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 OF AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN MEDICAL ASSOCIATION, AND OTHER MEDICAL SOCIETIES AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are 16 leading medical societies representing hundreds of thousands of clinicians who serve patients nationwide. They include:

The American College of Obstetricians and Gynecologists ("ACOG"). Representing more than 90% of board-certified OB/GYNs in the United States, ACOG is the nation's premier professional membership organization for obstetrician-gynecologists dedicated to providing access to high-quality, safe, and equitable obstetric and gynecologic care. ACOG maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. ACOG is committed to ensuring access for all people to the full spectrum of evidence-based quality reproductive health care, including abortion care, and is a leader in the effort to confront the maternal mortality crisis in the United States.

The American Medical Association ("AMA"). AMA is the largest professional association of physicians, residents, and medical students in the country. Through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process.

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[1] Pursuant to Rule 37.6, counsel for *amici* authored this brief in whole; no party's counsel authored, in whole or in part, this brief; and no person or entity other than *amici* and its counsel contributed monetarily to preparing or submitting this brief.

AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes.

The Society for Maternal-Fetal Medicine ("SMFM"). Founded in 1977, SMFM is the medical professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies. SMFM represents more than 7,000 members who care for high-risk pregnant people and provides education, promotes research, and engages in advocacy to advance optimal and equitable perinatal outcomes for all people who desire and experience pregnancy. SMFM and its members are dedicated to ensuring that all medically appropriate treatment options are available for individuals experiencing a high-risk pregnancy.

American Academy of Family Physicians ("AAFP"). Founded in 1947, AAFP is one of the largest national medical organizations, representing 129,600 family physicians and medical students nationwide. AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and by supporting its members in providing continuous comprehensive health care to all.

American Academy of Pediatrics ("AAP"). AAP was founded in 1930 and is a national, not-for-profit professional organization dedicated to furthering the interests of child and adolescent health. Since AAP's inception, its membership has grown from 60 physicians to over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 90 years, AAP has become a powerful voice for child and adolescent health through education, research,

advocacy, and the provision of expert advice. Among other things, AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's adolescents to ensure the availability of effective reproductive health care.

American College of Physicians ("ACP"). ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum—from health to complex illness.

American College of Preventative Medicine ("ACPM"). ACPM is a professional medical society representing approximately 2,000 physicians, dedicated to the practice of preventive medicine and improving the health and quality of life of individuals, families, and communities through disease prevention and health promotion. ACPM supports the peer-reviewed, evidence-based practice of medical care and comprehensive reproductive health services.

American Gynecological and Obstetrical Society ("AGOS"). AGOS is composed of individuals attaining national prominence in scholarship and leadership in the discipline of Obstetrics, Gynecology and Women's Health. AGOS's mission is to promote excellence in women's health care through advocacy for research and clinical training and the development of academic leaders in obstetrics and gynecology. AGOS is committed to enhancing diversity and inclusion across the organization.

American Society for Reproductive Medicine ("ASRM"). ASRM is dedicated to the advancement of science and the practice of reproductive medicine. Its members include approximately 8,000 medical professionals.

American Thoracic Society ("ATS"). ATS is the world's leading medical society dedicated to accelerating the advancement of global respiratory health through multidisciplinary collaboration, education, and advocacy. Core activities of the Society's more than 16,000 members are focused on leading scientific discoveries, advancing professional development, impacting global health, and transforming patient care.

North American Society for Pediatric Adolescent Gynecology ("NASPAG"). NASPAG is a voluntary, non-profit organization devoted to conducting, encouraging, and supporting programs of medical education and professional training in the field of pediatric and adolescent gynecology ("PAG"). NASPAG members reside in all 50 states and in countries abroad. Its focus is to serve and be recognized as the lead provider in PAG education, research, and clinical care; conduct and encourage multidisciplinary and inter-professional programs of medical education and research in the field of PAG; and advocate for the reproductive well-being of children and adolescents and the provision of unrestricted, unbiased, and evidence-based practice of PAG.

Society for Adolescent Health and Medicine ("SAHM"). Founded in 1968, SAHM is a multidisciplinary organization committed to the promotion of optimal health and well-being for all adolescents and young adults by supporting adolescent health and medicine professionals

through the advancement of clinical practice, care delivery, research, advocacy, and professional development.

Society of General Internal Medicine ("SGIM"). SGIM is a member-based internal medical association of over 3,300 of the world's leading general internists, who are dedicated to improving access to care for all populations, eliminating healthcare disparities, and enhancing medical education. SGIM's mission is to cultivate innovative educators, researchers, and clinicians in general internal medicine, leading the way to better health for everyone. SGIM members advance the practice of medicine through their commitment to providing comprehensive, coordinated, and cost-effective care to adults, educating the next generation of outstanding physicians, and conducting cutting-edge research to improve quality of care and clinical outcomes of all patients.

Society of Gynecologic Oncology ("SGO"). SGO is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. SGO contributes to the advancement of women's cancer care by encouraging research, providing education, raising standards of practice, advocating for patients and members and collaborating with other domestic and international organizations.

Society of OB/GYN Hospitalists ("SOGH"). SOGH is a rapidly growing group of physicians, midwives, nurses, physician assistants, and other individuals in the health care field who support the OB/GYN Hospitalist model. SOGH is dedicated to improving outcomes for hospitalized women and supporting those who share this mission. SOGH's vision is to shape the future of OB/GYN by

establishing the Hospitalist model as the care standard. SOGH values excellence, collaboration, leadership, quality, and community.

