Nos. 23-235, 23-236

IN THE

Supreme Court of the United States

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 FOR 263 MEMBERS OF CONGRESS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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A complete list of the 50 U.S. Senators and the 213 Members of the U.S. House of Representatives participating as amici curiae is provided as an appendix to the brief. Among them are:

Sen. Charles E. Schumer
Sen. Patty Murray
Sen. Bernard Sanders
Sen. Richard J. Durbin
Sen. Richard Blumenthal

Rep. Hakeem Jeffries
Rep. Katherine Clark
Rep. Frank Pallone, Jr.
Rep. Jerrold Nadler
Rep. Diana DeGette
Rep. Barbara Lee

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are 263 Members of Congress—50 Senators and 213 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 United States Court of Appeals for the Fifth Circuit incorrectly affirmed the district court's stay of the U.S. Food and Drug Administration's 2016 and 2021 actions with respect to mifepristone's approved conditions of use. The Fifth Circuit's decision 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*, 597 U.S. 215 (2022). Accordingly, *Amici* respectfully urge this Court to reverse the Fifth Circuit's affirmance of the district court's stay of the U.S. Food and Drug Administration's 2016 and 2021 actions.

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1. Pursuant to Rule 37.6 of the Rules of this Court, *amici* state that no counsel for a party wrote this brief in whole or in part. No party, party's counsel or any person other than the *amici curiae*, their members, or their counsel contributed money that was intended to finance the preparation or submission of this brief.

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"), 21 U.S.C. §§ 301 to 399i, 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 maintaining the district court's stay of mifepristone's current, FDA-approved conditions of use, the Fifth Circuit

has disrupted the longstanding statutory framework and erroneously countenanced an extraordinary remedy. Decades after FDA's initial approval—yet somehow in an emergency posture—the district court and the Fifth Circuit 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 misguided stay of mifepristone's current FDA-approved conditions of use will reduce access to abortion, exacerbating an already significant reproductive health crisis. Although the district court styled its relief as "less drastic" than a mandatory injunction, it is not apparent that its consequences are less disruptive. Since this 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 effects 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 Fifth Circuit's order would exacerbate these adverse health outcomes by limiting access to the most common method of early abortion—a two drug regimen of mifepristone and misoprostol.

Therefore, this Court's reversal of the Fifth Circuit's order with respect to FDA's 2016 and 2021 actions 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-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.[2] 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 intended use before they can be sold in the United States. *See* 21 U.S.C. § 355; *see also id.* § 393(b)(2)(B).

2. *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 (Jan.-Feb. 2006), https://www.fda.gov/files/Promoting-Safe-and-Effective-Drugs-for-100-Years-%28download%29.pdf.

FDA is the expert agency charged by Congress with reviewing and approving drug applications and any subsequent changes to those applications.[3] 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.[4] 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.[5]

FDCA's review provisions do not invite the courts to substitute their judgment for the expert assessment of FDA scientists, but to treat their "finding[s] . . . 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. 1995) ("[J]udgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us."); 5 U.S.C. § 706(2) (limiting scope of review to certain circumscribed grounds); *Balt.*

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3. *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 FDA Commissioner of Food and Drugs. *See* Food & Drug Administration; Delegation of Authority, 86 Fed. Reg. 49,337 (Sept. 2, 2021).

4. *See* 21 U.S.C. § 355(b)(1).

5. *See* 21 U.S.C. § 355(d).

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) (stating that 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—now upheld in material part by the Fifth Circuit—appears to be the very first time in FDA's history that a court has stayed the conditions of approval of a widely marketed drug over the agency's objection.

