No. 26-30203

IN THE

United States Court of Appeals for the Fifth Circuit

THE STATE OF LOUISIANA, ET AL.,

Plaintiffs-Appellants / Cross-Appellees,

v.

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

Defendants-Appellees,

v.

GENBIOPRO, INCORPORATED,

Intervenor-Appellee / Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellee / Cross-Appellant.

On Appeal from the United States District Court
for the Western District of Louisiana (Lafayette)
No. 6:25-cv-01491, Hon. David C. Joseph

BRIEF OF AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS, ET AL. AS *AMICI CURIAE* IN SUPPORT OF APPELLEES AND AFFIRMANCE OF THE DENIAL OF PLAINTIFFS-APPELLANTS' MOTION FOR PRELIMINARY RELIEF

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The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 of the United States Court of Appeals for the Fifth Circuit 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 Obstetricians & Gynecologists
- Society of Family Planning
- America's Physician Groups
- Society of General Internal Medicine
- American College of Medical Genetics and Genomics
- American College of Preventive Medicine
- The Society of Gynecologic Oncology
- American College of Nurse-Midwives
- Society for Maternal-Fetal Medicine
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[1] The twelve organizations listed as *amici curiae* are non-profit corporations that have no parent corporation. Furthermore, no publicly held corporation owns 10% or more of their stock.

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- Autistic Self-Advocacy Network
- Autistic Women and Nonbinary Network
- Centennial Institute at Colorado Christian University
- Center for Urban Renewal & Education
- Christian Law Association
- Christian Medical & Dental Associations
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- Justice Foundation
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- Christ Medicus Foundation
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- Ethics and Public Policy Center
- 2,796 Women Injured by Abortion
- Justice Foundation
- Center Against Forced Abortions
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- National Institute of Family and Life Advocates
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INTEREST OF *AMICI CURIAE*[2]

The American College of Obstetricians & Gynecologists ("ACOG") is a professional membership organization representing more than 90% of board-certified obstetrician-gynecologists in the United States. ACOG maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness of the changing issues facing women's healthcare. ACOG is committed to ensuring access to high-quality, safe, and equitable obstetric and gynecologic care, including abortion care.

In addition to ACOG, *amici curiae* include eleven other leading medical societies: Society of Family Planning; America's Physician Groups; Society of General Internal Medicine; American College of Medical Genetics and Genomics; American College of Preventive Medicine; The Society of Gynecologic Oncology; American College of Nurse-Midwives; Society for Maternal-Fetal Medicine; Society for Adolescent Health and Medicine; American College of Physicians; and the American Academy of Nursing. These organizations collectively represent hundreds of thousands of medical practitioners who serve patients nationwide and who have deep expertise in medical research and the treatment of patients.

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[2] This brief is submitted pursuant to Federal Rule of Appellate Procedure ("FRAP") 29(a), with the consent of all parties. Pursuant to FRAP 29(a)(4)(E), the undersigned certify that 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.

Amici submit this brief to provide a medical and scientific perspective on the issues before the Court. Courts frequently rely on *amici*'s medical and scientific expertise in cases involving pregnancy.[3] *Amici* believe that all patients are entitled to timely, complete, and unbiased healthcare that is medically and scientifically sound. The relief that Plaintiffs-Appellants seek—the reinstatement of the in-person dispensing requirement for mifepristone—would jeopardize that care.

More than two decades of rigorous scientific testing has demonstrated that mifepristone is safe and effective when used for abortion care and miscarriage management, ***regardless of whether it is dispensed in person***. The U.S. Food & Drug Administration's ("FDA") official decision to remove the requirement that mifepristone be dispensed in person, which FDA announced in 2021 and formally issued as part of its 2023 Risk Evaluation and Mitigation Strategy ("2023 REMS"), was supported by the overwhelming weight of medical evidence, including the substantial body of real-world data and scientific literature borne out of the COVID-19 pandemic.

[3] *See, e.g.*, *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2402–09 (2020) (Ginsburg, J., dissenting); *June Med. Servs. LLC v. Russo*, 591 U.S. 299, 340 (2020); *Whole Woman's Health v. Hellerstedt*, 579 U.S. 582, 613 (2016); *Stenberg v. Carhart*, 530 U.S. 914, 916, 928, 932 (2000); *Whole Woman's Health v. Paxton*, 978 F.3d 896, 910 (5th Cir. 2020); *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, 1158 n.10 (Okla. 2023).

Amici's members have prescribed mifepristone safely for more than twenty-five years—including by mail and at local pharmacies, which can be vital where a patient lives in a healthcare desert or is unable to travel in person to a healthcare center. Accordingly, *amici* have a strong interest in preserving that access, which remains supported by evidence-based science.