Society for Academic Specialists in General Obstetrics and Gynecology ("SASGOG"). SASGOG seeks to support academic generalist physicians of all backgrounds throughout the lifespan of their careers by providing education, fostering excellence in scholarship and research, and promoting inclusive leadership opportunities.

* * *

These organizations collectively represent hundreds of thousands of medical practitioners across the country, with deep expertise in medical research and the treatment of patients in real-world settings. Courts frequently rely on *amici*'s medical and scientific expertise in cases involving pregnancy.[2] Ensuring robust 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 the current Food and Drug Administration ("FDA") regulations for the prescription and use of mifepristone align with the overwhelming weight of medical evidence and allow

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[2] *See*, *e.g.*, *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2131 (2020); *Whole Woman's Health v. Hellerstedt*, 579 U.S. 582, 612–13 (2016); *Stenberg v. Carhart*, 530 U.S. 914, 928 (2000); *Whole Woman's Health v. Paxton*, 978 F.3d 896, 910 (5th Cir. 2000); *Planned Parenthood S. Atl. v. State*, 882 S.E.2d 770, 787–88 (S.C. 2023); *Okla. Call for Reprod. Just. v. Drummond*, 526 P.3d 1123, 1152 n.10 (Okla. 2023).

amici to safely administer the drug in a manner consistent with medical ethics and medically appropriate standards of care.

Amici's ability to effectively care for patients can require access to mifepristone, which has undergone rigorous testing and review and has been safely used by *amici*'s members in the United States for more than 20 years. Accordingly, *amici* have a strong interest in preserving that access and ensuring that the science surrounding mifepristone's safety, efficacy, and administration is correctly understood.

SUMMARY OF THE ARGUMENT

At issue in this case are FDA regulations that allow clinicians to prescribe, and patients to access, one of the two drugs used in the standard protocol for medication abortion and miscarriage management, known in its generic form as mifepristone. Mifepristone is extremely safe. Over more than two decades, hundreds of medical studies and vast amounts of data have confirmed its safety and efficacy as part of this two-drug regimen. The scientific evidence is overwhelming: major adverse events occur in ***less than 0.32%*** of patients. The risk of death is almost non-existent. Few drugs have been so extensively studied after their approval by FDA and can boast such a clear and compelling record of safe use. Access to mifepristone under current FDA protocols is supported by the safety profile of the medication and enables practitioners to provide safe, medically-appropriate, evidence-based, and effective care.

Amici are the nation's leading medical organizations, representing hundreds of thousands of members, including those most familiar with the use of mifepristone in reproductive health care. Their members are the obstetricians, gynecologists, family physicians, emergency room doctors, maternal-fetal subspecialists, midwives, nurses, physician assistants, and many other providers who care for pregnant patients. Many of *amici*'s members regularly prescribe mifepristone and have extensive experience in their own practices with the risks and benefits for the many patients who rely on it.

Respondents, who represent a group of clinicians opposed to abortion, make inaccurate and disproven assertions about mifepristone's effects and the

experiences of clinicians who prescribe and patients who use the drug. The Fifth Circuit accepted these assertions with no evidentiary hearing, while simultaneously discounting the overwhelming evidence that mifepristone is a safe and essential component of reproductive health care. The decision is disconnected from the science and effectively sanctions Respondents' misuse of the drug regulatory system to create barriers to care. By seeking to limit access to a safe and effective drug in every state in the country, regardless of that state's laws related to abortion and the fact that mifepristone is also used for miscarriage management and other purposes, Respondents attempt an end run around this Court's commitment in *Dobbs* to leave it to the states and the elective process to address the question of abortion.

Respondents purport to be concerned that treating pregnancy loss induced by mifepristone will be psychologically damaging to them as providers. They urge nationwide restrictions on access to an essential medication to alleviate that fear. But Respondents' prospective personal concerns should not be a basis to deny medically-appropriate care to patients. *All* patients are entitled to prompt, complete health care that is firmly rooted in science, and all members of the medical profession are obligated by their codes of ethics to put patients' welfare above their own self-interests and to provide medically-necessary and appropriate care.[3] And

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[3] *See*, *e.g.*, ACOG, Code of Professional Ethics, at 1–2 (Dec. 2018) ("The respect for the right of individual patients to make their own choices about their health care (*autonomy*) is fundamental," and "the welfare of the patient must form the basis of all medical judgments."); AMA, AMA Principles of

inevitably, all clinicians who treat patients experiencing the end of a pregnancy must be able to address excessive bleeding—including patients who may need a subsequent procedure—because that is a potential complication when the uterus is emptied, whether from a spontaneous abortion, an induced abortion, or any other reason.[4]

Turning back the clock to reimpose unnecessary restrictions on mifepristone will exacerbate existing inequities in maternal health for women of color, low-income women, and those living in rural areas. Restricting access to mifepristone will not only jeopardize health, but worsen racial and economic inequities and deprive women of the choices that are at the very core of individual autonomy and well-being. *Amici* urge this Court not to let the speculative fears of a handful of doctors deprive patients throughout the country of an essential medication that FDA has deemed safe for use. For all of these reasons, *amici* join Petitioners in asking this Court to reverse.

