UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF LOUISIANA

LAFAYETTE DIVISION

THE STATE OF LOUISIANA, *et al*., *Plaintiffs*, U.S. FOOD AND DRUG ADMINISTRATION, *et al*., *Defendants.*	Civil No. 6:25-CV-01491 Judge David C. Joseph Mag. Judge: David J. Ayo

AMICUS BRIEF OF AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS, ET AL. AS *AMICI CURIAE* IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY RELIEF AND IN SUPPORT OF INTERVENORS' MOTIONS TO DISMISS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY RELIEF

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INTEREST OF *AMICI CURIAE*

The American College of Obstetricians and Gynecologists ("ACOG") represents more than 90% of board-certified OB/GYNs in the United States. It 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 of the changing issues facing women's health care. A leader in the effort to confront the maternal mortality crisis in the United States, ACOG is committed to ensuring access for all people to the full spectrum of evidence-based, quality reproductive health care, including abortion care.[1]

In addition to ACOG, *amici curiae* include fourteen other leading medical societies: the Society for Maternal-Fetal Medicine; the American Academy of Family Physicians; the American College of Physicians; the American College of Preventative Medicine; the American Gynecological and Obstetrical Society; the American Society for Reproductive Medicine; the North American Society for Pediatric Adolescent Gynecology; the Society for Adolescent Health and Medicine; the Society of General Internal Medicine; the Council of University Chairs of Obstetrics & Gynecology; the Society of Gynecologic Oncology; the Society of Gynecologic Surgeons; the Society of OB/GYN Hospitalists; and the American Medical Women's Association.

[1] Contrary to statements made in the American Association of Pro-Life Obstetricians and Gynecologists' (AAPLOG) February 13, 2026, amicus brief, ACOG does not itself generate scientific data. ACOG develops clinical guidance for practitioners based on a thorough review of all available scientific evidence, prioritizing the findings of studies based on a rigorous evaluation of study design and methodological integrity. This widely accepted process is the very foundation of evidence-based medicine. Similarly, when AAPLOG attempts to undermine ACOG guidance by pointing to express disclosures that statements may be based on "limited or inconsistent scientific evidence" it deliberately misconstrues language used to evaluate levels of evidence that is standard in the industry. That language promotes transparency and scientific integrity as normative judgments on whether the conclusions are appropriately supported by the various levels of evidence. As we make clear in our substantive arguments, there is significant evidence establishing the safety of abortion counseling by telehealth and dispensing of mifepristone via mail or certified pharmacy. *See* Br. of *Amicus Curiae* Am. Ass'n of Pro-Life Obstet. & Gynecol. and Samaritan's Purse in Supp. of Pls.' Mot. For Prelim. Inj., ECF No. 96 at 8.

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 in real-world settings. *Amici* share a dedication to ensuring robust access to evidence-based health care and promoting health care policy that improves patient health.

Courts frequently rely on *amici*'s medical and scientific expertise in cases involving pregnancy.[2] *Amici* believe that all patients are entitled to prompt, complete, and unbiased health care that is medically and scientifically sound. Mifepristone—which has undergone rigorous testing and review—is a medically and scientifically sound drug used for abortion and miscarriage management, among other conditions. *Amici* submit this brief to explain that mifepristone is a safe and effective treatment, ***regardless of whether it is dispensed in person***. In particular, *amici* support the U.S. Food & Drug Administration's ("FDA") decision to remove the requirement that mifepristone be dispensed in person, which FDA issued as part of its 2023 Risk Evaluation and Mitigation Strategy ("2023 REMS"). That decision was supported by the safety profile of the medication and overwhelming weight of medical evidence.

Amici's members have safely prescribed mifepristone in the United States for more than twenty-five years. Those prescriptions include distribution of mifepristone by mail, which can be vital where a patient lives in a health care desert or is unable to travel in person to a health care center. Accordingly, *amici* have a strong interest in preserving that access, which remains supported by sound science and data today. *Amici* further have an interest in ensuring that the science surrounding mifepristone's safety, efficacy, and administration is correctly understood.

[2] *See, e.g.*, *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).

