Matt Cartwright

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Rep. Chris Deluzio

Rep. Mark DeSaulnier

Rep. Debbie Dingell

Rep. Lloyd Doggett

Rep. Veronica Escobar

Rep. Anna G. Eshoo

Rep. Adriano Espaillat

Rep. Dwight Evans

Rep. Lizzie Fletcher

Rep. Bill Foster

Rep. Valerie Foushee

Rep. Lois Frankel

Rep. Maxwell Alejandro Frost

Rep. Ruben Gallego

Rep. John Garamendi

Rep. Robert Garcia

Rep. Jesús G. “Chuy” García

Rep. Marie Gluesenkamp Perez

Rep. Dan Goldman

Rep. Jimmy Gomez

Rep. Josh Gottheimer

Rep. Al Green

Rep. Raúl M. Grijalva

Rep. Brian Higgins

Rep. Jim Himes

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Rep. Steny H. Hoyer

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