Medical Ethics (2001) ("A physician shall, while caring for a patient, regard responsibility to the patient as paramount.").

[4] While the term "abortion" is most often associated with induced abortion, the majority of pregnancies that do not end in a live birth are an "abortion" in medical terms. Angela M. Mills & Elizabeth M. Danter, *Pregnancy-Related Complications, in* PEDIATRIC EMERGENCY MEDICINE 676, 676-677 (Jill M. Baren et al., eds., 2008).

ARGUMENT

I. Mifepristone Is an Essential Component of Reproductive Care.

The medically relevant facts, derived from decades of reliable research, should inform the Court's decision—as they did FDA's determination to revise previously imposed restrictions. *Amici* believe it is important for the Court to understand how mifepristone is prescribed and used in practice, as well as its safety profile and relative advantages for patients. It is an essential medication used in reproductive care, with vanishingly small risk and material benefits to countless patients.

Mifepristone is used in combination with misoprostol to provide a safe and effective way to end a pregnancy or manage a miscarriage. The preferred protocol for medical management of early pregnancy loss (including spontaneous abortions, missed abortions, incomplete abortions, and inevitable abortions) provides that mifepristone is administered approximately 24 hours before misoprostol to empty the contents of the uterus.[5] This medication protocol has exceptionally low rates of major adverse events. Although a misoprostol-only regimen can be used, the two-drug regimens are the preferred therapy for medication abortion and miscarriage management because they are "more effective than misoprostol-only regimens."[6] Mifepristone increases the protocol's overall efficacy and mitigates the risk that

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

[6] ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (Oct. 2020, *reaff'd* 2023).

subsequent procedural intervention will be needed.[7] When used in combination with misoprostol, mifepristone allows for the termination of pregnancy within a few days, at home.[8] This helps ensure access to potentially life-saving care for individuals who live in maternity care deserts or cannot travel long distances without significant hardship. Timing matters: ending a pregnancy at home, within a discrete period of time, can meaningfully improve patient well-being. By allowing greater access to mifepristone, FDA's current approach improves the quality of health care and outcomes for patients.

Focus on the use of mifepristone for induced abortion disregards how similarly essential it is to the safe and effective treatment of miscarriage or early pregnancy loss. Miscarriage is common. Of the roughly 5.5 million pregnancies estimated to occur in the United States each year, between 10% and 26% end in miscarriage.[9] For the million or more patients who experience early pregnancy loss annually, mifepristone is often a critical component of care.

Respondents submit that abortion induced by mifepristone results in "bleeding and cramping," which they characterize as a "complication" that they may be called upon to treat, and believe warrants imposing heightened restrictions on the medication. *Amici* object to this characterization. Medically

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7 *Id.*

8 *Id.*

9 *See* ACOG Practice Bulletin No. 200, *supra* n.5; Centers for Disease Control and Prevention, *U.S. Pregnancy Rates Drop During Last Decade* (Apr. 12, 2023); Carla Dugas & Valori H. Slane, *Miscarriage*, NAT'L LIBR. MED. (June 27, 2022) ("as many as 26% of all pregnancies end in miscarriage and up to 10% of clinically recognized pregnancies"); *see also Miscarriage*, MARCH OF DIMES (Feb. 2023).

speaking, bleeding and cramping are not a "complication"—that is *how* the body expels the uterine lining and contents, and it is what happens when the uterus is emptied.[10] It is a process familiar to practitioners from menstruation and miscarriage, as well as medication abortion using the two-drug protocol, including mifepristone. Mifepristone is not unique in inducing bleeding and cramping; if anything, mifepristone eases that process of emptying the uterus and reduces the risks that it will be prolonged or incomplete—which is one of the reasons it is so frequently prescribed off-label[11] for miscarriage management.[12]

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

The overwhelming weight of scientific evidence and two decades of medical practice show that mifepristone is safe and effective. To date, mifepristone has been discussed in more than 780 medical reviews and used in more than 630

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[10] "Common terms used interchangeably to refer to problems arising from medical . . . treatments include 'complication'[] [and] 'side effect'. . . . Complications refer to other diseases or symptoms that occur in relation to a given disease. Side effects refer to undesirable effects that occur concomitantly with the originally intended outcome." Young-Kyun Kim, *Malpractice and Complications*, 43 J. KOREAN ASS'N ORAL & MAXILLOFACIAL SURGEONS 1, 1 (2017).

[11] "Off-label" use of a drug—for new indications or under a regimen that deviates from FDA-approved labeling—is widespread and permitted in all areas of medicine. It allows clinicians to practice evidence-based medicine in accordance to the latest scientific advances so that patients consistently receive the best available treatment.

[12] ACOG Practice Bulletin No. 200, *supra* n.5.

published clinical trials—of which more than 420 were randomized controlled studies, the gold standard in research design.[13]

Over decades of research and hundreds of studies, the findings are stark and consistent: mifepristone is exceptionally safe and it is rare for patients to experience even *minor* complications from medication abortion.[14] When used in medication abortion, major adverse events—significant infection, excessive blood loss, or hospitalization—occur in ***less than 0.32%*** of patients, according to a highly regarded study with more than 50,000 patients.[15] Serious infection is exceptionally rare, occurring in only 0.015% to 0.07% of patients.[16] The risk of death is almost non-existent.[17] A 2021 analysis of FDA

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

[14] *See*, *e.g.*, ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone US Post-Marketing Adverse Events Summary Through 6/30/2021,"* UNIV. OF CAL., S.F. 2 (2022) [hereinafter ANSIRH, *Adverse Events 2021*]; Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 NEW ENG. J. MED. 57, 57 (2022) (concluding that after restrictions on mifepristone were eliminated in Canada, the rates of "adverse events and complications remained stable," even though "the proportion of abortions provided by medication increased rapidly").