SUMMARY OF THE ARGUMENT

This case concerns 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. Specifically, Plaintiffs challenge FDA's 2023 REMS, which eliminated the requirement of in-person dispensing of mifepristone and made it possible for patients to receive mifepristone by certified pharmacy or mail. For the reasons set forth below, including overwhelming data supporting the safety of mifepristone, *amici* ask this Court to deny in full Plaintiffs' Motion for Preliminary Relief (ECF No. 20; "Plaintiffs' Motion" or the "Motion") and grant in full Intervenor Danco Laboratories LLC's Motion to Dismiss Plaintiffs' Complaint (ECF No. 52-3; "Danco's Motion") and Intervenor GenBioPro Inc.'s Motion in Opposition to Plaintiffs' Motion for Preliminary Relief (ECF No. 54-4; "GenBioPro's Motion" and, together with Danco's Motion, the "Intervenors' Motions").

Mifepristone—whether dispensed in person or not—is extremely safe. More than two decades, hundreds of medical studies, and vast amounts of data have confirmed mifepristone's safety and efficacy for abortion care and miscarriage management. The scientific evidence is overwhelming: serious adverse events occur in ***less than one-third of 1%*** of patients—again, whether dispensed in person or not—and the risk of death is almost non-existent.

Since initially approving the drug, FDA has actively monitored and studied mifepristone. To date, the results of FDA's evidence-based study are clear: remote access to mifepristone is supported by the compelling safety profile of the medication and enables practitioners to provide safe, medically appropriate, and effective care.

In connection with their Motion, Plaintiffs make 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 overwhelming evidence

that mifepristone is a safe and essential component of reproductive health care. Eschewing sound science, Plaintiffs ask this Court to create unnecessary barriers to care by staying the 2023 REMS and with it the ability to dispense mifepristone by certified pharmacy or mail. In doing so, Plaintiffs effectively demand a ***nationwide*** return to mandatory, in-person dispensing of mifepristone, which would severely limit access to mifepristone and deny medically appropriate and legal care to patients both within and far beyond the boundaries of Louisiana.

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 living with disabilities, and/or patients living 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 very core of individual autonomy and well-being. *Amici* urge this Court to reject Plaintiffs' request that it curtail access for patients throughout the country to an essential medication that FDA appropriately has deemed safe for use.

ARGUMENT

I. Mifepristone Is an Essential Component of Reproductive Care.

At its core, mifepristone 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.[3] Under the preferred protocol in the United States, mifepristone is administered

[3] Studies also have 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). In addition, mifepristone is 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 (2014); Mario Tristan et al., *Mifepristone for Uterine Fibroids*, COCHRANE DATABASE OF 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. OF CLINICAL & EXPERIMENTAL MED. 2234, 2239 (2020); *see also* Blake M. Autry & Roopma Wadhwa, *Mifepristone,* STATPEARLS (last updated Feb. 28, 2024).

approximately twenty-four hours before misoprostol to empty the contents of the uterus.[4] This combination is key to reducing adverse effects: studies have shown that use of the two drugs together mitigates the risk that a patient will need subsequent procedural intervention.[5]

Although medication abortion undoubtably causes some bleeding and cramping, those effects are not "complications"[6] but instead medically necessary parts of the treatment process.[7] Much like during a menstrual cycle or miscarriage, bleeding and cramping are how the body expels the uterine lining and contents. Mifepristone eases that process and reduces the risks that it will be prolonged or incomplete.[8]

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

Despite Plaintiffs' assertions to the contrary, 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 901 medical reviews and used in at least 670 published clinical trials—of which 462 were randomized controlled studies, the gold standard in research design.[9] Based on these 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.[10]

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[4] ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2025).
[5] 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 CONTRACEPTION 1, 5 (2023).
[6] Plaintiffs mislabel "side effects," which are expected effects of treatment, as "complications." *See* 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.").
[7] ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2025).
[8] ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2025).
[9] This is based on a review of PubMed, the National Institute of Health's sponsored database of research studies.
[10] *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) (concluding that after restrictions on mifepristone were eliminated in Canada,

Specific examples of clinical studies help to highlight the safety of mifepristone. For example, a highly regarded study involving more than 50,000 patients that had abortions showed that serious adverse events—those requiring hospitalization, surgery, or blood transfusion—occurred in ***less than 0.32%*** of patients who had medication abortions.[11] Studies have found that serious infection following medication abortion is exceptionally rare, occurring in ***only 0.015%*** of patients.[12] In addition, the risk of death is ***almost non-existent***; FDA's 2024 analysis of data examining potential mifepristone-related deaths yielded an extremely low mortality rate—in that instance, 0.00048%.[13]

