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 MEDICAL AND PUBLIC HEALTH SOCIETIES AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLANTS

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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.

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American College of Pediatricians
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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 the Food and Drug Administration's ("FDA") approval, as well as its decision to eliminate certain 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 twenty years. Accordingly, *amici* have a strong interest in ensuring that the science surrounding mifepristone's safety and efficacy is correctly understood.

PRELIMINARY STATEMENT

Amici urge this Court to set aside the unprecedented opinion of the District Court and preserve more than two decades of FDA approval and patient access to an exceptionally safe and important drug. Without any form of evidentiary hearing and in complete disregard to the overwhelming body of evidence proving that mifepristone is safe, the District Court's order (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. This Court should not uphold a decision that is so demonstrably at odds with the facts and so hostile to *amici*'s patients.

Each *amici* organization and its members adhere to a standard of ethics and practice centered on patient care, and on the bedrock principal to "do no harm." The District Court's erroneous decision to suspend mifepristone threatens the very core of *amici*'s medical practice by preventing the provision of appropriate, safe, and standard care for their 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 non-existent.

In the two intervening decades since the FDA approved mifepristone, it has become an essential medicine for the treatment of miscarriage as well. Miscarriage[4] is common. It can be dangerous, even life-threatening. The District Court's order purporting to prevent the use of mifepristone harms these patients too. Depriving patients of standard, safe care that will protect their lives, health, and ability to carry future pregnancies to term is an extraordinary departure from the provision of evidence-based medicine and the patient-centered approach that *amici* and their members advocate and practice.

The District Court's insistence that pregnancy is "not an illness" and therefore that pregnant patients do not deserve or warrant medical treatment (and should not have access to mifepristone for abortion care) disregards the countless ways in which pregnancy itself is a medical condition capable of jeopardizing patient health. Pregnancy can be dangerous. The risks of maternal mortality in the

[4] *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2021) ("Early pregnancy loss is defined as a nonviable, intrauterine pregnancy with either an empty gestational sac or a gestational sac containing an embryo or fetus without fetal heart activity within the first 12 6/7 weeks of gestation. In the first trimester, the terms miscarriage, spontaneous abortion, and early pregnancy loss are used interchangeably[.]").

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 dangerous physiological conditions. These dangers directly impair the health and well-being of pregnant patients, often in material ways. Abortion, including medication abortion involving a regimen of mifepristone and misoprostol, is an essential component of reproductive care that remains a legal choice in states throughout the U.S. The District Court's decision removes that choice and endangers the patients who live in those states.

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.

Failing to stay the Order will cause profound and irreparable harm to patients across the country—in addition to destabilizing the medical profession, whose providers have relied on the use of mifepristone to provide patient care for

over two decades. 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 who have limited access to alternative procedures (i.e., procedural abortion) or lack the ability to travel long distances for health care. The FDA's approval is supported by law and the overwhelming weight of medical evidence and this Court should grant Appellants' request to stay the Order.

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.[5] Mifepristone followed by misoprostol is used both to induce abortion,[6] and in the treatment of miscarriage or early pregnancy loss (which can be life threatening),[7] a term which includes spontaneous abortion, missed abortion, incomplete abortion, or inevitable abortion.

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[5] 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*, 1, 4 (Oct. 2020, *reaff'd* 2023).

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

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

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: (1) mifepristone is safe and effective; (2) medication abortion offers specific benefits compared with other abortion methods for many patients; and (3) it is not medically necessary to impose additional safeguards 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 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.[8] The District Court is wrong to conclude otherwise.[9]

The FDA first approved the use of mifepristone in 2000, basing its decision on multiple, extensive clinical trials and sound research.[10] 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,

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[8] *See* Appendix A-19 at 79; *see also* R. Morgan Griffin, *Making the Decision on NSAIDs*, WEBMD (Oct. 17, 2005), https://www.webmd.com/arthritis/features/making-decision-on-nsaids.

[9] Memorandum Opinion and Order, 2:22-CV-00223-Z, Apr. 7, 2023, ECF No. 137, ("Mem."), at 47. 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 a medication abortion in accordance with the FDA's approved labeling, without so much as a factual inquiry or an evidentiary hearing.

[10] *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* (Aug. 2008), at 15-16; 2000 FDA Approval Memorandum, Compl. Ex. 24, ECF No. 1-25.

and that the health benefits outweighed the known risks.[11] 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.[12] The FDA's safety analysis relied on 11 independent clinical studies conducted between 2008 and 2015, covering "well over 30,000 patients,"[13] a randomized control trial,[14] and several observational studies,[15] all of which demonstrated the safety and effectiveness of mifepristone up to the ten-week gestational period.[16] Those

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[11] *See* Development & Approval Process: Drugs, FDA (Aug. 08, 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."

[12] 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 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.

[13] 2016 FDA Medical Review at 1, 50.

[14] *See id.* at 79.

[15] *See e.g.*, *id.* at 18, 35-38.