SUMMARY OF THE ARGUMENT

This case concerns FDA regulations that allow clinicians to prescribe and patients to access mifepristone, one of the two drugs that comprise the standard protocol for medication abortion and miscarriage management. Specifically, Plaintiffs-Appellants ask the Court to stay the 2023 REMS and reinstate a nationwide requirement that mifepristone be dispensed only at a hospital, clinic, or medical office, rather than by mail or at a pharmacy. For the reasons set forth below, *amici* ask this Court to deny Plaintiffs-Appellants' request for a stay and affirm the denial of Plaintiffs-Appellants' December 17, 2025 motion for preliminary relief.

Mifepristone—whether dispensed in person or via telehealth—is extremely safe. More than two decades, hundreds of medical studies, and vast amounts of data have confirmed this. The scientific evidence is overwhelming: serious adverse events occur in ***less than one-third of 1%*** of patients—whether mifepristone is dispensed in person or not—and the risk of death is almost nonexistent. Mifepristone's compelling safety profile remains strong and stable regardless of

where patients fill their prescriptions, and the option of mail and pharmacy dispensing enables practitioners to provide safe, medically appropriate, and effective care to the many patients that face barriers to basic reproductive healthcare, including miscarriage management.

In seeking preliminary relief before the District Court, Plaintiffs-Appellants made inaccurate, unsubstantiated, and disproven assertions about mifepristone's effects and the experiences of patients who use and clinicians who prescribe the drug. These distortions of the scientific record discount the medical community's consensus: mifepristone is a safe and essential component of reproductive healthcare, including when dispensed by mail and at pharmacies. Eschewing sound science, Plaintiffs-Appellants seek a nationwide return to mandatory, in-person dispensing of mifepristone. This would severely limit access to mifepristone and deny medically appropriate and legal care to patients across the country.

Turning back the clock to reimpose unnecessary restrictions on mifepristone will exacerbate existing inequities in maternal health for patients of color, patients of low income, patients with disabilities, and patients who live in rural areas—the populations most likely to rely on remote care. These restrictions would worsen racial and economic inequities and deprive patients of choices that are at the core of individual autonomy and well-being. *Amici* urge this Court to reject Plaintiffs-

Appellants' request that it curtail access throughout the country to an essential medication that FDA has deemed safe for use, regardless of how it is dispensed.

ARGUMENT

I. Mifepristone Is an Essential Component of Reproductive Care.

Mifepristone is an essential medication that, in combination with misoprostol, safely and effectively ends pregnancy or manages miscarriage, with material benefits and vanishingly small risks.[4] Under the preferred protocol in the United States, mifepristone is administered approximately twenty-four hours before misoprostol to soften and prepare the cervix and block progesterone.[5] While misoprostol alone is a safe and effective regimen for medication abortion, studies have shown that use of mifepristone and misoprostol together maximizes efficacy and minimizes side effects.[6]

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[4] Studies also have examined mifepristone for a range of other maternal-health purposes, including treatment of uterine fibroids and endometriosis. Mifepristone is also used off-label to reduce the duration of bleeding or hemorrhaging during certain serious pregnancy complications. *See* Y.X. Zhang, *Effect of Mifepristone in the Different Treatments of Endometriosis*, 43 CLINICAL & EXPERIMENTAL OBSTET. & GYNECOL. 350, 350 (2016); Mario Tristan et al., *Mifepristone for Uterine Fibroids*, COCHRANE DATABASE SYSTEMATIC REVS. 1 (2012); 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, 2239 (2020); *see also* Blake M. Autry & Roopma Wadhwa, *Mifepristone,* STATPEARLS (last updated Feb. 28, 2024).

[5] ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2025); ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (Oct. 2020, *reaff'd* 2023).

[6] ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2025); Elizabeth G. Raymond et al., *Medication Abortion with Misoprostol-Only: A Sample Protocol,* 121 CONTRACEPT. 1, 5 (2023).

Although medication abortion causes bleeding and cramping, those effects are not "complications"[7] but are instead medically necessary parts of the treatment process.[8] Much like during a menstrual cycle, bleeding and cramping are how the body expels the uterine lining and contents. In the context of both abortion care and early pregnancy loss, research shows that mifepristone eases the process and reduces the chance that it will be prolonged or incomplete.[9]

II. Studies Show that Mifepristone Is Conclusively Safe.

Scientific studies, in combination with the overwhelming weight of evidence from more than two decades of use, show that mifepristone is safe and effective. Mifepristone has been discussed in more than 900 medical reviews and has been studied in at least 670 published clinical trials—of which 464 were randomized controlled studies, the gold standard in research design.[10] The findings are consistent

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[7] Plaintiffs-Appellants have mislabeled expected effects of treatment as "complications." *Compare* ROA.107, 119, *with* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2025). *See also* Young-Kyun Kim, *Malpractice and Complications*, 43 J. KOREAN ASS'N ORAL & MAXILLOFACIAL SURGEONS 1, 1 (2017) ("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.").

