No. 23-10362

IN THE

United States Court of Appeals for the Fifth Circuit

ALLIANCE FOR HIPPOCRATIC MEDICINE ET AL.,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS (AMARILLO)
NO. 2:22-CV-00223-Z

BRIEF OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN MEDICAL ASSOCIATION, SOCIETY FOR MATERNAL-FETAL MEDICINE, ET AL. AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLANTS

SHANNON ROSE SELDEN
COUNSEL OF RECORD
ADAM AUKLAND-PECK
DEBEVOISE & PLIMPTON LLP
66 Hudson Blvd.
New York, NY 10001
(212) 909-6000

Counsel to Amici Curiae

MEGAN MCGUIGGAN
DEBEVOISE & PLIMPTON LLP
801 Penn. Ave, NW
Washington, D.C. 20004
(202) 383-8000

Counsel to Amici Curiae

MOLLY MEEGAN
JESSICA MORRIS*
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
409 12th Street, SW
Washington, D.C. 20024
**Application for Admission forthcoming*

CERTIFICATE OF INTERESTED PERSONS

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.

Plaintiff-Appellees
Alliance for Hippocratic Medicine
American Association of Pro-Life Obstetricians & Gynecologists
American College of Pediatricians
Christian Medical & Dental Associations
George Delgado
Regina Frost-Clark
Shaun Jester
Tyler Johnson

Counsel to Plaintiff-Appellees
Erik Baptist
Julie-Marie Blake
Denise Harle
Christian D. Stewart

Defendant-Appellants
Food & Drug Administration
United States Dept. of Health and Human Services
Xavier Becerra, Secretary of U.S. Department of Health and Human Services
Robert M. Califf, Commissioner of Food and Drugs
Patrizia Cavazzoni
Janet Woodcock

Intervenor Defendant-Appellant
Danco Laboratories, L.L.C.

Counsel to Defendant-Appellants
Cynthia Barmore
Sarah Elaine Harrington
Michael S. Raab
Daniel Schwei

Counsel to Intervenor Defendants-Appellants
Jessica Lynn Ellsworth

Amici Curiae
American College of Obstetricians and Gynecologists
American Medical Association
Society for Maternal-Fetal Medicine
American Academy of Family Physicians
American Academy of Nursing
American Academy of Pediatrics
American Gynecological and Obstetrical Society
American Society for Reproductive Medicine
North American Society for Pediatric and Adolescent Gynecology
Society for Academic Specialists in General Obstetrics and Gynecology
Society for Adolescent Health and Medicine
Society of Gynecologic Oncology
Society of OB/GYN Hospitalists

Counsel to Amici Curiae
Shannon Rose Selden
Adam Aukland-Peck
Megan McGuiggan
Debevoise & Plimpton LLP

Molly Meegan
Jessica Morris
American College of Obstetricians and Gynecologists

Dated: May 1, 2023

Respectfully submitted,

/s/ Shannon Rose Selden

Shannon Rose Selden
Counsel of Record
Adam Aukland-Peck
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, N.Y. 10001
(212) 909-6000

Megan McGuiggan
DEBEVOISE & PLIMPTON LLP
801 Pennsylvania Ave, NW
Washington, D.C. 20004
(202) 383-8000

Molly Meegan
Jessica Morris*
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
409 12th Street, SW
Washington, D.C. 20024
**Application for Admission forthcoming*

Counsel to Amici Curiae

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INTEREST OF AMICI CURIAE[1]

Amici curiae are leading medical and public-health societies representing physicians, clinicians, and public-health professionals who serve patients in Texas and nationwide. Among other organizations, they include the American College of Obstetricians and Gynecologists ("ACOG"), the nation's leading organization of over 60,000 member physicians who provide health services unique to people seeking obstetric or gynecologic care; the American Medical Association ("AMA"), the largest professional association of physicians, residents, and medical students in the country; and the Society for Maternal-Fetal Medicine ("SMFM"), the professional society for maternal-fetal medicine subspecialists who are obstetricians with additional training in high-risk pregnancies.[2] Courts frequently rely on *amici*'s medical and scientific expertise in cases involving pregnancy.[3]

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[1] This brief is submitted under Federal Rule of Appellate Procedure 29(a) with the consent of all parties. No counsel for a party authored this brief, in whole or in part, and no counsel for a party, nor any person other than the *amici curiae*, their members, or their counsel, contributed money that was intended to fund the preparation or submission of this brief.

[2] Additional *amici* and their interests in this matter are explained in further detail in *amici*'s accompanying Motion for Leave.

[3] *See, e.g.*, *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2131 (2020); *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2312, (2016); *Whole Woman's Health v. Paxton*, 978 F.3d 896, 910 (5th Cir); *Stenberg v. Carhart*, 530 U.S. 914, 928 (2000); *Planned Parenthood Ctr. for Choice v. Abbott*, No. A-20-CV-323, 2020 WL 1815587, at *4–5 (W.D. Tex. Apr. 9, 2020).

Ensuring access to evidence-based health care and promoting health care policy that improves patient health are central to *amici*'s missions. *Amici* believe that all patients are entitled to prompt, complete, and unbiased health care that is medically and scientifically sound. *Amici* submit this brief to explain that mifepristone is exceedingly safe and effective, and that the Food and Drug Administration's ("FDA") approval, as well as its decision to eliminate certain Risk Evaluation and Mitigation Strategies ("REMS") restrictions on mifepristone, were and continue to be based on sound medical science.