[15] *See* Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175, 175 (2015) (a study of nearly 55,000 abortions found a major complications rate of 0.31% for medication abortion).

[16] FDA Ctr. For Drug Eval. & Rsch., *Medical Review Application No. 020687Orig1s020*, at 53–54 (Mar. 29, 2016) [hereinafter 2016 FDA Medical Review].

[17] A 2021 analysis of FDA data examining potential mifepristone-related deaths over an 18-year period by the University of San Francisco Medical Center, for example, found

data examining potential mifepristone-related deaths over a more than 20-year period found that only 13 deaths were possibly or probably related to medication abortion, yielding an approximate mortality rate of 0.00027%.[18] These strikingly low rates of adverse outcomes are observed regardless of the indication for its use. The District Court's conclusion that FDA's loosening of restrictions "resulted in many deaths" is simply not true.[19] The statistics on which the District Court relied, and the Fifth Circuit impliedly endorsed, are taken entirely out of context, at best, and plainly wrong, at worst.

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an approximate mortality rate of just 0.00035%. ANSIRH, *Adverse Events 2021*, *supra* n.14; *see also* Katherine Kortsmit et al., *Abortion Surveillance—United States, 2021*, 72 CDC MORBIDITY & MORTALITY WKLY. REP. 1 (2023).

[18] *See* ANSIRH, *Adverse Events 2021*, *supra* n.14, at 1–2; *see also id.* at 3 ("The 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, *U.S. Studies on Medication Abortion Without In-Person Clinician Dispensing of Mifepristone*, UNIV. OF CAL., S.F. (2021); Elizabeth Raymond & Hillary Bracken, *Early Medical Abortion Without Prior Ultrasound*, 92 CONTRACEPT. 212 (2015); Upadhyay et al., *supra* n.15.

[19] *All. for Hippocratic Med. v. FDA*, 2:22-CV-00223-Z, Memorandum Opinion and Order, Apr. 7, 2023, ECF No. 137, at 57–58 [hereinafter "District Court Opinion"]. For instance, the Court cited one study that observed "20 deaths" out of more than 3,000 patients who had taken mifepristone. But that study did not conclude that those deaths were possibly or probably related to the use of mifepristone. Indeed, the study recognized that, of the 20 deaths observed, at least three were due to homicide, one was attributable to suicide, and four were overdose-related. Kathi Aultman et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 ISSUES LAW & MED. 3–26 (2021).

To the extent the lower courts suggest that any adverse-event rate above *zero* is too much—*amici* submit that such a result is neither possible nor expected in the practice of medicine or the administration of *any* drug.

Mifepristone is not just safe—it is ***far safer*** than countless other medications and among the safest medications or devices approved by FDA and being used in medical practice. Mifepristone has a safety profile comparable to that of ibuprofen, which more than 30 million Americans take in any given day.[20] Using Viagra is more dangerous than using mifepristone; Viagra has a rate of 4.9 deaths for every 100,000 prescriptions.[21] Colonoscopies are a routine procedure, widely used in preventive care—yet death occurs in about 0.03% of colonoscopy cases.[22] Medication abortion involving mifepristone is among the safest medical interventions in any category, pregnancy-related or not.

Amici are deeply concerned at the flawed and selective studies used by Respondents and the lower courts to stoke fears about mifepristone that are not supported by credible data. These studies are far outside the medical consensus and starkly inconsistent with the overwhelming weight of credible, peer-reviewed, evidence-based work.

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[20] *See* NAT'L ACADS. OF SCI., ENG'G & MED., *The Safety and Quality of Abortion Care in the United States (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.

[21] *See* Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 J. AM. MED. ASS'N 590, 591 (2000).

[22] ASGE, Standards of Practice Comm., *Complications of Colonoscopy*, 74 AM. SOC'Y FOR GASTROINTESTINAL ENDOSCOPY 745, 747 (2011).

Providing a court's imprimatur on unreliable data and studies designed to serve an ideological end does not serve patients or further the health of our medical systems.

The District Court's conclusion that "adverse events from chemical abortion drugs can overwhelm the medical system" is unfounded.[23] As described above, complications from medication abortion requiring emergency care are exceedingly rare, and there is no evidence to suggest, nor have *amici* observed, *any increase* in such events since FDA loosened restrictions. Much of Respondents' "evidence" to the contrary comes from studies that have been widely critiqued by researchers and scholars for their serious methodological flaws. For example, for its inaccurate conclusion that a majority of women regretted having a medication abortion, the District Court relied on statistics from a review of 98 anonymous blog posts from the anti-abortion advocacy website "abortionchangesyou.com," which has none of the indicia of reliability of an evidence-based randomized and controlled study.[24] The publications' own authors admitted that it was a "qualitative case study" and "lack[ed] [] generalizability."[25] Furthermore, the District Court's reliance on a "study" published by James Studnicki

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[23] District Court Opinion, at 7. The District Court's use of the term "chemical abortion" itself is an indicator of its approach to the case. FDA-approved drugs are not referred to as "chemicals" when prescribed for conditions unrelated to abortion, and the term should not be used here.