[8] ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2025).

[9] *Id.*; Elizabeth G. Raymond et al., *Medication Abortion with Misoprostol-Only: A Sample Protocol,* 121 CONTRACEPT. 1, 5 (2023).

[10] This is based on a review of PubMed, the National Institute of Health's sponsored database of research studies.

and overwhelming: mifepristone is safe and effective for abortion care and miscarriage management, and even ***minor*** complications are exceedingly rare.[11]

A highly regarded clinical study that followed the health outcomes of more than 50,000 patients in the six weeks after receiving abortion care showed that serious adverse events requiring hospitalization, surgery, or blood transfusion occurred in ***less than 0.32%*** of patients who had medication abortions.[12] Other studies have found that serious infection following medication abortion is also exceptionally rare, occurring in ***only 0.015%*** of patients.[13] The risk of death is ***almost non-existent***; FDA's 2024 analysis demonstrated that the mortality rate for mifepristone users is ***only 0.00048%***.[14] Mifepristone has a lower associated

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[11] *See, e.g.*, ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone US Post-Marketing Adverse Events Summary Through 12/31/2022,"* UNIV. OF CAL., S.F. 2 (2024) (hereinafter, "ANSIRH, *Adverse Events 2024*"); Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 NEW ENG. J. MED 57, 57 (2022); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175, 176, 178 (2015).

[12] *See* Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175, 175 (2015). A more recent study analyzing patients who received mifepristone via non-in-person dispensing found that serious adverse events occurred in ***only 0.25%*** of patients. *See* Ushma D. Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, 30 NATURE MED. 1191, 1191 (2024).

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

[14] *See* U.S. FOOD & DRUG ADMIN., NDA NO. 020687 & NO. ANDA 091178, *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2024* (2025). As FDA has noted, there is no clear causal link attributing mifepristone to reported fatalities, and some are self-evidently unrelated (e.g., homicide, suspected homicide, suicide, and substance abuse / drug overdose). *Id.*

mortality rate than many common medications and devices approved by FDA.[15] Viagra has a mortality rate of 0.004%[16]—over eight times higher than the reported mifepristone-associated mortality rate referenced above.[17] Colonoscopies have a mortality rate of 0.03%—over sixty-two times higher than the reported mifepristone mortality rate referenced above.[18] Medication abortion utilizing mifepristone is among the safest medical interventions in any category, pregnancy-related or not.

III. Mifepristone's Safety Is Not Affected by the Dispensing Method.

Mifepristone is safe, whether it is dispensed in a healthcare facility, or by mail or through a certified pharmacy following a consultation. Since April 2021, FDA has permitted patients to fill mifepristone prescriptions at pharmacies or by mail, after clinical evaluation and counselling that can occur either via telehealth or in person. After completing the medication regimen, providers instruct patients to confirm their treatment was effective with an at-home pregnancy test or blood test

[15] ANSIRH, Adverse Events 2024 at 2–3 (concluding "[o]ther medications that are common[] [or] administered in outpatient settings also have risks, including a small risk of death," and that "[a]cetaminophen (Tylenol) overdose is the most common cause of acute liver failure in the US and accounts for over 600 deaths annually").

[16] *See* Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA 590, 591 (2000).

[17] *See* ANSIRH, Adverse Events 2024 at 3.

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

at a local lab. Providers direct patients to seek in-person care for certain clinical indications like heavy bleeding or signs of infection.

Reproductive health clinics and providers have developed specific protocols and technologies to ensure adequate patient contact and monitoring, including health questionnaires, specialized patient platforms, messaging and chat functions, and phone or video calls, all of which enable care with fewer in-person visits. With mifepristone prescriptions for use in medication abortion or early pregnancy loss, telehealth protocols offer the same protections, level of care, and effectiveness as in-person dispensing.[19] In the context of telehealth care, qualified healthcare providers evaluate patients, ask them about their symptoms, counsel them on the risks and benefits of their options, and engage in shared decision-making with them to determine the appropriate course of treatment—just as they would in person.[20]

Since the removal of mifepristone's in-person dispensing requirement, there has been ***no significant difference*** reported in mifepristone's safety. One recent study analyzing known abortion outcomes of over 4,450 patients in twenty states concluded, "[t]elehealth medication abortion is effective, safe, and comparable to

[19] *See* Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA 482, 489 (2022).