Amici's ability to effectively care for patients often requires access to mifepristone, which has undergone rigorous testing and review and has been approved for use in the United States for over 20 years. Accordingly, *amici* have a strong interest in ensuring that the science surrounding mifepristone's safety and efficacy is correctly understood.

PRELIMINARY STATEMENT

On behalf of the nation's leading medical organizations and the patients they serve, *amici* urge this Court to preserve access to mifepristone under the conditions of use established by the FDA. Those conditions—set aside without proper basis by the District Court's order (the "Order")—are scientifically sound and supported by decades of evidence and ensure access to an exceedingly safe and

commonly used medication that is necessary to preserve the life and health of countless patients.

Without any form of evidentiary hearing and in complete disregard of the overwhelming body of evidence proving that mifepristone is safe, the Order purports to suspend the use of a treatment essential to *amici*'s patients, in order to further its own ideological agenda and that of Appellees. The decision is rife with medically inappropriate assumptions and terminology. It disregards decades of unambiguous analysis supporting the use of mifepristone in miscarriage and abortion care. It relies on pseudoscience and on speculation, and adopts wholesale and without appropriate judicial inquiry the assertions of a small group of declarants who are ideologically opposed to abortion care and at odds with the overwhelming majority of the medical community and the FDA. The Order endangers *amici*'s patients by depriving them of medically appropriate, safe access to an effective and important medicine. This Court should not uphold a decision that is so demonstrably at odds with the facts and so hostile to *amici*'s patients.

Amici urge this Court to uphold science and the rule of law. Mifepristone is safe and effective. Hundreds of medical studies and vast amounts of data amassed over the course of two decades have confirmed it. The FDA based its initial approval on robust evidence showing mifepristone was extremely safe. When mifepristone is used in medication abortion, as part of a two-step, two-drug

regimen with misoprostol, serious side effects are exceedingly rare compared to many commonly used medications, occurring in ***less than 1%*** of patients. Major adverse events—significant infection, blood loss, or hospitalization—occur in ***less than 0.3%*** of patients. The risk of death is almost nonexistent.

The REMS at issue do nothing to protect patients given mifepristone's demonstrated safety and instead act only as a barrier to access. Science proves that. The hundreds of studies conducted prior to 2016 were more than sufficient to justify the FDA's decision to begin lifting restrictions. And studies conducted since 2016 have shown ***no increase*** in adverse events. The absence of adverse events was important, but it was far from the only reason the FDA revised the REMS. The FDA reviewed studies focused specifically on each of the now-lifted restrictions—and every single study supported its conclusion that the REMS restrictions were not medically necessary to ensure patient safety.

Denying or limiting access to mifepristone will not make patients safer—it will actively jeopardize their health. Pregnancy can be dangerous. The risks of maternal mortality in the U.S. are alarmingly high and drastically higher for Black women, poor women, and all those whose access to reproductive care has been historically and geographically limited. Pregnancy can cause hemorrhaging, infection, dangerously high blood pressure, and many other critical physiological conditions. These dangers directly impair the health and well-being of pregnant

patients, often in material ways. Abortion, including medication abortion involving mifepristone, is an essential component of reproductive care that is protected in many states—including for the management of miscarriage. Miscarriage is common. It can be dangerous, even life threatening. The Order harms these patients too. In light of the harrowing treatment of women and girls in states that are banning or severely restricting abortion, it is essential that miscarriage management remain available and accessible in all states. Limiting access to mifepristone simply endangers patients, regardless of whether they are seeking abortion or miscarriage care.

The District Court's claim that mifepristone increases the burden on our health care system is also incorrect. Medication abortion actively ***reduces*** any burden, as patients in need of abortion care are able to take mifepristone at home following consultation with their health care provider. And because mifepristone is an effective treatment for miscarriage as well as a range of other pregnancy-related conditions, enjoining its use will ***increase*** the burden on patients, clinicians, and the health care system as a whole by eliminating an established and effective form of care.

Upholding the District Court's decision will cause profound and irreparable harm to patients across the country. These impacts will be most severe for people of color as well as low-income and rural patients, who are more likely to die or

develop serious complications from pregnancy and more likely to have limited access to alternative procedures (i.e., procedural abortion) or lack the ability to travel long distances for health care. In purporting to analyze the medical evidence and weigh the limited risks of mifepristone against its significant benefits, the District Court has supplanted the FDA's judgment with its own—a dangerous precedent that will lead to uncertainty and destabilize the drug approval process in the United States.

Both the FDA's initial approval of mifepristone and its decision to remove certain restrictions on the use of mifepristone are supported by law and the overwhelming weight of medical evidence. This Court should grant the relief sought by Appellants.

ARGUMENT

The most common method of medication abortion in the U.S. is a two-drug regimen in which mifepristone is used in conjunction with misoprostol to end an early pregnancy by emptying the contents of the uterus.[4] Mifepristone followed by

[4] Combined mifepristone-misoprostol regimens are the preferred therapy for medication abortion because they are more effective than misoprostol-only regimens. *See* ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* at 1, 4 (Oct. 2020, *reaff'd* 2023).

misoprostol is used both to induce abortion[5] and in the treatment of miscarriage or early pregnancy loss (which can be life threatening),[6] a term that includes spontaneous abortion, missed abortion, incomplete abortion, or inevitable abortion.

The overwhelming weight of the scientific evidence supports the FDA's finding that mifepristone is safe and effective. Mifepristone is one of the most studied medications prescribed in the U.S. and has a safety profile comparable to ibuprofen. Hundreds of studies and more than two decades of medical practice show that mifepristone is safe and effective, medication abortion offers specific benefits compared with other abortion methods for many patients, and it is not medically necessary to impose additional restrictions around mifepristone's use.