In fact, mifepristone has a lower associated fatality rate than many common medications and devices approved by FDA. Studies have shown that mifepristone is associated with fewer deaths than nonsteroidal anti-inflammatory drugs ("NSAIDs"), a class of drugs that includes many common, over-the-counter drugs used by tens of millions of Americans each day, such as aspirin and ibuprofen.[14] Using Viagra is more dangerous than using mifepristone; Viagra has a mortality

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the rates of "adverse events and complications remained stable," even though "the proportion of abortions provided by medication increased rapidly"); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175, 176, 178 (2015) (finding a minor complication rate of less than 5% for the over 11,000 medication abortions studied, with minor complications defined as anything but serious unexpected adverse events requiring hospital admission, surgery, or blood transfusion).

[11] *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 rate of major complications—defined as "serious unexpected adverse events requiring hospital admission, surgery, or blood transfusion"—of 0.31% for the over 11,000 that had a medication abortion). 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).

[12] FDA Ctr. For Drug Eval. & Rsch., *Medical Review Application No. 020687Orig1s020*, at 53-54 (Mar. 29, 2016) [hereinafter, "2016 FDA Medical Review"] (explaining that "[i]nfections requiring hospitalization or IV antibiotics were rare in the studies . . . with rates ranging from 0-0.015%").

[13] *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). This study shows no clear causal link between the recorded deaths and mifepristone, noting that fatalities were included "regardless of causal attribution to mifepristone." The causes of these mortalities included sepsis, ruptured ectopic pregnancy, suspected homicide, and late-onset toxic shock syndrome among other causes.

[14] NAT'L ACADS. OF SCI., ENG'G & MED., *The Safety and Quality of Abortion Care in the United States* (2018); *see also* Rohab Sohail et al., *Effects of Non-steroidal Anti-inflammatory Drugs (NSAIDs) and Gastroprotective NSAIDs on the Gastrointestinal Tract: A Narrative Review*, 15 CUREUS 1 (2023); ANSIRH, Adverse Events 2024 at 2–3

rate of 0.004%[15]—over eight times higher than the reported mifepristone-associated fatality rate referenced above.[16] Colonoscopies are a routine procedure, widely used in preventive care. That routine procedure has a mortality rate of 0.03%—over 62 times higher than the reported mifepristone mortality rate referenced above.[17] Medication abortion involving mifepristone is among the safest medical interventions in any category, pregnancy-related or not.

The contrary statistics on which Plaintiffs rely are taken entirely out of context, at best, and plainly wrong, at worst. ***First***, Plaintiffs attempt to stoke fears that mifepristone will lead to excess bleeding or infection by highlighting one-off examples and pointing to FDA's inclusion of a "black box warning"[18] that "serious and sometimes fatal infections or bleeding" may occur.[19] However, as noted above, bleeding and cramping are expected parts of the treatment process and, while the use of any drug presents some risk, incidents of life-threatening bleeding or infection due to mifepristone are almost nonexistent.[20] In addition, although a boxed warning signals that the advantages of a drug must be weighed against serious risks, it does not communicate that those risks occur frequently (a concern that is allayed by the actual data). Boxed warnings appear on

(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").

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

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

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

[18] Plaintiffs purposefully use inflammatory language to falsely imply that mifepristone is dangerous. Like many other drugs, mifepristone has what is officially referred to as a "boxed warning" to alert users of potential risks. Carmen Pope, *What is a Boxed Warning?*, Drugs.com (Aug. 12, 2025), https://www.drugs.com/article/what-are-boxed-warnings.html.

[19] Compl. ¶ 38; Pl.'s Mem. in Supp. of Mot. for Prelim. Inj. 6, ECF No. 20-26 [hereinafter "Prelim. Inj. Mem".].