[20] Elizabeth G. Raymond et al., *Commentary: No-test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond*, 101 CONTRACEPT. 361, 364 (2020).

published rates of in-person medication abortion care."[21] In another recent study of 585 patients across six states, patients who obtained medication abortion after a telehealth screening with no ultrasound or in-person testing reported a 94.4% rate of complete abortions.[22] In comparison, patients who received a medication abortion after an in-person clinic visit had a 93.3% rate of complete abortions—statistically similar to that of patients relying on telehealth.[23] In a survey of 1,600 patients who received abortion care through telemedicine, "[n]early all participants were very satisfied with telehealth abortion."[24] Nearly 96% of those surveyed felt it was the right decision, and patients reported that telehealth allowed them to receive care quickly, privately, and at a lower cost.[25]

In the District Court, Plaintiffs-Appellants attempted to obscure the safety of mifepristone with statistically unsupported anecdotes[26] that do not speak to the drug's overall safety record or the impact of dispensing via mail or pharmacy. These

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[21] Ushma D. Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, 30 NATURE MED. 1191, 1191 (2024).

[22] Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 903 (2024).

[23] *Id.* at 902–03.

[24] Leah R. Koenig et al., *Patient Acceptability of Telehealth Medication Abortion Care in the United States, 2021–2022: A Cohort Study*, 114 AM. J. PUB. HEALTH 241, 248 (2024).

[25] *Id.* at 247–248.

[26] ROA.119, 2512, 2534-36, 2562.

anecdotes do not provide any information about how the patients obtained the drug or any comparison to the number of patients who used the drug without complications. To the extent Plaintiffs-Appellants suggest that any adverse-event rate or treatment failure rate above zero is too much, *amici* submit that a flawless record is neither possible nor expected in the practice of medicine or the administration of any drug.[27] Reproductive healthcare should not be held to an unattainable standard.

Since mifepristone became available by mail during the COVID-19 pandemic, *amici* have not observed ***any increase*** in the incidence of adverse events. Plaintiffs-Appellants point to a speculative increase in emergency department or urgent-care "visits" associated with dispensing of mifepristone by mail or pharmacy.[28] However, as FDA observed, emergency department visits frequently do not involve any serious adverse event or any medical treatment ***at all***.[29] It is not uncommon for patients to seek reassurance or monitoring at emergency departments in the absence of any medical complication requiring clinical intervention.[30] The

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[27] *See, e.g.*, U.S. Food & Drug Admin., *Development & Approval Process: Drugs* (updated Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs ("All drugs have risks.").

[28] *See* Pls.-Appellants' Opening Br. 59–60, ECF No. 147 (citing ROA.1082, 1085-86, 1088, 1093).

[29] *See* ROA.379 ("half of the ED/urgent care visits did not entail any medical treatment."); *see also* ROA.1093.

[30] *See* Ushma D. Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, 30 NATURE MED. 1191, 1191 (2024) (finding that of the 1.3% of abortions via

Court should not endorse an approach that would override FDA's strongly supported scientific judgment with an unsupported characterization of the medical evidence.

IV. The Regulatory Timeline Shows that FDA's Elimination of the In-Person Dispensing Requirement Is Grounded in Scientific Data.

FDA has grounded its decisions to remove burdensome restrictions on mifepristone, including the in-person dispensing requirement, in copious data confirming mifepristone's safety and efficacy. For example, in 2000, FDA first approved mifepristone based on multiple, extensive clinical trials and sound research spanning over a decade and involving thousands of patients. That research demonstrated that mifepristone was safe and effective and that the health benefits outweighed the known risks.[31]

Over the extended period that the drug has been in widespread use, FDA has relaxed some (though far from all) of its restrictions on mifepristone. In 2016, FDA provided a REMS update removing some of the unnecessary restrictions on mifepristone and updating the mifepristone labeling to reflect evolutions in

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telemedicine that were followed by a known emergency department visit, nearly 40% resulted in no treatment); *see also, e.g.*, Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175, 175–183 (2015); 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. 88, 88 (2018).