Here, rather than affording due deference to FDA, the district court's order (affirmed in part by the Fifth Circuit) appears to have second-guessed FDA's expert determinations with cherry-picked anecdotes and studies, and on that basis, imposed a remedy that will significantly upend the status quo. *See, e.g.*, Appendix to the Petition for a Writ of Certiorari at 166a-167a, *U.S. Food & Drug Administration, et al. v. Alliance for Hippocratic Med., et al.* No. 23-235 (Sept. 12, 2023) [hereinafter Pet. App.] (asserting that "chemical abortion drugs do not provide a meaningful therapeutic benefit over surgical abortion"); Pet. App. at 171a (claiming that surgical abortion is a far safer procedure); Pet. App. at 177a (relying on "myriad stories and studies brought to the Court's attention"); Pet. App. at 183a-184a (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."[6] Numerous courts have rejected the expert testimony of the physicians whose submissions the district court accepted at face value.[7] 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).

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 a court to invalidate on substantive grounds—and over FDA's objection—approval for a drug with a history of safe and effective use or the drug's conditions of use.

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6. 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.

7. *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), *review granted*, No. SC22-1050, 2023 WL 356196 (Fla. Jan. 23, 2023).

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. *See* Joint Appendix at 224, *U.S. Food & Drug Administration, et al. v. Alliance for Hippocratic Med., et al.* Nos. 23-235 & 23-236 (Jan. 23, 2024) [hereinafter Joint App.] (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.[8]

The integrity of FDA's approval process for mifepristone, including actions after the 2000 approval, 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."[9] The GAO

8. *See Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, 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.

9. U.S. Gov't Accountability Off., GAO-08-751, Food & Drug Admin., *Approval and Oversight of the Drug Mifeprex*, at 6

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."[10] 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.[11] The GAO report considered many of the same concerns raised by plaintiffs in this case fifteen years later.

In 2016, after approving risk evaluation and mitigation strategies ("REMS") for mifepristone, FDA approved a supplemental NDA. *See* Joint App. at 283-291. In 2018, the GAO reviewed this 2016 approval, and after evaluating 62 studies and articles that supported the efficacy of the proposed labeling changes as well as safety information and adverse event data, concluded FDA "followed its standard review process when it approved the [2016 supplemental new drug application] and revised labeling."[12] The report further found that "FDA has conducted a variety of monitoring activities and these have not identified significant concerns

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(2008), https://www.gao.gov/assets/gao-08-751.pdf. The report was prepared at the request of three Republican members of Congress during the Bush administration: Senator Enzi, Senator DeMint and Representative Bartlett.

10. *Id.* at 38, 41.

11. *Id.* at 4.

12. U.S. Gov't Accountability Off., GAO-18-292, Food & Drug Admin., *Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts*, cover pg. (2018), https://www.gao.gov/assets/gao-18-292.pdf; *see also id.* at 11-16.

with the safety and use of [mifepristone], in accordance with its approved REMS."[13]

FDA's 2021 actions were likewise grounded in careful review of safety data and scientific literature. In April 2021, in light of COVID-19-related risks, FDA announced its intent to exercise enforcement discretion as to the in-person dispensing requirement, explaining that its decision was "the result of a thorough scientific review by experts" who evaluated "available clinical outcomes data and adverse event reports." Joint App. at 377. In December 2021, FDA further determined that "mifepristone will remain safe and effective for medical abortion if the in-person dispensing requirement is removed" and directed mifepristone's sponsors to initiate the process to modify the REMS accordingly. *Id.* at 378, *see also id. at* 373, 379; 21 U.S.C. § 355-1(g)(4)(B). FDA explained that its determination came after seeking out information from the drug's sponsors, *see* Joint App. at 399, evaluating "routinely monitor[ed] postmarketing safety data," *id.* at 398, and conducting an "extensive review of the published literature." *Id.* at 399. *See generally id.* at 397-408 (discussing review of available data and scientific literature).

Thus, FDA has repeatedly demonstrated that its approval of mifepristone and its conditions of use 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.[14]

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13. *Id.* at cover pg.

14. *See Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022* at 1, U.S. Food & Drug Admin.

III. A JUDICIAL STAY OF FDA'S CURRENT APPROACH TO REGULATING 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 Fifth Circuit's decision 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 current regulation of mifepristone, the Fifth Circuit has countenanced judicial interference that erroneously substitutes a court's judgment for FDA's scientific determination.