[20] *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); *see also* U.S. FOOD & DRUG ADMIN., NDA NO. 020687 & NO. ANDA 091178, *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2024* (2025) (finding in a summary report of approximately 7.5 million people who used mifepristone between 2000 and 2024, only 0.008% experienced blood loss requiring transfusions, 0.006% experienced an infection, and only 0.001% experienced a severe infection.)

commonly used drugs, such as NSAIDs,[21] and others prescribed to millions of patients, such as Metformin (the second-most prescribed drug in the United States as of 2023) and Zoloft, a.k.a. Sertraline (the eleventh-most prescribed drug in the United States as of 2023).[22]

Second, Plaintiffs cite flawed studies regarding adverse event statistics that are not supported by credible data. The studies from which these claims originate are far outside the medical consensus and starkly inconsistent with the overwhelming weight of credible, peer-reviewed, evidence-based work. For example, Plaintiffs cite to a self-published paper by the Ethics and Public Policy Center for inflated figures concerning the rate of adverse events in patients who took mifepristone.[23] However, that publication lacks the rigors of reliable science, including because: (1) it is not peer-reviewed; (2) it fails to clearly identify the source of the insurance data on which it is based; (3) of the patients who purportedly experienced serious adverse events, over half were identified as experiencing "other-abortion specific complications," without any elaboration; and (4) the paper identified "mifepristone abortions" based on prescriptions of mifepristone but failed to document whether patients followed the appropriate two-drug medication abortion regimen of mifepristone followed by misoprostol and failed to account for the fact that mifepristone is also prescribed as a treatment for miscarriage.[24]

Plaintiffs also misrepresent emergency room data related to mifepristone use. While Plaintiffs assert that "roughly 1 in 25 (or 4% of) women who receive an in-person visit with a

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[21] Theodore R. Fields, MD, FACP, *Guidelines to Help Reduce the Side Effects of NSAIDs (Nonsteroidal Anti-inflammatory Drugs)*, Hosp. for Special Surgery (Dec. 3, 2025), https://www.hss.edu/health-library/conditions-and-treatments/guidelines-reduce-side-effects-nsaids (explaining that "[t]he FDA has required a black box warning about cardiovascular thrombotic events be placed in the package description of all NSAIDs other than aspirin").

[22] ClinCalc, *Sertraline*, https://clincalc.com/DrugStats/Drugs/Sertraline (last visited Feb. 18, 2026); ClinCalc, *Metformin*, https://clincalc.com/DrugStats/Drugs/Metformin (last visited Feb. 18, 2026).

[23] Compl. ¶ 38.

[24] *See* Letter from Ctr. On Reprod. Health, Law, and Pol. at UNIV. CAL. L.A. SCHOOL OF LAW, & ANSIRH, UNIV. OF CAL. S.F., to the U.S. Food & Drug Admin. (Aug. 27, 2025), https://law.ucla.edu/sites/default/files/PDFs/Center_on_Reproductive_Health/Reproductive%20Health%20Researchers%20Comment%20Letter%20to%20FDA%208.27.25.pdf.

medical provider and take mifepristone *as directed* will end up in the emergency room,"[25] this statistic does not indicate severity of condition or whether any treatment was received at all. As a threshold matter, the mifepristone label cites two different U.S. studies finding two different rates—2.7% and 4%—and Plaintiffs cherry-pick the higher figure.[26] Even setting that aside, recent data confirms a lower rate than even the lower figure on the label, showing that only approximately 2.6% of medication abortion patients visit the emergency department. Further, of those visits, only 0.21% result in hospital admission.[27] This makes sense. The mifepristone label, as cited by Plaintiffs, directs users to "go to the nearest hospital emergency room" if they are unable to contact their health care provider and experience symptoms like heavy bleeding, abdominal pain, or fever.[28] These are not necessarily serious adverse events, and in the case of heavy bleeding and abdominal pain, are necessary side effects indicating the medication is working as intended. Indeed, Plaintiffs own cited sources show that, based on studies examining a total of 30,966 patients, "serious adverse reactions were reported in [less than] 0.5% of women," and true ***hospitalization*** related to medication abortion occurred with a frequency of just 0.04% to 0.6% in the United States.[29]

Plaintiffs also overstate the import of the statement on the mifepristone label that two to seven out of 100 patients require a "surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding."[30] That statement merely conveys that mifepristone is

[25] Prelim. Inj. Mem. 6, 22; *see also* Compl. ¶¶ 7, 35, 132; Pls.' Reply Mem. in Supp. of Prelim. Inj. 18–19, ECF No. 111.
[26] Compl. Ex. 9 at 8, ECF No. 1-9.
[27] Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Sudy* 182 JAMA 482, 487 (2022).
[28] Compl. Ex. 9 at 16, ECF No. 1-9. The labels of other common medications incorporate similar directions. *See, e.g.*, FDA-Approved Label for Viagra, at 29 (Mar. 2014) (stating "[i]f you accidentally take too much VIAGRA, call your doctor or go to the nearest hospital emergency room right away").
[29] Compl. Ex. 9 at 7–8, ECF No. 1-9.
[30] Compl. ¶ 35.