[31] *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-751, FOOD AND DRUG ADMINISTRATION APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX at 15–16, 26 (2008) (In contrast, five other drugs were approved under restrictive Subpart H with clinical sample sizes of "several hundred patients or less."); ROA.603-06; U.S. Food & Drug Admin., *Development & Approval Process: Drugs* (updated Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs.

evidence-based practice. FDA's safety analysis relied on eleven independent clinical studies covering well "over 30,000 patients";[32] randomized controlled trials;[33] and several prospective, retrospective, and observational studies,[34] which demonstrated the safety and efficacy of mifepristone under conditions of use closely resembling the proposed new 2016 conditions.[35] Subsequent data confirms these conclusions.[36]

In 2021, as evidence of mifepristone's safety continued to accumulate, including evidence of mifepristone's safety when it was dispensed through mail and

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[32] 2016 FDA Medical Review at 62.

[33] *See id.* at 27, 31, 60, 63, 79.

[34] *See id.* at 6, 18, 29–31, 50, 60; 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. *See* ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (Oct. 2020, *reaff'd* 2023).

[35] *See, e.g.*, Claudia Diaz Olavarrieta et al., *Nurse Versus Physician-Provision of Early Medical Abortion in Mexico: A Randomized Controlled Noninferiority Trial*, 93 BULL. WORLD HEALTH ORG. 249, 251 (2015) (study conditions included a seventy-day gestational age limit, 200 mg oral mifepristone and 800 mcg buccal misoprostol, at home administration, and non-physician prescription); 2016 FDA Medical Review at 44, 64–65 (demonstrating, in a combination of studies on almost 2,400 subjects, that "no single option [of conducting follow-up visits with patients] [wa]s superior to the others," and noting that "[u]se of ultrasound, serum and urine pregnancy test . . . and telephone calls have all been evaluated in the literature as options for follow-ups").

[36] *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-292, FOOD AND DRUG ADMINISTRATION: INFORMATION ON MIFEPREX LABELING CHANGES AND ONGOING MONITORING EFFORTS 15 (2018) (summarizing studies and explaining that ten studies and FDA ultimately concluded that "various methods of follow up, including home pregnancy testing and phone contact with the patient to inquire about symptoms, were acceptable alternatives to an in-clinic follow up").

pharmacies, FDA first suspended and then announced its intent to permanently lift the in-person dispensing requirement. These steps were grounded in science rather than political aims; they occurred more than six months ***before*** *Dobbs v. Jackson Women's Health Organization* overturned *Roe v. Wade* in June of 2022.

The regulatory history underscores that the 2021 REMS change was grounded in scientific evidence and related legal developments predating *Dobbs*. During the COVID-19 pandemic, the in-person dispensing requirement exposed patients to needless risks. As a result, *amici* ACOG, together with Council of Chairs of Obstetrics and Gynecology ("CUCOG"), filed a motion for injunctive relief from the in-person dispensing requirement for the duration of the COVID-19 pandemic. In July of 2020, ACOG and CUCOG won a preliminary injunction,[37] and during the six-month period in-person dispensing was enjoined by court order, FDA observed ***no increase*** in serious adverse events.[38] In April 2021, based on that real-world evidence and multiple research studies conducted during the pandemic supporting mifepristone's safety when dispensed by mail, FDA issued guidance suspending the

[37] *Am. Coll. of Obstet. & Gynecol. v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020), *stay granted*, *FDA v. Am. Coll. of Obstet. & Gynecol.*, 141 S. Ct. 578 (2021) (mem.).

[38] ROA.258-60.

in-person dispensing requirement for mifepristone for the duration of the public health emergency.[39]

A wealth of COVID-era evidence reinforced that in-person dispensing was unnecessary to ensure safety when dispensing mifepristone. In December 2021—over six months before the *Dobbs* decision and after more than a year of non-enforcement, first under the injunction and then under FDA's pandemic announcement—FDA announced that it would make the REMS change permanent.[40] That decision was based in part on a review of REMS assessment data, as well as FAERS data from during the COVID pandemic, when FDA did not enforce the in-person dispensing requirement.[41] FDA also based its decision on a review of scientific literature, as well as "information provided by advocacy groups,

[39] ROA.259-60. These findings were confirmed in FDA 2023 Summary Review. *See* ROA.1023 ("To better understand whether there was any impact on safety . . . during the periods when the in-person dispensing requirement was not being enforced, [FDA] requested additional information from [pharmaceutical distributors of mifepristone] to provide for [a] more comprehensive assessment of the REMS for [that] time period," including reports of adverse events to FDA Adverse Event Reporting System ("FAERS")). FDA concluded "there does not appear to be a difference in adverse events between periods when the in-person dispensing requirement was being enforced and . . . when [it] . . . was not being enforced." ROA.1026.