Appellees provide no scientific evidence supporting their position. They rely instead on anecdotes, speculation, and theories untested by cross-examination. The so-called studies on which the District Court relied are not scientifically tested or sound; they are produced by anti-abortion advocacy groups or contain serious (and often well-documented) methodological flaws—or both. If the District Court is going to disregard the well-supported and expert judgment of an executive

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[5] ACOG Committee Opinion No. 815, *Increasing Access to Abortion* at e107, e108 (Dec. 2020).

[6] *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2021).

agency and rule to upend the status quo, it should not be permitted to do so based on untested claims outside of mainstream and modern medical practice. If the District Court's decision is upheld, millions of women—whether seeking miscarriage or abortion care—stand to lose access to safe and effective medical care. This decision endangers the health and well-being of *amici*'s patients and disrupts the sound, evidence-based practice of medicine that is at the very core of *amici*'s missions.

I. Mifepristone Has Been Thoroughly Studied and Is Conclusively Safe.

Decades of evidence demonstrate that medication abortion is safe and effective, with exceptionally low rates of major adverse events. Appendix A lists a sampling of the hundreds of studies that prove this. Mifepristone's safety profile is on par with common painkillers like ibuprofen, which more than 30 million Americans take in any given day.[7] The District Court is wrong to conclude otherwise.[8]

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[7] *See* Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States*, NAT'L ACADS. PRESS 45, 79 (2018); *see also* R. Morgan Griffin, *Making the Decision on NSAIDs*, WEBMD (Oct. 17, 2005), https://www.webmd.com/arthritis/features/making-decision-on-nsaids.

[8] Memorandum Opinion and Order, 2:22-CV-00223-Z, Apr. 7, 2023, ECF No. 137, at 47 [hereinafter "Mem."]. Again, the District Court adopts as its own assertions made by Appellees, including statements that are purposefully inflammatory and are not based on the reality of what actually happens during

The FDA first approved the use of mifepristone in 2000, basing its decision on multiple, extensive clinical trials and sound research.[9] The FDA's analysis included an independent and unbiased review of the manufacturer's preclinical research and clinical test results to ensure that mifepristone was safe and effective and that the health benefits outweighed the known risks.[10] It considered trials conducted for more than a decade and involving thousands of women. When it revisited its guidance on mifepristone use in 2016, the FDA had exceptionally broad and strong confirmation of mifepristone's safety and efficacy.[11] The FDA's

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a medication abortion in accordance with the FDA's approved labeling, without so much as a factual inquiry or an evidentiary hearing.

[9] *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-751, *Report to Congressional Requestors: Food and Drug Administration Approval and Oversight of the Drug Mifeprex* at 15–16 (Aug. 2008); 2000 FDA Approval Memorandum, 2:22-CV-00223-Z, Nov. 18, 2022, Compl. Ex. 24, ECF No. 1-25 [hereinafter "2000 FDA Approval Memorandum"].

[10] *See* Development & Approval Process: Drugs, FDA (Aug. 8, 2008), https://www.fda.gov/drugs/development-approval-process-drugs. In contrast, five other drugs were approved under restrictive Subpart H with clinical sample sizes of "several hundred patients or less."

[11] The FDA ultimately concluded that mifepristone's safety profile was "well-characterized" and it could therefore remove the adverse reporting requirement on Danco Labs from the REMS. Contrary to what the District Court believes, this does *not* "ensur[e] that almost all new adverse events [will] go unreported or underreported. Mem. at 59. As the FDA recognized, Danco is still bound by 21 CFR § 314.80 to report serious, unexpected adverse events within 15

safety analysis relied on 11 independent clinical studies conducted between 2008 and 2015, covering "well over 30,000 patients,"[12] a randomized control trial,[13] and several observational studies,[14] all of which demonstrated the safety and effectiveness of mifepristone up to the 10-week gestational period.[15] Those studies conclusively demonstrated that "serious adverse events . . . are rarely reported . . . with rates ***generally far below 1.0%***."[16] This medicine is as safe as ibuprofen and safer than countless other drugs on the market. Based on this sound, scientific evidence, the FDA determined that it was appropriate to adjust the heavy

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days and all others on an annual basis. *See* FDA Ctr. For Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020*, 8 (Mar. 29, 2016) (hereinafter "2016 FDA Medical Review"), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

12 2016 FDA Medical Review at 1, 50.

13 *See id.* at 79.

14 *See, e.g.*, *id.* at 18, 35–38.

15 *See, e.g.*, Dina Abbas et al., *Outpatient Medical Abortion is Safe and Effective Through 70 Days Gestation*, 92 CONTRACEPT. 197 (2015); *see also* Appendix A-1 at 61–66; A-15 at 535–39; A-7 at 1070–76. More recent studies have again confirmed these results. For example, a 2020 evidence review recognized that medication abortion can safely and effectively be used up to at least 70 days of gestation. *See* ACOG Practice Bulletin No. 225, *supra* note 4.