[24] *See* District Court Opinion at 46 nn.40–41.

[25] Katherine A. Rafferty & Tessa Longbons, *#AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*, 36 HEALTH COMMC'N. 1485 (2021).

for the proposition that mifepristone unduly burdens our emergency-medical system has been widely and publicly criticized.[26]

Amici—the nation's leading medical organizations comprised of hundreds of thousands of members—urge this Court to correct inaccurate statements and recognize that the vast majority of women who seek abortion care, including medication abortion, report that they do not regret their decision. They do not suffer from emotional distress or negative mental-health outcomes. In fact, women who seek and are *able to obtain* abortion care experience better long-term outcomes than those who seek abortion care but are denied it.[27] Women seek abortion care for a variety of reasons, including socioeconomic and social factors—all of which must be recognized as critical to a patient's mental and

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[26] *See, e.g.*, SAGE Journals, *Expression of Concern*: *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions* (July 25, 2023), https://journals.sagepub.com/doi/full/10.1177/23333928231189400; Lauren Weber et al., *Unpacking the Flawed Science Cited in the Texas Abortion Pill Ruling*, WASH. POST (Apr. 13, 2023, 6:00 PM).

[27] *See*, *e.g.*, Brenda Major et al., *Abortion and Mental Health: Evaluating the Evidence*, 64 AM. PSYCH. 863 (2009); NAT'L ACADS. OF SCI., ENG'G & MED., *supra* n.20; Vignetta E. Charles et al., *Abortion and Long-Term Mental Health Outcomes: A Systematic Review of the Evidence*, 78 CONTRACEPT. 436 (2008); *Position Statement on Abortion and Women's Reproductive Health Care Rights*, AM. PSYCH. ASS'N (2020); 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 J. AM. MED. ASS'N PSYCH. 169, 177 (2017); 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).

physical well-being. Many women who seek abortion care are already mothers and cite the "need to focus on other children" as a key component of their decision-making.[28] Women also frequently cite partner-related and/or financial reasons as important factors.[29] These facts matter. The ability to choose when, whether, with whom, and under what circumstances to raise children is at the very core of individual autonomy and crucial to overall well-being. Study after study confirms that those who receive abortion care do not experience the regrets Respondents hypothesize, but go on to thrive, and experience direct measurable benefits from having been able to access this safe and essential form of reproductive care.[30]

III. There Is No Credible Scientific Basis for Rewinding the Clock on Evidence-Based Medical Practice to 2015.

Amici have been successfully providing reproductive care to millions of patients under the 2016 and 2021 FDA guidelines, and urge this Court to permit them to continue to provide care under that demonstrably safe regime. In removing certain prior restrictions on mifepristone when the overwhelming evidence confirmed they were not needed, FDA enhanced the quality and availability of essential reproductive care. It moved forward—as

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[28] M. Antonia Biggs et al., *Understanding Why Women Seek Abortions in the US*, 13 BMC WOMEN'S HEALTH 1 (2013).

[29] *Id.* at 1 (40% of patients cited financial reasons as contributing to their decision, 31% cited partner-related reasons as contributing to their decision, and 64% reported multiple reasons for seeking an abortion).

[30] *Supra* n.27.

medicine and science aspire to do—to ensure greater access to safer care for more patients and their providers. This Court should not turn back the clock to deprive patients of safe and effective modern medicine.

The FDA decisions at issue are well supported by credible studies and are consistent with *amici*'s experience in years of practice involving millions of patients. In 2016, FDA's safety analysis relied on 11 independent clinical studies conducted between 2005 and 2015, covering well "over 30,000 patients;"[31] randomized controlled trials[32] and several prospective, retrospective, and observational studies,[33] which demonstrated the safety and effectiveness of mifepristone up to the 10-week gestational period indicated on the current label.[34] This is an *enormous* and highly reliable data set—and those studies conclusively demonstrated that "[s]erious adverse events . . . are rarely reported . . . with rates ***generally far below 1.0%***."[35] A number

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[31] 2016 FDA Medical Review, *supra* n.16, at 49–50.

[32] *See id.* at 23.

[33] *See id.* at 19.

[34] *See id.* at 6; Adriana A. Boersma et al., *Mifepristone Followed by Home Administration of Buccal Misoprostol for Medical Abortion Up to 70 Days of Amenorrhoea in a General Practice in Curacao*, 16 EUR. J. CONTRACEPT. & REPROD. HEALTH CARE 61 (2011); Beverly Winikoff et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120 OBSTET. & GYNECOL. 1070 (2012); *see also* Dina Abbas et al., *Outpatient Medical Abortion is Safe and Effective Through 70 Days Gestation*, 92 CONTRACEPT. 197 (2015). 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* n.6.