As a result, the Fifth Circuit's order undermines the well-established statutory and regulatory framework for the approval and regulation of new drugs and the due process generally accorded to drug marketing application holders by statute.[15] 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,

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(Dec. 31, 2022), https://www.fda.gov/media/164331/download ("The estimated number of women who have used mifepristone in the U.S. for medical termination of pregnancy through the end of December 2022 is approximately 5.9 million women.").

15. 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.[16] 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.[17] 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 would 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, while public interest strongly favors preserving the integrity of FDA's drug-approval and review process.

IV. INVALIDATING FDA'S CURRENT APPROACH TO REGULATING MIFEPRISTONE WOULD REDUCE ACCESS TO ABORTION, EXACERBATING AN ALREADY SIGNIFICANT REPRODUCTIVE HEALTH CRISIS

In the aftermath of this Court's decision in *Dobbs v. Jackson Women's Health Organization*, abortion has become inaccessible in much of the United States. Abortion is banned, with extremely limited exceptions for life-endangerment, in 14 states, and access is severely

16. *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.

17. Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 2 (Apr. 2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.

restricted in an additional 10 states.[18] As of October 2022, 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."[19] At least 66 clinics across 15 states have stopped offering abortion care.[20] (Prior to June 24, 2022, those same 15 states had a total of 79 clinics that offered abortion care; as of October 2022, there were only 13 such clinics, all located in Georgia.[21]) As of December 2023, "almost 18 million women of reproductive age, in addition to transgender and nonbinary people who may need an abortion, no longer have access to abortion care in their state of residence."[22] Travel time and wait time to obtain abortion care have increased significantly across

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18. *See After Roe Fell: Abortion Laws by State*, Ctr. for Reprod. Rts., https://reproductiverights.org/maps/abortion-laws-by-state/ (last visited Jan. 22, 2024).

19. 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.

20. *See id.*

21. *See id.*

22. Kimya Forouzan & Isabel Guarnieri, *State Policy Trends 2023: In the First Full Year Since Roe Fell, a Tumultuous Year for Abortion and Other Reproductive Health Care*, Guttmacher Inst. (Dec. 19, 2023), https://www.guttmacher.org/2023/12/state-policy-trends-2023-first-full-year-roe-fell-tumultuous-year-abortion-and-other.

the United States.[23] In the first half of 2023, nearly one in five patients who obtained abortion care traveled to other states.[24] The shortage of providers has also stretched the capacity of clinics in states where abortion remains legal.[25]

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,[26] while others report developing sepsis,[27] being left bleeding for days after an incomplete miscarriage,[28] enduring the risk of rupture due to

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23. *See* Kirstein et al., *supra* note 19; *see also* Benjamin Rader et al., *Estimated Travel Time and Spatial Access to Abortion Facilities in the US Before and After the* Dobbs v Jackson Women's Health *Decision,* JAMA Network (Nov. 1, 2022), https://jamanetwork.com/journals/jama/fullarticle/2798215.

24. *See* Kimya Forouzan et al., *The High Toll of US Abortion Bans: Nearly One in Five Patients Now Traveling Out of State for Abortion Care,* Guttmacher Inst. (Dec. 7, 2023), https://www.guttmacher.org/2023/12/high-toll-us-abortion-bans-nearly-one-five-patients-now-traveling-out-state-abortion-care.

25. *See* Kirstein et al., *supra* note 19.

26. 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).

27. 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).

28. *See* 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/.

ectopic pregnancy or being forced to continue carrying a fetus diagnosed with a lethal fetal anomaly such as anencephaly.[29] For some individuals, pregnancy is a life-threatening condition, regardless of their desire to carry their fetus to term.[30] Since *Dobbs*, numerous individuals have been left struggling to access the essential health care they need.[31] 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."[32]

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29. *See* Complaint ¶¶ 82-94, *Zurawski*, *supra* note 27.