[16] *See, e.g.*, Appendix A-13; 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

studies conclusively demonstrated that "serious adverse events . . . are rarely reported . . . with rates ***generally far below 1.0%***."[17] 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 restrictions on mifepristone's use, and began unwinding previously mandated ultrasound requirements and other barriers.[18]

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 medical procedures. To date, mifepristone has been discussed in

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that medication abortion can safely and effectively be used up to at least 70 days of gestation. *See* ACOG Practice Bulletin No. 225.

17 2016 FDA Medical Review at 56 (emphasis added).

18 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. Compl. Ex. 24; Appendix A-14 at 214. 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 not predicated on FDA medication approvals. To ensure the safety and wellbeing 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. ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation*, 1, 4 (Oct. 2020).

more than 780 medical reviews and used in more than 630 published clinical trials—of which more than 420 were randomized controlled studies (the gold standard in research design).[19] These studies have repeatedly concluded that even minor complications arising from medication abortion are rare.[20]

Major adverse events—which include hospitalization and serious infection or bleeding—are "exceedingly rare," occurring in approximately 0.3% of cases.[21] Studies have shown an even smaller number, finding between 0.015% and 0.07% of patients experience serious infection.[22] 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 causal relationship between the use of MIFEPREX and misoprostol and [infections and bleeding] has been established."[23]

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

[20] *See*, *e.g.*, Appendix A-2; A-3; A-4; A-19.

[21] 2016 Medical Review at 56; *see also* Appendix A-20 at 175-83.

[22] 2016 Medical Review at 53-54.

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

The risk of death from medication abortion is near zero.[24] 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%.[25] Even when considering deaths that followed a medication abortion but did not appear to be related to mifepristone use, that number rises to only 0.00065%.[26] 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.[27]

The mifepristone safety profile is similar to that of procedural abortion—and both are comparatively low compared to other common medications and procedures.[28] There is a greater risk of complications or mortality for procedures

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[24] *See* Appendix A-18 at 29, tbl. 15.

[25] Appendix A-3 at 1-2.

[26] *Id.*

[27] Mem. at 61; PPGNHAIK Statement on Incorrect Indiana Data, PLANNED PARENTHOOD, April 11, 2023, https://www.plannedparenthood.org/planned-parenthood-great-northwest-hawaii-alaska-indiana-kentuck/press/ppgnhaik-statement-on-incorrect-indiana-data

[28] *Id.* 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

like wisdom-tooth removals, tonsillectomies, colonoscopies, and plastic surgeries, than by any abortion method (medication or procedural).[29] Using Viagra is more dangerous than using mifepristone. Studies have shown Viagra to be associated with 4.9 deaths per 100,000 prescriptions,[30] death by colonoscopy occurs in about 0.03% of cases, [31] and the "risk of death associated with childbirth [is] approximately 14 times higher" than the risk associated with an abortion.[32] 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.[33]

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continuing a pregnancy to term or using other common medications"); *see also* Appendix A-5; A-14; A-20.

[29] *Compare* Appendix A-4 at 1-24 (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 Surgeon*s, 105 Plastic & Reconstructive Surgery 436, 441 (2000) (mortality rate from liposuction was 20 deaths per 100,000 patients).

[30] *See* Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA, 590, 590–93 (Feb. 2, 2000).

[31] ASGE Standards of Practice Committee, *supra* note 28, at 747.

[32] Appendix A-39 at 215.

[33] Appellees also inaccurately claim that mifepristone acts as an "endocrine-disruptor" in adolescents. *See* Compl. ¶¶ 54, 60. Nothing suggests that medication abortion has any effect on adolescent development.

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.[34] *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 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.[35] 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.[36]

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

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[34] Mem. at 7 n. 9, 47 n. 45.

[35] Appendix A-43 at 177.

[36] Appendix A-24 at 7.

blog posts made on an anti-abortion website,[37] and on studies that have been widely critiqued by researchers and scholars for their serious methodological flaws.[38] The District Court's selective reliance on pseudoscience endangers *amici*'s patients and their ability to provide safe, effective reproductive care. It purports to suspend the use of a common and safe medicine based on studies that are directly contradicted by the *vast* majority of research—research that demonstrates overwhelmingly and conclusively that there is no association between medication abortion and adverse physical or psychological outcomes.[39] This Court should not endorse that dangerous result.

II. Medication Abortion Offers Comparative Benefits Against Other Forms of Abortion or Miscarriage Management.

Medication abortion must remain available to patients because it is an essential form of reproductive care, grounded in evidence and protected by law. Sometimes, medication is the *only* realistic form of abortion care available to patients, and sometimes, patients are in need of—and legally and medically entitled to—abortion care. While procedural abortion is also exceedingly safe,

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[37] *See* Mem. at 46 n. 40-41.

[38] *See* Mem. 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)).

[39] *See, e.g.*, Appendix A-22—A-35.

medication abortion offers unique benefits over a procedural abortion for many patients. In *amici*'s experience, patients choose medication abortion over procedural abortion for many reasons, which can include a need or desire to avoid sedation or anesthesia; to avoid physical contact or the trauma of having instruments inserted into their vagina due to prior sexual assault or trauma; to have the abortion in the company of family or loved ones; or simply a desire for privacy.