16 2016 FDA Medical Review at 56 (emphasis added).

restrictions on mifepristone's use and began unwinding previously mandated ultrasound requirements and other barriers.[17]

Mifepristone has been scrutinized and tested for decades. In the two decades since mifepristone's approval, and the many years since the FDA's 2016 review, hundreds of additional studies have reaffirmed that medication abortions are safe for patients—safer than pregnancy, safer than untreated miscarriage, and safer than countless other routine medical procedures. To date, mifepristone has been discussed in more than 780 medical reviews and used in more than 630 published

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[17] Although an ultrasound can help determine gestational age and identify ectopic pregnancies, these goals can be accomplished just as effectively by discussing the patient's medical history—and the decision of what method to use should be left to the provider's reasonable judgment, on a case-by-case basis. 2000 FDA Approval Memorandum, *supra* note 9; *see also* Elizabeth Raymond & Hillary Bracken, *Early Medical Abortion Without Prior Ultrasound*, 92 CONTRACEPT. 212, 214 (2015). The District Court's purported concern that the FDA was abdicating its responsibilities and "assum[ing] physicians will ascertain gestational age" fundamentally misunderstands the practice of medicine—which is predicated on far more than FDA medication approvals. To ensure the safety and well-being of their patients, physicians, and other practitioners follow clinical guidance and use their years of training, expertise, and experience to treat patients, which before prescribing mifepristone, require them to determine gestational age. *See* ACOG Practice Bulletin No. 225, *supra* note 4. The District Court's assumption that clinicians must be told how make a clinical judgment of gestational age based on medical experience and expertise is belied by millions of interactions with patients every year.

clinical trials—of which more than 420 were randomized controlled studies (the gold standard in research design).[18] These studies have repeatedly concluded that even minor complications arising from medication abortion are rare.[19]

Major adverse events—which include hospitalization and serious infection or bleeding—are "exceedingly rare," occurring in approximately 0.3% of cases.[20] Studies have shown an even smaller number, finding between 0.015% and 0.07% of patients experience serious infection.[21] The FDA has made clear that the same complications can be observed following a miscarriage, procedural abortion, or medication abortion—i.e., any time the pregnant uterus is emptied—and that "[n]o

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[18] Based on a review of PubMed, the National Institute of Health's sponsored database of research studies.

[19] *See, e.g.*, Advancing New Standards in Reproductive Health ("ANSIRH"), *Analysis of Medication Abortion Risk and the FDA Report: Mifepristone U.S. Post-marketing Adverse Events Summary through 6/30/2021*, UNIV. OF CAL., S.F. at 2 (Nov. 2022) [hereinafter "ANSIRH, Adverse Events 2021"]; ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report: Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018*, UNIV. OF CAL., S.F. (Apr. 2019) [hereinafter "ANSIRH, Adverse Events 2018"]; ANSIRH, *Safety of Abortion in the United States*, UNIV. OF CAL., S.F. (Dec. 2014) [hereinafter "ANSIRH, Abortion Safety"]; Nat'l Acads. of Sci., Eng'g. & Med., *supra* note 7.

[20] 2016 FDA Medical Review at 56; *see also* Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175, 175–83 (2015).

[21] 2016 FDA Medical Review at 53–54.

causal relationship between the use of MIFEPREX and misoprostol and [infections and bleeding] has been established."[22]

The risk of death from medication abortion is near zero.[23] A 2019 analysis of FDA data examining potentially mifepristone-related deaths over an 18-year period by the University of San Francisco Medical Center found that only 13 deaths were possibly or probably related to medication abortion, yielding an approximate mortality rate of 0.00035%.[24] Even when considering deaths that followed a medication abortion but did not appear to be related to mifepristone, that number rises to only 0.00065%.[25] While the District Court claims that "at least two women" died from medication abortion last year, this is demonstrably false—and underscores the danger of banning mifepristone before a hearing on the merits.[26]

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[22] Mifeprex Prescribing Information, FDA at 2, 5 (Mar. 2016) https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

[23] *See* Katherine Kortsmit et al., *Abortion Surveillance – United States, 2019*, 70 CDC MORBIDITY & MORTALITY WKLY. REP. 1, 29, tbl. 15 (2021).

[24] ANSIRH, Adverse Events 2018, *supra* note 19, at 1–2.

[25] *Id.*

[26] Mem. at 61; *cf.* Planned Parenthood Great Northwest ("PPGNHAIK"), *PPGNHAIK Statement on Incorrect Indiana Data* (Apr. 11, 2023), https://www.plannedparenthood.org/planned-parenthood-great-northwest-

The mifepristone safety profile is similar to that of procedural abortion—and both are comparatively low compared to other common medications and procedures.[27] There is a greater risk of complications or mortality for procedures like wisdom-tooth removals, tonsillectomies, colonoscopies, and plastic surgeries than by any abortion method, medication or procedural.[28] Using Viagra is more dangerous than using mifepristone. Studies have shown Viagra to be associated with 4.9 deaths per 100,000 prescriptions,[29] death by colonoscopy occurs in about

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hawaii-alaska-indiana-kentuck/press/ppgnhaik-statement-on-incorrect-indiana-data.

[27] *See* ANSIRH, Adverse Events 2018, *supra* note 19 at 2 ("[t]he safety profile [of medication abortion with mifepristone and misoprostol] is similar to that of vacuum aspiration abortion, and medication abortion is safer than continuing a pregnancy to term or using other common medications"); ANSIRH, Adverse Events 2021, *supra* note 19 at 3 (same); *see also* Appendix A-5; A-14; A-20.

[28] *Compare* ANSIRH, Abortion Safety, *supra* note 19, at 2 (complication rate for wisdom-tooth extraction is approximately 3.5x higher than abortions; complication for tonsillectomies is approximately 4x higher than abortions) *with* ASGE Standards of Practice Comm., *Complications of Colonoscopy*, 74 AM. SOC'Y FOR GASTROINTESTINAL ENDOSCOPY 745, 745 (2011) (up to 33% of colonoscopies result in minor complications); Frederick M. Grazer & Rudolph H. de Jong, *Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons*, 105 PLASTIC & RECONSTR. SURGERY 436, 441 (2000) (mortality rate from liposuction was 20 deaths per 100,000 patients).