[40] U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Apr. 8, 2026), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[41] ROA.1042.

individuals, the [pharmaceutical distributors of mifepristone] and the plaintiffs in the *Chelius v. Becerra* litigation."[42]

Plaintiffs-Appellants' assertion that the scientific literature on which FDA relied did not support the removal of the in-person dispensing requirement is incorrect.[43] FDA determined that the scientific literature—which was only one component of FDA's holistic review—is "***not inconsistent*** with" the removal of the in-person dispensing requirement.[44] FDA further elaborated that the studies it examined "generally support a conclusion that dispensing by mail is safe," and "there was no increased frequency of" serious adverse events.[45] Regardless, the entirety of FDA's review—which was not limited to review of scientific literature and included a review of real-world data—supported the conclusions that "[t]here [were] no new safety concerns identified . . . since the [2021] REMS Modification Notification letters," and "mifepristone w[ould] remain safe and effective . . . if the in-person dispensing requirement [wa]s removed."[46]

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[42] ROA.1042.

[43] Pls.-Appellants' Opening Br. 57–58, ECF No. 147.

[44] ROA.1042 (emphasis added).

[45] ROA.1042, 2880.

[46] ROA.982, 1042.

FDA's 2016 change to prescriber reporting of adverse events was similarly well-reasoned and did not unreliably stack the deck in favor of FDA's decision to remove the in-person dispensing requirement by limiting adverse reporting. ***First***, even after FDA's decision to align adverse event reporting for mifepristone more closely with the protocol applicable to most other prescription drugs, FDA continues to impose more extensive reporting requirements for mifepristone.[47] The agency's decision to remove some of the additional reporting requirements was based on the reasoned conclusion that after fifteen years of analyzing adverse event reports, mifepristone's safety profile was "well-characterized."[48] ***Second***, prescribers are not the only source of adverse event reporting. FDA's 2016 change to prescriber reporting requirements did nothing to alter that parties submitting new drug applications and abbreviated new drug applications—like Danco Laboratories, LLC and GenBioPro, Inc.—are required by law to report serious, unexpected adverse events within fifteen days, and all other adverse events on an annual basis.[49] In reaching its 2023 REMS decision, FDA specifically requested this FAERS data from

[47] *Compare* 21 C.F.R. §§ 314.80–81 *with* ROA.991.

[48] ROA.1018.

[49] *See* 21 C.F.R. §§ 314.80, 314.98 (2014); *see also* 2016 FDA Medical Review at 8.

the period during which FDA did not enforce in-person dispensing (as explained above).[50]

Even in the absence of in-person dispensing, FDA ***still regulates mifepristone more stringently than nearly any other of the 20,000 drugs*** it regulates—including highly addictive and dangerous opioids.[51] Indeed, as the court in *Purcell v. Kennedy* found, mifepristone continues to receive "restrictive treatment" by FDA in spite of peer-reviewed research confirming that mifepristone remains extremely safe and effective when regulated normally like other prescription drugs.[52]

V. Restricting the Use of Mifepristone Will Harm Patients and Have Severe Negative Impacts on the Broader Healthcare System.

An order staying the 2023 REMS will impair access to mifepristone nationwide—including in states where abortion is legally protected, state policy is designed to support access to reproductive healthcare through telemedicine, and thousands of patients rely on mail and pharmacy dispensing of mifepristone. Such an order also would limit mifepristone access for indications other than abortion care, such as miscarriage management. This far-reaching impact endangers pregnant patients, particularly those from vulnerable populations.

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[50] ROA.1023.

[51] ACOG et al., FDA Citizen Petition, at 12 (Jan. 31, 2025); *Purcell v. Kennedy*, No. CV 17-00493 JAO-RT, 2025 WL 3101785, at *4 (D. Haw. Oct. 30, 2025).

[52] *Purcell*, 2025 WL 3101785, at *2, *22, *25–*27.

Mifepristone is an extremely safe and effective medication for abortion care and early pregnancy loss, and is markedly safer than pregnancy itself. Patients are significantly more likely to die during childbirth than as a result of an abortion[53] and are at an increased risk of experiencing hemorrhage, infection, and injury to other organs during pregnancy and childbirth.[54] Pregnancy and childbirth impose significant physiological changes that can exacerbate underlying conditions and severely compromise health, sometimes permanently.[55]

The dangers of pregnancy are far greater, and the benefits of telehealth all the more crucial, for patients of color, patients with low-incomes, patients with disabilities, and patients in rural areas or healthcare deserts.[56] The majority of

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[53] *See* Maria W. Steenland et al., *Pregnancy- and Abortion-Related Mortality in the US, 2018–2021*, 9 JAMA NETWORK OPEN 1, 1 (2026) (concluding that "the ratio of pregnancy- to abortion-related mortality from 2018 to 2021 ranged from 44.3 to 69.6").