[35] 2016 FDA Medical Review, *supra* n.16, at 56 (emphasis added).

of the studies on which FDA relied assessed the effect of multiple departures from the previous conditions of use and closely resembled the proposed new conditions.[36] Based on this sound scientific evidence, FDA determined that it was appropriate to adjust the heavy restrictions on mifepristone's use and begin unwinding previously mandated requirements and other barriers to access.[37]

These adjustments better serve patients, including the many patients that are currently facing critical shortages of health care providers in large portions of the country or experiencing the unacceptably high rates of maternal morbidity and mortality in the United States due in part to limitations on access to care. Before these first adjustments were made in 2016, FDA's complicated requirements made care unnecessarily difficult to access. As the data shows, there is no medical reason to expect a patient who has taken mifepristone to make two follow-up visits to a health center afterwards.[38] It provides no benefit to the

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[36] *See*, *e.g.*, Appellants Addendum to Emergency Motion for a Stay Pending Appeal, *All. for Hippocratic Med., v. FDA*, No. 23-10362 (5th Cir.), Doc. 27, at Add. 782 (citing Claudia Diaz Olavarrieta, et al., *Nurse versus physician-provision of early medical abortion in Mexico: a randomized controlled non-inferiority trial*, 93 BULL. WORLD HEALTH ORG. 249, 249–58 (2015) (study conditions included a 70-day gestational age limit, 200 mg oral mifepristone and 800 mcg buccal misoprostol, at-home administration, and non-physician prescription)).

[37] As Petitioners describe and as set forth above, FDA adjusted both the "Conditions of Use" printed on the medication's label and eliminated certain REMS. *See* 2016 FDA Medical Review, *supra* n.16, at 7–8.

[38] *See*, *e.g.*, U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-292, FOOD AND DRUG ADMINISTRATION: INFORMATION ON MIFEPREX

patient and can be burdensome, disruptive, and costly, rendering access to an essential medical protocol inaccessible to many patients. To the extent after-care is needed or requested by a patient, comprehensive telehealth protocols adopted by clinics[39] make it easy for patients to communicate with their providers and discuss questions or medical concerns that arise after use of mifepristone—without mandating multiple in-person visits that may be difficult or impossible for patients to accomplish given their personal circumstances or the required distance they must travel. And, of course, alleviating the requirement for follow-up visits in no way prevents patients who prefer in-person consultation from doing that instead.

FDA's subsequent decision in 2021, formalized in 2023, to eliminate the in-person dispensing requirement and to permit distribution of mifepristone by mail similarly improved patient outcomes, using telehealth combined with mail distribution to improve patient access. And in any case where there is a need or concern, patients can be and are seen in person by a clinician.

The growth of telehealth, which is now widely utilized across many areas of practice including reproductive care, is another (and perhaps one of the most important) means to alleviate barriers to care and improve health outcomes in the United States. Many health care clinics—including brick-and-mortar locations—offer comprehensive telehealth services, and reproductive care providers are no different.

LABELING CHANGES AND ONGOING MONITORING EFFORTS 15 (2018) (summarizing studies).

[39] *See infra* p.23.

The latest data, collected from more than 6,000 patients in 20 states, shows that "[t]elehealth medication abortion is effective, safe, and comparable to published rates of in-person medication abortion care."[40] Reproductive health clinics and providers have developed specific protocols and technologies to ensure adequate patient contact and monitoring, including health questionnaires, specialized patient platforms (e.g., a patient "portal"), messaging and chat functions, and phone or video calls, all of which enable the provision of care with fewer in-person visits. For prescription of mifepristone for use in medication abortion or early pregnancy loss, telehealth protocols offer the same protections as in-person dispensing and provide an equivalent level of care. Patients are still evaluated by a qualified health care provider—just as they would be in person. They are asked about their symptoms and about facts needed to determine medical eligibility—just as they would be in person. They are counseled on their options and on the risks and benefits of each one—just as they would be in person.[41]

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[40] Ushma D. Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, NATURE MED. (forthcoming 2024).

[41] *See* Raymond & Bracken, *supra* n.18; Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 J. AM. MED. ASS'N INTERNAL MED. 482, 489 (2022) (finding "mifepristone can be dispensed safely either in person or by mail" and suggesting "the mifepristone label could be revised to explicitly state that ultrasonography or clinical examination is not required if pregnancy duration can be reasonably estimated by history and if no symptoms or risk factors for ectopic pregnancy are present"); 2000 FDA Approval Memorandum, 2:22-CV-00223-Z, Nov. 18, 2022, Compl. Ex. 24, ECF No. 1-25,

FDA continues to require involvement of a specially trained practitioner for telehealth visits, but allows that provider to prescribe mifepristone, and the patient to use it, without in-person dispensing. Under FDA's current approach, instead of being required to physically retrieve the medication from a doctor's office or certified pharmacy,[42] the patient can have it delivered to her home after being evaluated by a clinician (via telehealth or in person) and counseled regarding the medication, including its administration and side effects. Then, instead of being expected to return to the provider's office to confirm she is no longer pregnant, the patient can answer a series of questions asked by the provider, take an at-home pregnancy or blood test and communicate the results to her provider via telehealth.

Amici do not believe their patients would be better served by returning to an era that mandated repeated, wholly unnecessary office visits for the prescription and use of an exceedingly safe medication, and are aware of no medical basis to exclude those in need of reproductive care from accessing it through telemedicine. Although some patients will continue to prefer in-person care, telehealth provides an important alternative and offers substantial benefits for patients who choose it. In a study of 1,600 patients who received abortion

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at 6 ("In practice, dating pregnancies occurs through using other clinical methods, as well as through using ultrasound.").