[29] *See* Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA 590, 590–93 (2000).

0.03% of cases,[30] and the "risk of death associated with childbirth [is] approximately 14 times higher" than the risk associated with an abortion.[31] Every drug has side effects, and every procedure has risks—but medication abortion is among the safest medical interventions in any category, pregnancy-related or not.[32]

The District Court did not consider these facts. Instead, it selectively relied on a narrow minority of biased and flawed studies to set aside decades of safe, FDA-approved use. For example, it recites statistics on emergency room visits from a study whose author is an employee of an anti-abortion organization and a member of one of the Plaintiff groups.[33] *Amici* strongly disagree with the District Court's approach and conclusions.

The District Court's unquestioning endorsement of Appellees' view that medication abortion causes emotional and physical harm is again unsupported by scientific fact. Studies show that patients who seek an abortion, including

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30 ASGE Standards of Practice Committee, *supra* note 28, at 747.

31 Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTET. & GYNECOL. 215, 215 (2012).

32 Appellees also inaccurately claim that mifepristone acts as an "endocrine-disruptor" in adolescents. *See* Complaint, 2:22-CV-00223-Z, Nov. 18, 2022, ECF No. 1, at ¶¶ 54, 60 [hereinafter "Compl."]. Nothing suggests that medication abortion has any effect on adolescent development.

33 Mem. at 7 n.9, 47 n.45.

medication abortion, do not suffer from emotional distress or negative mental-health outcomes and experience better long-term outcomes than those who seek abortion care but are denied it.[34] Participants who received abortion care confirmed in one study that they believed it had been the "right decision for them" in the years that followed.[35]

The District Court chose to rely on studies that served its agenda, including one cited "study" authored by an anti-abortion research group that was based on blog posts made on an anti-abortion website,[36] and on studies that have been widely critiqued by researchers and scholars for their serious methodological flaws.[37] The District Court's selective reliance on pseudoscience endangers *amici*'s patients and their own ability to provide safe, effective reproductive care. It purports to suspend the use of a common and safe medicine based on studies that

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[34] M. Antonia Biggs et al., *Women's Mental Health and Well-Being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA PSYCHIATRY 169, 177 (2017).

[35] Corrine H. Rocca et al., *Decision Rightness and Emotional Responses to Abortion in the United States: A Longitudinal Study*, 10 PLOS ONE 1, 7 (2015).

[36] *See* Mem. at 46 nn.40–41.

[37] *Id.* at 11 (citing David C. Reardon et al., *Deaths Associated with Pregnancy Outcome: A Record Linkage Study of Low Income Women*, 95 S. MED. J. 834, 834–41 (2002); Priscilla K. Coleman, *Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995–2009*, 199 BRITISH J. PSYCHIATRY 180, 180–86 (2011)).

are directly contradicted by a *vast* body of research—research that demonstrates overwhelmingly and conclusively that there is no association between medication abortion and adverse physical or psychological outcomes.[38] This Court should not endorse that dangerous result.

II. REMS Restrictions Are Not Necessary to Ensure Patients' Safety.

When it revisited its guidance on mifepristone use in 2016, the FDA had exceptionally broad and strong confirmation of mifepristone's safety and efficacy. It inappropriately concluded that it could revisit certain aspects of the REMS put in place 16 years prior. Each change to the REMS since 2016 has been fully supported by scientific evidence and has not changed mifepristone's safety profile.

As described above, the FDA reviewed extensive safety data and numerous scientific studies when it considered the mifepristone REMS in 2016.[39] The FDA concluded that because mifepristone's safety profile was "well-characterized," it could remove the adverse reporting requirement previously imposed on Danco

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[38] *See, e.g.*, Brenda Major et al., *Abortion and Mental Health: Evaluating the Evidence*, 64 AM. PSYCH. 863 (2009); M. Antonia Biggs et al., *Mental Health Diagnoses After Receiving or Being Denied an Abortion in the United States*, 105 AM. J. OF PUB. HEALTH 2557 (2015); Vignetta E. Charles et al., *Abortion and Long-Term Mental Health Outcomes: A Systematic Review of the Evidence*, 78 CONTRACEPT. 436 (2008).

[39] *Supra* text accompanying nn.11–17.

Labs from the REMS.[40] Contrary to the District Court's assumption, this does *not* "ensur[e] that almost all new adverse events [will] go unreported or underreported."[41] As the FDA recognized in its 2016 Medical Review, Danco is still bound by 21 CFR § 314.80 to report serious, unexpected adverse events within 15 days and all others on an annual basis.[42] The suggestion that recent safety data is somehow tainted by this decision or materially different from the data gathered between 2000 and 2016 is simply incorrect. Adverse events are still being reported, and mifepristone continues to be used safely and effectively.

This Court's previous suggestion that mifepristone's safety must have been a *result* of the REMS misunderstands the science. For example, the ultrasound requirement was removed because, although an ultrasound *can* help determine gestational age and identify ectopic pregnancies, these goals can be accomplished *just as effectively* by discussing the patient's medical history—and that holds true even if the medical history is collected via telemedicine rather than in person.[43]

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40 *See* 2016 FDA Medical Review, *supra* note 11, at 8

41 Mem. at 59.

42 *See* 2016 FDA Medical Review, *supra* note 11, at 8.