[54] *See* Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTET. & GYNECOL. 215, 215–217 fig. 1 (2012) ("The risk of death associated with childbirth is approximately 14 times higher than that with abortion.").

[55] *See, e.g.*, ACOG Clinical Consensus No. 1, *Pharmacologic Stepwise Multimodal Approach for Postpartum Pain Management* (Sept. 2021, *reaff'd* 2025); ACOG Practice Bulletin No. 222, *Gestational Hypertension and Preeclampsia* (June 2020, *reaff'd* 2026); ACOG & Soc'y for Maternal Fetal Med. Obstet. Care Consensus No. 7, *Placenta Accreta Spectrum* (Dec. 2018, *reaff'd* 2025); ACOG Committee Opinion No. 794, *Quantitative Blood Loss in Obstetric Hemorrhage* (Dec. 2019, *reaff'd* 2025).

[56] *See* Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Key Issues*, KFF (Dec. 3, 2025); Ctrs. for Medicare & Medicaid Servs., *Advancing Rural Maternal Health Equity* 1 (2022); Leah R. Koenig et al., *The Role of Telehealth in Promoting Equitable Abortion Access in the United States: Spatial Analysis*, 9 JMIR PUB. HEALTH & SURVEILLANCE 1, 8–9 (2023).

abortion care patients identify as people of color, and, when measured in 2021 to 2022, "almost three-quarters of all abortion patients were living at or below 200% of the federal poverty level."[57] Pregnant people of color are also more likely to experience early pregnancy loss or miscarriage, the treatment of which can include mifepristone.[58] These populations—composed of individuals who are most likely to die from pregnancy-related complications—are disproportionately harmed by restrictions on abortion care and miscarriage management.[59] Telehealth allows such patients to avoid significant costs associated with travel to obtain care, childcare expenses, and lost wages—burdens that deter and delay care.[60]

Telehealth also enables patients to avoid long wait times at physical clinics[61]—a particularly urgent concern as state abortion bans have increased

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[57] Tracy A Weitz, *Making Sense of the Economics of Abortion in the United States*, 56 PERSPS. ON SEXUAL & REPROD. HEALTH 199, 200 (2024).

[58] *See* Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department, 2006–2016*, 2 J. AM. COLL. OF EMERGENCY PHYSICIANS OPEN 1, 1–2, 4 (2021).

[59] *See* ACOG Committee Statement No. 16, *Increasing Access to Abortion* (Feb. 2025); Rachel K. Jones et al., *COVID-19 Abortion Bans and Their Implications for Public Health*, 52 PERSPS. ON SEXUAL & REPROD. HEALTH 65, 66 (2020); Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Key Issu*es, KFF (Dec. 3, 2025).

[60] *See* Andréa Becker et al., *"It Was So Easy in a Situation That's So Hard": Structural Stigma and Telehealth Abortion*, 67 J. HEALTH & SOC. BEHAV. 120, 121, 125–6 (2025); *see also The High Toll of US Abortion Bans: Nearly One in Five Patients Now Traveling Out of State for Abortion Care.*, Guttmacher Inst. (Dec. 2023), https://www.guttmacher.org/2023/12/high-toll-us-abortion-bans-nearly-one-five-patients-now-traveling-out-state-abortion-care.

[61] Andréa Becker et al., *"It Was So Easy in a Situation That's So Hard": Structural Stigma and Telehealth Abortion*, 67 J. HEALTH & SOC. BEHAV. 120, 125 (2025).

demand for abortion care in many states where abortion remains lawful.[62] Reinstating in-person dispensing requirements would increase burdens on the healthcare system and impede patient access through delay. Reimposing unnecessary restrictions on mifepristone will exacerbate existing inequities and pose the greatest danger to those who already have difficulty accessing essential reproductive healthcare.

There is substantial evidence that denial of abortion care causes harm. Patients who are able to access abortion care are more likely to experience a reduction in physical intimate partner violence compared to patients who are denied requested abortion care.[63] The denial of abortion care undermines maternal health, exacerbates the risks inherent in pregnancy, and worsens patients' economic

[62] Rachel K. Jones et al., *The Number of Brick-and-Mortar Abortion Clinics Drops, as US Abortion Rate Rises: New Data Underscore the Need for Policies that Support Providers*, Guttmacher Inst. (June 2024), https://www.guttmacher.org/report/abortion-clinics-united-states-2020-2024 (noting that "[s]ome states that share a border with one or more ban states absorbed the additional patients with little or no increase in the numbers of brick-and-mortar clinics between 2020 and March 2024").