[42] As of January 2024, no major national retail pharmacy has received certification, though some had applied. *See*, *e.g.*, Walgreens, *Walgreens and Mifepristone: The Facts* (last visited Jan. 26, 2024), https://www.walgreensbootsalliance.com/walgreens-and-mifepristone-facts.

care through telemedicine, "nearly all participants were very satisfied with telehealth abortion"—96% of those surveyed felt it was the right decision—and patients reported that choosing telehealth not only made care more accessible, but allowed them to receive care quickly, privately, at lower cost, and in the comfort of their own home.[43]

The position advanced by Respondents that telehealth should not be available to patients in need of reproductive care who live in areas without access to in-person providers—healthcare deserts—because they fear patients in those areas will not have access to "emergency care" is both misguided and inconsistent with the facts. Access to a demonstrably safe medication that can be taken at home is not adding risk to these geographies. The fact that a patient lacks a local provider is not a basis to deny them ibuprofen; it should not be a basis to deny them another medication that is just as safe because it is used for reproductive care.

Speculation that removing the in-person dispensing requirement from mifepristone labeling increases risk to patients smacks of fearmongering, not facts. Study after study—and years of experience—confirm this is demonstrably false. Mifepristone has been available by mail since FDA's 2021 determination, and in those three-plus years, *amici*'s members have observed *no change whatsoever* in the incidence of adverse events from mifepristone and have no reason to expect that to change if FDA's determination remains in effect.

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[43] *See* Leah R. Koenig et al., *Patient Acceptability of Telehealth Medication Abortion Care in the United States, 2021–2022: A Cohort Study*, AM. J. PUB. HEALTH (2024), published online ahead of print, https://doi.org/10.2105/AJPH.2023.307437.

The percentage of patients that ever visit an emergency room for abortion-related complications remains exceedingly small,[44] and the underlying manner in which the medication is prescribed does not alter its safety profile. The drug itself is exceptionally safe, and that remains true regardless of whether it is handed to a patient in person or shipped by mail.

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

Amici are concerned that if the Fifth Circuit's decision is allowed to stand, it will impair access to mifepristone nationwide—even for miscarriage management and even in states where abortion remains legal—and endanger pregnant patients.

Fundamentally, mifepristone is one of the most safe and effective medications used to provide abortion care or treat early pregnancy loss. Without it, pregnancy will be even more dangerous than it already is. To date, the empirical evidence shows that women are at least 14 times more likely to die during childbirth than during any abortion

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[44] That patients sometimes seek emergency care for reasons other than the severity of their symptoms is consistent with prior studies. A 2018 study concluded that only 0.01% of emergency department visits among women aged 15–49 were abortion-related and that many could have been "managed at a less costly level of care." Ushma D. Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, 16 BMC MED. 1, 10 (2018).

procedure [45] and are at an increased risk of experiencing hemorrhage, infection, and injury to other organs during pregnancy and childbirth.[46] Even under the best of circumstances, pregnancy and childbirth impose significant physiological changes that can exacerbate underlying conditions and severely compromise health, sometimes permanently.[47] Pregnancy, particularly when coupled with preexisting conditions, can quickly

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[45] *See* Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childhood in the Unites States*, 119 OBSTET. & GYNECOL. 215, 216 tbl.1 (2012). The U.S. mortality rate associated with live births from 1998 to 2005 was 8.8 deaths per 100,000 live births. *Id.* Rates have sharply increased since then, and the average U.S. maternal mortality rate associated with live births from 2018 to 2021 was 23.6. *See* Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last reviewed Mar. 16, 2023). By contrast, the mortality rate associated with abortions performed from 2013 to 2020 was 0.45 deaths per 100,000 legal procedures. *See* Katherine Kortsmit et al., *Abortion Surveillance—United States, 2021*, 72 CDC MORBIDITY & MORTALITY WKLY. REP. 1 (2023). 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 [deaths] per 100,000 [patients])." NAT'L ACADS. OF SCI., ENG'G & MED., *supra* n.20, at 74.

[46] *See* Raymond & Grimes, *supra* n.45, at 216–17 fig.1.

[47] *See*, *e.g.*, ACOG Clinical Consensus No. 1, *Pharmacologic Stepwise Multimodal Approach for Postpartum Pain Management* (Sept. 2021); ACOG Practice Bulletin No. 222, *Gestational Hypertension and Preeclampsia* (June 2020); ACOG Obstetric Care Consensus No. 7, *Placenta Accreta Spectrum* (Dec. 2018); ACOG Practice Bulletin No. 183, *Postpartum Hemorrhage* (Oct. 2017).

evolve into a life-threatening situation necessitating critical care.

The dangers of pregnancy in the U.S. are far greater for women of color, low-income women, and those living in rural areas.[48] These populations are most likely to experience severe maternal morbidity, more likely to die from pregnancy-related complications, and are disproportionately harmed by restrictions on abortion care.[49] The majority of abortion patients identify as people of color, and "75% of those seeking abortion [care] are living at or below 200% of the federal poverty level."[50] Pregnant people of color are also more likely to experience early pregnancy loss or miscarriage, the treatment for which can include mifepristone.[51]

Reimposing unnecessary restrictions on mifepristone will exacerbate these existing inequities and pose the greatest danger to those who are already the most poorly served by our maternal health system. These patients are among those who have benefitted most from increased access to care

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48 *See* Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them*, KFF (Nov. 2022); Office of Minority Health, *Advancing Rural Maternal Health Equity*, CTRS. FOR MEDICARE & MEDICAID SERVS., at 1 (2022).