43 2000 FDA Approval Memorandum, *supra* note 9, at 6 ("In practice, dating pregnancies occurs through using other clinical methods, as well as through using ultrasound."); Raymond & Bracken, *supra* note 17, 214 (2015) (noting that gestational dating using last monthly period rather than ultrasound may be

The decision of which method to use should be left to the trained provider's reasonable judgment based on the facts before them.

The District Court's purported concern that the FDA in 2016 was abdicating its responsibilities and "assum[ing] physicians will ascertain gestational age"[44] also fundamentally misunderstands the practice of medicine—which is not predicated solely on FDA medication approvals. To ensure the safety and well-being of their patients, physicians, and other practitioners follow clinical guidance and use their years of training, expertise, and experience to treat patients, which, before prescribing mifepristone, require them to determine gestational age.[45]

Similarly, mifepristone's in-person dispensing requirement was removed in 2021 based on scientific evidence that doing so would not pose any additional harm to patients. In response to the COVID-19 pandemic, the FDA initially

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reasonable for selected patients before medication abortion); *see also* Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA INTERNAL MED. 482, 489 (2022) (finding that mifepristone labels could be revised to state that "if pregnancy duration can be reasonably estimated by history and if no symptoms or risk factors for ectopic pregnancy are present," ultrasonography should not be required); Holly Anger et al., *Clinical and Service Delivery Implications of Omitting Ultrasound before Medication Abortion Provided via Direct-to-Patient Telemedicine and Mail in the U.S.*, 104 CONTRACEPT. 659 (2021).

44 Mem. at 51.

45 ACOG Practice Bulletin No. 225, *supra* note 4 at 1, 4.

exercised its enforcement discretion to suspend the in-person dispensing requirement—but only after determining that the science "[did] not appear to show" that doing so would result in any "increases in serious safety concerns (such as hemorrhage, ectopic pregnancy, or surgical interventions)."[46] Months later, the FDA denied a Citizens Petition by anti-abortion organizations seeking to reinstate that constraint[47]—having confirmed that eliminating the in-person requirement had no effect on mifepristone's safety profile based on a comparison of adverse events data from before and during the suspension of this requirement.[48]

Given these facts and the dearth of accessible in-person health care in large portions of this country,[49] there is no logical reason to declare the FDA's reasoned

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[46] Letter from Janet Woodcock, Acting Comm'r, FDA, to Maureen G. Phipps, Chief Exec. Officer, Am. Coll. of Obstetricians and Gynecologists, and William Grobman, President, Soc'y for Maternal-Fetal Med. at 2 (Apr. 12, 2021), https://www.aclu.org/wp-content/uploads/legal-documents/fda_acting_commissioner_letter_to_acog_april_12_2021.pdf.

[47] *See* Response Letter from FDA Ctr. for Drug Evaluation & Rsch. to Amer. Ass'n of Pro-Life Obstetricians and Gynecologists and Amer. Coll. of Pediatricians, Docket No. FDA-2019-P-1534 (Dec. 16, 2021), https://www.regulations.gov/document/FDA-2019-P-1534-0016.

[48] *Id.* at 26–27.

[49] Indeed, 6.9 million women of childbearing age live in areas of the United States where maternity care is limited or nonexistent. *See Maternity Care Desert*, MARCH OF DIMES (Oct. 2022), https://www.marchofdimes.org/peristats/data?top=23&lev=1&slev=0.

judgment arbitrary and capricious, or to create a precedent allowing a court to substitute its judgment and reinstate requirements that have been shown, time and again, to provide no meaningful health benefits to patients.

III. Enjoining the Use of Mifepristone Will Harm Pregnant Patients and Have Severe Negative Impacts on the Broader Health Care System.

A. Patients Will Suffer if Denied Access to a Safe and Effective Protocol for Medication Abortion.

The Order will make mifepristone unavailable nationwide—even in states where abortion remains legal—and impose a severe, almost unimaginable, cost on pregnant patients. Even temporary lack of access to mifepristone will cause patients to suffer serious physical harm and even death. And because mifepristone has many uses outside of medication abortion, enjoining its use will also cause irreparable harm to patients who are prescribed the drug for miscarriage management and other conditions.

Abortion care can be lifesaving, especially for people suffering from serious health conditions or experiencing early pregnancy loss. Medication abortion's relative availability makes it more accessible to patients with limited access to medical care, including low-income patients and patients of color[50]—the very

[50] *See* Rachel K. Jones et al., *COVID-19 Abortion Bans and Their Implications for Public Health*, 52 PERSPS. ON SEXUAL & REPROD. HEALTH 65–67 (2020); *see also* Appendix A-47 at 416; A-52 at 11; *see also* Ctrs. for Medicare & Medicaid Servs., *CMS Rural Health Strategy* at 2 (2018),

people who are most likely to experience severe maternal morbidity and more likely to die from pregnancy-related complications.[51] Indeed, 75% of those seeking abortion care are living below 200% of the federal poverty level, a majority of whom identify as people of color.[52] Pregnant people of color are also more likely to experience early pregnancy loss or miscarriage, the treatment for which can include procedural or medication abortion.[53] Enjoining the use of mifepristone would only harm these patients by removing a relatively accessible and entirely safe treatment from the marketplace—resulting in the denial of medical care.

Substantial evidence demonstrates that the *denial* of abortion care alone causes harm. Patients who are denied abortions are more likely to experience intimate partner violence compared with patients who were able to have an

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https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.