30. *See*, *e.g.*, Ioannis T. Farmakis et al., *Maternal Mortality Related to Pulmonary Embolism in the United States, 2003-2020*, 5 A.M. 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 Jan. 22, 2024).

31. *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.

32. 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), ECF No. 99.

- 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.[33]

- 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."[34] Mifepristone is part of standard treatment to manage early pregnancy loss.[35]

These examples bespeak a broader public health crisis aggravated by providers denying care for fear that their

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33. *Id.* at 9-10.

34. 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.

35. *See* 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.").

treatment will contravene state criminal law and lead to prosecution.[36] No other practice of medicine bears witness to these types of denials of care based on state restrictions and ideological interference.

The Fifth Circuit's order will exacerbate these adverse health outcomes by limiting access to the most common method of early abortion.[37] It will also create additional confusion on top of the post-*Dobbs* uncertainty surrounding the legality of different forms of reproductive health care. As a result, childbearing individuals may 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 methods of medication abortion that do not involve mifepristone or to travel to find a distributing physician, even though FDA has concluded that mifepristone remains safe and effective with the in-person dispensing requirement removed. *See* Joint App. at 378, 407.

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 amongst a more costly procedural abortion, costly travel and an unwanted pregnancy.[38]

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36. *See, e.g.*, Westwood, *supra* note 34.

37. *See* 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.

38. *See* Katharine O'Connell White, *POV: Overturning* Roe v. Wade *Will Worsen Health Inequities in All Reproductive Care*,

These particularly vulnerable groups may include low-income individuals, people of color, young people and those residing in rural areas.[39] 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.[40] By curtailing access to the most common method of medication abortion, the Fifth Circuit's order 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

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BU Today (June 24, 2022), https://www.bu.edu/articles/2022/overturning-roe-v-wade-will-worsen-health-inequities/.

39. *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).

40. *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."); *see also* Chantel Boyens et al., *Access to Paid Leave Is Lowest Among Workers with the Greatest Needs* 2, Urban Inst. (July 2022), https://www.urban.org/sites/default/files/2022-07/Access%20to%20Paid%20Leave%20Is%20Lowest%20among%20Workers%20with%20the%20Greatest%20Needs.pdf.

children and parents.[41] *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.[42]

The limited availability 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,[43] 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.[44] In 2020, maternal death rates were 62 percent higher in abortion-restriction states than in abortion-access states.[45] From 2018 to 2020, the maternal mortality rate increased nearly twice as fast in states with abortion restrictions than in states without

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41. 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).

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

43. *See* Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, Ctrs. for Disease Control & Prevention (Mar. 16, 2023), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm.

44. *See id.*; *see also* Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2020*, Ctrs. for Disease Control & Prevention (Feb. 23, 2022), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm.

45. *See* Declercq et al., *supra* note 39, at Exhibit 4.

them.[46] In 2021, the maternal mortality rate in states which restricted abortion and later banned abortion after *Dobbs* was 2.4 times that in states with a supportive environment for access to abortion care.[47] 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.[48]

The Fifth Circuit's decision will further restrict abortion access, exacerbating the harmful effects of existing limitations. Just as *Dobbs* upended abortion access and led to chaos following the decision, a disruption of mifepristone's current conditions of use will further narrow options for care.

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46. *See id.*

47. *See The State of Reproductive Health in the United States: The End of Roe and the Perilous Road Ahead for Women in the* Dobbs *Era* 7, 15 n.9, Gender Equity Pol'y Inst. (Jan. 19, 2023), https://thegepi.org/wp-content/uploads/2023/06/GEPI-State-of-Repro-Health-Report-US.pdf.

48. *See id.* at 9-10 (Conclusion).

CONCLUSION

For the foregoing reasons, *Amici* Members of Congress respectfully request that this Court reverse the Fifth Circuit's affirmance of the district court's stay of FDA's 2016 and 2021 actions.

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January 30, 2024

APPENDIX

TABLE OF APPENDICES

APPENDIX A — LIST OF *AMICI CURIAE*

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Sen. Richard Blumenthal

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