Patients experiencing miscarriage may choose to take mifepristone and misoprostol for the same reasons, rather than to opt for an in-clinic procedure for treatment or expectant management. Requiring clinicians to use a more invasive (but still safe) procedure, rather than offering a non-invasive, equally effective option preferred by and appropriate for the patient will force physicians to act against patient autonomy and medical ethics as a whole.[40]

Medication abortion may be the only option that is reasonably accessible to patients, especially for patients from historically marginalized populations, those with low incomes, and patients living in rural areas or long distances from medical

[40] ACOG, Code of Professional Ethics at 1 ("respect for the right of individual patients to make their own choices about their health care (autonomy) is fundamental"); ACOG, Committee Opinion No. 819, Informed Consent and Shared Decision Making in Obstetrics and Gynecology (Feb. 2021); AMA, Code of Medical Ethics Opinion 2.1.1.

facilities.[41] Even when medical facilities are reasonably accessible to patients, a significant number that provide abortion care offer only medication abortion.[42] For patients with certain medical conditions, disabilities, or other extenuating life circumstances (such as a lack of access to child care, the inability to take time off work, or not being able to travel long distances), medication abortion is by far the safest and most accessible option. The District Court entirely failed to consider this critical and very real aspect of the problem.

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.

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[41] *See* March of Dimes, *Maternity Care Desert* (Oct. 2022), https://www.marchofdimes.org/peristats/data?reg=99&top=23&stop=641&lev=1&slev=4&obj=9&sreg=99&creg; *see also* Appendix A-57; A-46.

[42] *See* Appendix A-60.

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[43]—the very people who are most likely to experience severe maternal morbidity and more likely to die from pregnancy-related complications.[44] 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.[45] 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.[46] 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.

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[43] *See* Appendix A-47 at 416; A-52 at 11; A-58 at 66; *see also* Ctr. for Medicare & Medicaid Serv., *CMS Rural Health Strategy* at 2 (2018), https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.

[44] *See* Ctr. for Medicare & Medicaid Serv., *Advancing Rural Maternal Health Equity* at 1 (May 2022), https://www.cms.gov/files/document/maternal-health-may-2022.pdf; *see also* Appendix A-54 at 215.

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

[46] *See* Appendix A-57.

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 abortion.[47] 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."[48]

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"[49]—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[50] and are at an increased risk of experiencing hemorrhage,

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47 *See* Appendix A-44 at 6.

48 Appendix A-38 at 412.

49 *See* Compl. ¶ 51.

50 *See* Appendix A-39 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. Appendix A-37 at 385, 86. By contrast, the mortality rate associated with abortions performed from 1998 to 2005 was 0.6 deaths per 100,000 procedures. Appendix A-39 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

infection, and injury to other organs during pregnancy and childbirth as well.[51] 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.[52] 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.

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

As with many medications, mifepristone also has many critical off-label uses beyond abortion.[53] Mifepristone is already widely prescribed for management and treatment of miscarriages, including spontaneous, missed, inevitable, and

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small fraction of that for childbirth (8.8 [death] per 100,000 [patients]).” Appendix A-19 at 74.

[51] Appendix A-39 at 215, 216–17, fig.1.

[52] *See, e.g.*, ACOG Practice Bulletin No. 190, *Gestational Diabetes Mellitus* (Feb. 2018); ACOG Practice Bulletin No. 222, *Gestational Hypertension and Preeclampsia* (Dec. 2018); ACOG Practice Bulletin No. 183, *Postpartum Hemorrhage* (Oct. 2017); ACOG Obstetric Care Consensus, *Placenta Accreta Spectrum* (July 2012, reaff’d 2021); ACOG Practice Bulletin No. 198, *Prevention and Management of Obstetric Lacerations at Vaginal Delivery* (Sept. 2018, reaff’d 2022); ACOG Clinical Consensus No. 1, *Pharmacologic Stepwise Multimodal Approach for Postpartum Pain Management* (Sept. 2021).

[53] Appendix A-64 at 982-90.

incomplete abortions.[54] 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).[55] Mifepristone is also used off-label to reduce the duration of bleeding or hemorrhaging during certain serious pregnancy complications, and may have beneficial effects on the cervix in full-term pregnancies, which in turn may affect the likelihood of successful labor.[56]

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

Enjoining the use of mifepristone approval will, at a macro level, increase the burden on the nation's health care system, particularly women's health and OBGYN care. Medical facilities will experience an increased strain on already-limited resources.[57] Medication abortion allows a patient to ingest their prescription safely at home after consultation with their health care providers,

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[54] Mara Gordon & Sarah McMannon, *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.

[55] *See* Appendix A-63; A-66 at 350-53.

[56] *See* Appendix A-65 at 2234-40.

[57] *See* Appendix A-45.

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, like requiring physicians to dispense the medication to patients in person or making patients travel 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."[58] 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 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.

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

CONCLUSION

For these reasons and those in Appellants' Motion, we strongly urge the Court to grant the relief sought and stay the entry of the Order pending resolution on the merits after a full evidentiary hearing.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 11, 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.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 5,019 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.

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APPENDIX A

Safety of Mifepristone

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