93–98% effective. Like any medication, there is some risk mifepristone will not be 100% effective. However, in the rare case medication abortion is not effective after the first treatment, additional rounds of misoprostol or a procedural abortion are both safe and effective ways to complete the process.[31] Treatment for incomplete abortion "is part of standard medical practice and does not indicate a serious adverse event—just a different path to the same safe outcome."[32]

Third, Plaintiffs purport to bolster their junk science with personal anecdotes, lacking in both the specificity needed to give those statements credibility and the weight and statistical significance needed to give those statements import. Plaintiffs add uncited and unsupported assertions of an unnamed doctor who purports to have seen a number of "abortion-drug complications" during a two-month period.[33] As described above, serious adverse events from medication abortion are exceedingly rare, and there is no evidence to suggest, nor have *amici* observed, any increase in such events since FDA removed the in-person dispensing requirement through the 2023 REMS.

Despite Plaintiffs' distortions, the science is clear: mifepristone is safe and effective.[34]

III. Reliable Scientific Data Confirms the Safety of Non-In-Person Dispensing.

Mifepristone is safe not just when it is dispensed in a health care facility but also when it is dispensed by mail or certified pharmacy after the patient has been evaluated and counseled via

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[31] World Health Organization, *Incomplete abortion management: Recommendations 35-38 (3.5.2)*, https://srhr.org/abortioncare/chapter-3/post-abortion-3-5/incomplete-abortion-management-recommendations-35-38-3-5-2/ (last visited Feb. 20, 2026); Florian Recker et al., *Advancing Knowledge and Public Health: A Scientific Exploration of Abortion Safety*, 312 ARCHIVES OF GYNECOL. AND OBSTETS. 643, 643 (May 24, 2025) (stating that "[s]urgical abortion…offers comparable safety [to medication abortion] with a major complication rate below 0.2%").

[32] Kelly Baden et al., *The War on Mifepristone: How Junk Science and False Narratives Threaten US Abortion Access*, GUTTMACHER INSTITUTE (2025).

[33] Compl. ¶ 125; Parise Decl. ¶¶ 9–13, ECF No. 20-23.

[34] *See, e.g.*, U.S. FOOD & DRUG ADMIN., NDA NO. 020687 & NO. ANDA 091178, *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2024* (2025); Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 NEW ENG. J. MED. 57, 57 (2022); ANSIRH, *Adverse Events 2024*; Ushma D. Upadhay, et al., *Outcomes and Safety of History-Based Screening for Medication Abortion A Retrospective Multicenter Cohort Study,* 182 JAMA 482, 487 (2022).

telehealth. Under the 2023 REMS, a patient is not required to physically retrieve mifepristone from a doctor's office. Instead, the patient can fill their prescription at a pharmacy or by mail and can request home delivery after being clinically evaluated and counseled either via telehealth or in-person at a health center. After completing the medication regimen, patients are directed to confirm that the treatment was effective with an at-home pregnancy or blood test. If at any point there is a clinical indication for it, the patient is directed to in-person care.

Reproductive health clinics and providers—like health care providers in many fields of medicine—have developed specific protocols and technologies to ensure adequate patient contact and monitoring, including health questionnaires, specialized patient platforms (e.g., patient "portals"), 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, level of care, and effectiveness as in-person dispensing.[35] 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. Further, patients engage in shared-decision making with their trusted clinician to determine the appropriate course of treatment—just as they would in person.[36]

No decrease in mifepristone's safety has been observed since the removal of the in-person dispensing requirement, and patients report high rates of satisfaction. In a recent study of 585 patients across six different U.S. states, patients who obtained medication abortion after a no-test,

[35] *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).
[36] Elizabeth G. Raymond et al., *Commentary: No-test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond*, 101 CONTRACEPTION 361, 364 (June 2020).