[63] 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); *cf.* Dhaval Dave et al., *Abortion Restrictions and Intimate Partner Violence in the Dobbs Era*, 104 J. HEALTH ECON. 1, 1, 13 (2025) (finding that that abortion restrictions significantly increased the rate of intimate partner violence among reproductive-aged women).

hardships.[64] In addition, existing children of women denied desired abortion care are more likely to live in poverty and less likely to reach developmental milestones.[65]

Restricting access to mifepristone endangers ***anyone*** who is pregnant—including patients managing miscarriage or early pregnancy loss,[66] which occur in approximately 10% to 20% of known pregnancies.[67] Untreated, the miscarriage process can take two to eight weeks to resolve, exacerbating the emotional strain of pregnancy loss.[68] *Amici*'s members frequently prescribe mifepristone when a patient is experiencing early pregnancy loss because it can ease the process and lead to better

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[64] *See* ANSIRH, *The Harms of Denying a Woman a Wanted Abortion Findings from the Turnaway Study*, UNIV. OF CAL., S.F. 2 (2020); 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, 407, 411–12 (2018); *cf.* Dovile Vilda et al., *State Abortion Policies and Maternal Death in the United States, 2015–2018*, 111 AM. J. PUB. HEALTH 1696, 1697 (2021).

[65] ANSIRH, *Women's Access to Abortion Improves Children's Lives*, UNIV. OF CAL., S.F. 1 (2019).

[66] *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2025); *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, at 11:19 ET), https://www.npr.org/sections/healthshots/2019/01/10/666957368/a-drug-that-eases-miscarriages-isdifficult-for-women-to-get.

[67] *See Miscarriage*, Mayo Clinic (Sept. 8, 2023), https://www.mayoclinic.org/diseases-conditions/pregnancy-loss-miscarriage/symptoms-causes/syc-20354298.

[68] Dr. Kristyn Brandi, *What to Know About Abortion and Miscarriages With or Without Mifepristone*, ACOG (last reviewed Feb. 2025), https://www.acog.org/womens-health/experts-and-stories/the-latest/what-to-know-about-abortion-and-miscarriages-with-or-without-mifepristone; Linda Li et al., *Mifepristone as Controlled Substances: Implications for the Management of Non-Abortion Related Conditions*, KFF (Apr. 3, 2025), https://www.kff.org/womens-health-policy/classifying-misoprostol-and-mifepristone-as-controlled-substances-implications-for-the-management-of-non-abortion-related-conditions/.

health outcomes.[69] Patients already enduring miscarriage should not be forced to suffer through limited access to a safe and effective medication.

Amici also urge this Court to recognize that the vast majority of patients who seek abortion care, including medication abortion, report that their overwhelming feeling after abortion care is relief and that they do not regret their decision, suffer from emotional distress, or experience other negative mental health outcomes.[70] Study after study confirms that those who receive abortion care experience direct measurable benefits from having access to this safe and essential form of reproductive care.[71]

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[69] *See, e.g.*, ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2025); Jessica Beaman et al., *Medication to Manage Abortion and Miscarriage*, 35 J. GEN. INTERNAL MED. 2398, 2400 (2020).

[70] *See* Corinne H. Rocca et al., *Emotions and Decision Rightness over Five Years Following an Abortion: An Examination of Decision Difficulty and Abortion Stigma*, 248 Soc. Sci. & Med. 112704 (2020), at 8 (finding relief was the most commonly felt emotion at all time points across the five-year study and that the "overwhelming majority of women felt that the abortion was the right decision for them"). *Contra* ROA.92. Plaintiffs-Appellants relied in the district court on anonymous, online blog posts about abortion on a website then named "www.abortionchangesyou.com." This is not representative of the general population for several reasons: (1) the analyses included posts from just 98 participants; (2) someone experiencing negative feelings in connection with abortion would be far more likely to seek out this kind of website as compared to someone who is content with their decision and experience; and (3) as the study itself says, "there is a lack of generalizability due to the limited scope: [the study] only analyzed women's medication abortion narratives anonymously posted on one website." ROA.460-61.

[71] *See, e.g.*, 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, 411–12 (2018); Tanya Albert Henry, *Access to Abortion and Women's Health: What the Research Shows*, Am. Med. Ass'n (July 5, 2022), https://www.ama-assn.org/public-health/population-health/access-abortion-and-women-s-health-what-research-shows.

CONCLUSION

For the reasons set forth above, *amici* urge this Court to deny Plaintiffs-Appellants' request for a stay of the 2023 REMS and affirm the denial of Plaintiffs-Appellants' December 17, 2025 motion for preliminary relief.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on July 22, 2026, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ *Shannon Rose Selden*
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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 6,046 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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