[51] *See* Ctrs. for Medicare & Medicaid Servs., *Advancing Rural Maternal Health Equity* at 1 (2022), https://www.cms.gov/files/document/maternal-health-may-2022.pdf; *see also* Juanita Chinn et al., *Health Equity Among Black Women in the United States*, 30 J. WOMEN'S HEALTH 212, 215 (2021).

[52] ACOG Committee Opinion No. 815, *Increasing Access to Abortion* (Dec. 2020).

[53] *See* Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department, 2006–2016*, 2 J. AM. COLL. EMERGENCY PHYSICIANS OPEN e12549 at 2 (2021).

abortion.[54] Studies have repeatedly shown that being denied an abortion also exacerbated patients' economic hardships, revealing "large and statistically significant differences in the socioeconomic trajectories of women who were denied requested abortions compared with women who received abortions—with women denied abortions facing more economic hardships."[55]

Appellees' claim that continuing a pregnancy is a safer alternative—specifically, that "pregnancy rarely leads to complications that threaten the life of the mother or the child"[56]—is not based on science. Empirical evidence shows that women are at least 14 times more likely to die during childbirth than during any abortion procedure[57] and are at an increased risk of experiencing hemorrhage,

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[54] *See* Sarah Roberts et al., *Risk of Violence from the Man Involved in the Pregnancy After Receiving or Being Denied an Abortion*, 12 BMC MED. 1, 6 (2014).

[55] 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).

[56] *See* Compl. ¶ 51.

[57] *See* Raymond & Grimes, *supra* note 31, at 216–17, fig. 1. The U.S. mortality rate associated with live births from 1998 to 2005 was 8.8 deaths per 100,000 live births. *Id.* at 216. Rates have sharply increased since then. David Boulware, *Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues*, 128 OBSTET. & GYNECOL. 385, 386 (2016). By contrast, the mortality rate associated with abortions performed from 1998 to 2005 was 0.6 deaths per 100,000 procedures. *See*

infection, and injury to other organs during pregnancy and childbirth as well.[58] Even under the best of circumstances, pregnancy and childbirth impose significant physiological changes that can exacerbate underlying conditions and can severely compromise health, sometimes permanently.[59] Pregnancy, particularly when coupled with preexisting conditions, can quickly evolve into a life-threatening situation necessitating critical care, including abortion. Providing access to that care in a nonjudgmental and clinically sound way is what physicians do.

Raymond & Grimes, *supra* note 31, at 216. A committee of the National Academies in a 2018 peer-reviewed, evidence-based report similarly concluded that abortion is safer than pregnancy; specifically, "the risk of death subsequent to a legal abortion (0.7 [deaths] per 100,000 [patients]) is a small fraction of that for childbirth (8.8 [death] per 100,000 [patients])." Nat'l Acads. of Sci., Eng'g. & Med., *supra* note 7, at 7.

[58] Raymond & Grimes, *supra* note 31 at 215, 216–17, fig.1.

[59] *See, e.g.*, ACOG Practice Bulletin No. 190, *Gestational Diabetes Mellitus* (Feb. 2018); ACOG Practice Bulletin No. 222, *Gestational Hypertension and Preeclampsia* (June 2020); ACOG Practice Bulletin No. 183, *Postpartum Hemorrhage* (Oct. 2017); ACOG Obstetric Care Consensus No. 7, *Placenta Accreta Spectrum* (Dec. 2018); ACOG Practice Bulletin No. 198, *Prevention and Management of Obstetric Lacerations at Vaginal Delivery* (Sept. 2018); ACOG Clinical Consensus No. 1, *Pharmacologic Stepwise Multimodal Approach for Postpartum Pain Management* (Sept. 2021).

B. Patients Experiencing Pregnancy Loss and Beyond Will Suffer if Denied Access to Mifepristone.

As with many medications, mifepristone also has critical off-label uses beyond abortion.[60] Mifepristone is already widely prescribed for management and treatment of miscarriages, including spontaneous, missed, inevitable, and incomplete abortions.[61] Studies have also examined its use for a range of other maternal-health purposes, including treatment of uterine fibroids (tumorous growths of uterine muscle) and treatment of endometriosis (abnormal tissue growth outside the uterus, which can cause severe pain and infertility).[62] Mifepristone is also used off-label to reduce the duration of bleeding or hemorrhaging during certain serious pregnancy complications, and it may have beneficial effects on the cervix in full-term pregnancies, which in turn may affect the likelihood of

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60 *See* Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87 MAYO CLINIC PROC. 982–80 (2012).

61 Mara Gordon & Sarah McCammon, *A Drug that Eases Miscarriages is Difficult for Women to Get*, NPR (Jan. 10, 2019), https://www.npr.org/sections/health-shots/2019/01/10/666957368/a-drug-that-eases-miscarriages-is-difficult-for-women-to-get.

62 *See* Y. X. Zhang, *Effect of Mifepristone in the Different Treatments of Endometriosis*, 43 CLIN. AND EXP. OBSTET. & GYNECOL. 350 (2016); *see also* Appendix A-63.

successful labor.[63] Patients who may benefit from these and other treatments for reasons unrelated to abortion will also suffer as a result of the District Court's decision.[64]

C. The District Court's Order Will Destabilize the FDA's Regulatory Process and the Medical Profession.

Should the District Court's Order stand, the FDA's drug regulatory process will be completely upended, causing chaos and confusion throughout the healthcare system. Upholding the District Court's manufactured result will undoubtedly prompt ideological challenges to other safe medications that have been long approved by the FDA—which providers and patients rely on every single day. The District Court's Order has already caused concern amongst leading medical organizations,[65] with experts foreseeing the decision, if upheld, to

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63 *See* Yanxia Cao et al., *Efficacy of Misoprostol Combined with Mifepristone on Postpartum Hemorrhage and its Effects on Coagulation Function*, 13 INT. J. CLIN. EXP. MED. 2234 (2020).