49 *See* Rachel K. Jones et al., *COVID-19 Abortion Bans and Their Implications for Public Health*, 52 PERSPS. ON SEXUAL & REPROD. HEALTH 65, 66 (2020); *see also* Christine Dehlendorf & Tracy Weitz, *Access to Abortion Services: A Neglected Health Disparity*, 22 J. HEALTH CARE FOR POOR & UNDERSERVED 415, 416-17 (2011); ACOG Committee Opinion No. 815, *Increasing Access to Abortion* (Dec. 2020).

50 *Id.*

51 *See* Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department, 2006–2016*, 2 J. AM. COLL. EMERGENCY PHYSICIANS OPEN e12549, at 6–7 (2021).

through telemedicine and who will suffer most from its loss. For example, one recent study found that for patients who are low-income, rural, or persons of color, and were able to obtain timely abortion care, approximately half were able to do so specifically because of telehealth.[52]

If this Court is to consider whether patient care is improved or undermined by FDA's actions, it ought to consider the substantial evidence demonstrating that *denial* of abortion care causes harm. Patients who are denied requested abortion care are more likely to experience intimate partner violence compared with patients who were able to access this care.[53] Forced pregnancy undermines maternal and fetal health and exacerbates the risks inherent in pregnancy itself.[54] Studies have repeatedly shown that being denied an abortion not only leads to worse health outcomes, but exacerbates patients' economic hardships, revealing "large and statistically significant differences in the socioeconomic trajectories of women who were denied

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[52] *See* Leah R. Koenig et al., *The Role of Telehealth in Promoting Equitable Abortion Access in the United States: Spatial Analysis*, JMIR PUB. HEALTH & SURVEILLANCE (2023) (finding, in part, that "telehealth made it possible to obtain timely abortion care . . . [for] patient populations who are known to face the most structural barriers to abortion care, such as younger people, those experiencing food insecurity, those residing in rural areas, and those who resided far from an abortion facility").

[53] *See* Sarah C.M. 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).

[54] *See* Nadine El-Bawab et al., *In post-Roe America, Women Detail Agony of Being Forced to Carry Nonviable Pregnancies to Term* (Dec. 14, 2023), https://abcnews.go.com/US/post-roe-america-women-detail-agony-forced-carry/story?id=105563349.

requested abortions compared with women who received abortions—with women denied abortions facing more economic hardships."[55] These effects are not isolated; many patients seeking abortion have children already, and the dangers to them—physically, emotionally, and economically—ripple outwards within each family and community. As medical providers throughout the country, *amici* are seriously concerned that making it more difficult to obtain mifepristone will make it more difficult to provide medication abortion care to those who need or seek it, consistent with the current standard of care. This alone endangers patients.

Restricting access to mifepristone endangers *anyone* who is pregnant—because its use in the practice of medicine goes far beyond abortion care. Mifepristone has critical off-label uses in maternal care beyond abortion,[56] and, as mentioned, is widely prescribed for management and treatment of miscarriages, including spontaneous, missed, inevitable, and incomplete abortions.[57] Nearly one

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[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* Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87 MAYO CLINIC PROC. 982, 982–85 (2012).

[57] *See* ACOG Practice Bulletin No. 200, *supra* n.5; *see also* Honor MacNaughton et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 AM. FAM. PHYSICIAN 473, 475 (2021); 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.

out of every five women who becomes pregnant will experience a miscarriage at some point in her life—more than a million patients each year.[58] Untreated, miscarriage can occur over two to eight weeks, exacerbating the emotional strain of pregnancy loss.[59] *Amici*'s members frequently prescribe mifepristone when a patient is experiencing early pregnancy loss because it can ease the process and lead to better health outcomes.[60] Patients already enduring miscarriage should not be forced to suffer through limited access to a safe and effective medication.

Studies have also examined mifepristone 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).[61] Mifepristone is also used off-label to reduce the duration of bleeding or hemorrhaging during certain serious pregnancy complications.[62] Restricting access to

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[58] *See supra* n.9.

[59] *See* Carla Dugas & Valori H. Slane, *supra* n.9 (stating that "[a]pproximately 80% of women achieve complete passage of intrauterine contents within 8 weeks").

[60] *See*, *e.g.*, ACOG Practice Bulletin No. 200, *supra* n.5; Jessica Beaman et al., *Medication to Manage Abortion and Miscarriage*, 35 J. GEN. INTERNAL MED. 2398, 2400 (2020).

[61] *See* Y. X. Zhang, *Effect of Mifepristone in the Different Treatments of Endometriosis*, 43 CLINICAL & EXPERIMENTAL OBSTET. & GYNECOL. 350 (2016); Mario Tristan et al., *Mifepristone for Uterine Fibroids*, COCHRANE DATABASE SYSTEMATIC REVS. (2012).

[62] *See* Yanxia Cao et al., *Efficacy of Misoprostol Combined with Mifepristone on Postpartum Hemorrhage and Its Effects on Coagulation Function*, 13 INT'L. J. CLINICAL & EXPERIMENTAL MED. 2234 (2020).

mifepristone will prevent patients from receiving much-needed treatment for these conditions as well. In short, Respondents should not be permitted to undermine the nation's longstanding drug approval system or deny patients and providers access to a safe and effective medication used to promote maternal health based on their opposition to abortion.

CONCLUSION

For the reasons set forth above, *amici* urge this Court to reverse the Fifth's Circuit's decision.

Respectfully submitted,

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