64 *See, e.g.*, Press Release, *Endocrine Society Alarmed by Texas Court Ruling Banning Mifepristone*, ENDOCRINE SOC'Y (Apr. 10, 2023) (recognizing that "mifepristone is [also] used to treat people with Cushing's syndrome and diabetes or high blood sugar who are not surgical candidates or have failed surgery," and that the District Court's decision could restrict access to such treatment).

65 *See* Pam Belluck & Christina Jewett, *Drug Company Leaders Condemn Ruling Invalidating F.D.A.'s Approval of Abortion Pill*, N.Y. TIMES (Apr. 10, 2023), https://www.nytimes.com/2023/04/10/health/abortion-ruling-pharma-

invite challenges to "vaccines, drugs for HIV treatment, and more"[66] as well as to medication used to treat cancer or arthritis that may incidentally affect unknown pregnancies.[67] This deeply destabilizing result—i.e., allowing the courts to usurp the FDA's role in the regulatory process by declaring medications unsafe despite medical evidence to the contrary—will reverberate far beyond the context of abortion or even maternal health.

D. Physicians and Hospitals Will Experience Significant Costs and Burdens Without Any Medical Justification.

Enjoining the use of mifepristone will also, at a macro level, increase the burden on the nation's health care system, particularly women's health and

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executives.html#:~:text=the%20main%20story-,Drug%20Company%20Leaders%20Condemn%20Ruling%20Invalidating%20F.D.A.'s%20Approval%20of,the%20pharmaceutical%20and%20biotech%20industries; Press Release, *30 Patient and Provider Groups Warn that Mifepristone Ruling Threatens All FDA-Approved Drugs*, AM. CANCER SOC'Y CANCER ACTION NETWORK (Apr. 11, 2023) ("This decision risks emboldening other courts to block access to FDA-approved drugs and treatments for reasons having nothing to do with their safety or efficacy."); Press Release, *Statement on Alliance for Hippocratic Medicine v. FDA*, AM. SOC'Y OF HOSPITAL PHARMACISTS (Apr. 10, 2023); Endocrine Society, *supra* at 64.

[66] Fanta Cherif and Amanda Okaka, *Three Ways the Abortion Pill Ruling Could Impact Life Sciences*, Advisory Board (Apr. 13, 2023), https://www.advisory.com/daily-briefing/2023/04/13/fda-authority#fda-authority-ec.

[67] Jack Resneck, Jr., *This Could Be One of the Most Brazen Attacks on Americans' Health Yet*, N.Y. TIMES (Apr. 20, 2023), https://www.nytimes.com/2023/04/20/opinion/abortion-pill-case-supreme-court.html.

OBGYN care. Medical facilities will experience an increased strain on already-limited resources.[68] Medication abortion allows a patient to ingest their prescription safely at home after consultation with their health care providers, freeing clinicians and in-patient resources to focus on providing other needed medical care. The same is true of prior restrictions on mifepristone use that the FDA has since lifted, such as requiring physicians to dispense the medication to patients in person or making patients travel, in many cases long distances, to a facility for medically unnecessary follow-up appointments.

Medical ethics also support continued access to a demonstrably safe and effective drug that a majority of patients choose over less effective or more invasive alternatives (which offer no safety benefit in comparison). At core, medical ethics require that "the welfare of the patient must form the basis of all medical judgments."[69] Clinicians respect these ethical duties by providing patients with information on and access to the full range of medical treatments approved by the FDA for providing benefits that outweigh the risks. There is simply no rational or legitimate basis for a single judge without so much as an evidentiary hearing to

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[68] *See* Alexander Janke, *An Emergency in U.S. Emergency Care: Two Studies Show Rising Strain*, U. MICH. INST. OF HEALTHCARE POL'Y & INNOVATION (Oct. 7, 2022), https://ihpi.umich.edu/news/emergency-us-emergency-care-two-studies-show-rising-strain.

[69] ACOG, *Code of Professional Ethics* at 2 (Dec. 2018).

override the expert judgment of the FDA, backed by decades of research, and deprive medical professionals and their patients of access to mifepristone, particularly before the merits of this dispute have even been reached.

CONCLUSION

For these reasons and those in Appellants' Motion, *amici* strongly urge the Court to reverse the District Court's decision.

Dated: May 1, 2023

Respectfully submitted,

/s/ Shannon Rose Selden

Shannon Rose Selden
Counsel of Record
Adam Aukland-Peck
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, N.Y. 10001
(212) 909-6000

Megan McGuiggan
DEBEVOISE & PLIMPTON LLP
801 Pennsylvania Ave, NW
Washington, D.C. 20004
(202) 383-8000

Molly Meegan
Jessica Morris*
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
409 12th Street, SW
Washington, D.C. 20024

**Application for Admission forthcoming*

Counsel to Amici Curiae

CERTIFICATE OF SERVICE

I certify that on May 1, 2023, I electronically 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. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Shannon Rose Selden
Shannon Rose Selden

Counsel to Amici Curiae

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6490 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman font size 14.

/s/ Shannon Rose Selden
Shannon Rose Selden

Counsel to Amici Curiae

APPENDIX A

Safety of Mifepristone

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