no-ultrasound telehealth screening had a 94.4% rate of complete abortions.[37] Notably, patients who received medication abortion after an in-person clinic visit had a 93.3% rate of complete abortions—a statistically similar rate to that of patients relying on telehealth.[38] Another study, which collected data from more than 6,000 patients in twenty states, shows that "[t]elehealth medication abortion is effective, safe, and comparable to published rates of in-person medication abortion care."[39] In a study of 1,600 patients who received abortion care through telemedicine, "[n]early all participants were very satisfied with telehealth abortion."[40] Specifically, nearly 96% of those surveyed felt it was the right decision, and patients reported that choosing telehealth not only made care more accessible but also allowed them to receive care quickly, privately, at a lower cost, and in the comfort of their own home.[41]

Plaintiffs' attempt to obscure this reality with statistically unsupported anecdotes.[42] However, those anecdotes say nothing about mifepristone's safety profile or the safety of remote dispensing, as they provide no comparison to the number of patients who used the drug without complications and no information about the method in which the drug was obtained. To the extent Plaintiffs suggest that any adverse-event rate or treatment failure 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.

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[37] Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 903 (2024).
[38] *Id.* at 902–03.
[39] Ushma D. Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, 30 NATURE MED. 1191, 1191 (2024) (also finding that "[o]verall, 1.3% (95% CI = 1.1–1.6%) of abortions were followed by a known emergency department visit, 38.3% of which resulted in no treatment").
[40] 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).
[41] *Id.* at 247–248.
[42] Compl. ¶ 125; Decl. of Angela Parise, M.D. ¶¶ 9–13, ECF No. 20-23; Decl. of Christina Francis, M.D. ¶¶ 45–49, ECF No. 20-21; Decl. of John Voltz, M.D. ¶¶ 8–10, ECF No. 20-11.

Nor does an increase in the still very low risk of adverse events with increasing gestation necessitate in-person dispensing. Plaintiffs contend, with no source, that "[r]emotely dispensed abortion drugs present even greater risks to women because, without an in-person examination, prescribers cannot confirm and therefore are more likely to misdate the gestational age…"[43] However, high-quality studies demonstrate the opposite. For instance, one study that compared in-person medication abortion care with telehealth care concluded that "medication abortion following no-test telehealth screening and mail-order pharmacy dispensing of medications was associated with similar rates of complete abortion as in-person care with ultrasonography, met the prespecified threshold for noninferiority, and had low rates of [adverse events] overall."[44] Another study showed no difference in serious adverse events between patients who received pre-abortion ultrasound and those who did not.[45] In addition, a systematic review and meta-analysis of the literature confirms medication abortion after telehealth consultation is as safe and effective as in-person care, with a "shorter waiting time for medication delivery."[46]

Plaintiffs further contend that the in-person dispensing requirement is the "sole opportunity to screen women for an ectopic pregnancy."[47] This is flatly incorrect.[48] Findings suggest that no-test telehealth abortion care does not delay and sometimes facilitates earlier detection and

[43] Compl. ¶ 37.
[44] Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 903 (2024).
[45] *Id.* at 898.
[46] *See* Leonardo Cely-Andrade et al., *Telemedicine For The Provision Of Medication Abortion To Pregnant People At Up To Twelve Weeks Of Pregnancy: A Systematic Literature Review And Meta-Analysis,* 21 REPROD. HEALTH 136, 156 (2024) (conducting meta-analysis of twenty-one articles published between 2011 and 2022 and concluding there are no significant differences in safety, effectiveness, or patient satisfaction when comparing telehealth care to in-person abortion care). If there is a legitimate medical question regarding a patient's gestational age, the 2023 REMS do not prevent an in-person visit; health care professionals routinely make individualized assessments of this nature.
[47] Prelim. Inj. Mem. at 22; *see also* Br. of Amicus Curiae Am. Ass'n of Pro-Life Obstet. & Gynecol. and Samaritan's Purse in Supp. of Pls.' Mot. For Prelim. Inj. at 17.
[48] *See* ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (Oct. 2020, *reaff'd* 2023).

treatment of ectopic pregnancy.[49] Moreover, even when FDA did require in-person dispensing prior to 2023, it never required an ultrasound (a means of diagnosing an ectopic pregnancy) before a medication abortion. Therefore, turning back the clock on the 2023 REMS does nothing to resolve any risk associated with mifepristone use during an ectopic pregnancy, a rare condition.[50] Moreover, there is no indication that ectopic pregnancies are going undetected as a result of medication abortion or non-in-person dispensing of mifepristone.[51] Instead, studies have consistently shown that medication abortion without an ultrasound is safe and effective.[52]

Plaintiffs' assertions that FDA should require in-person dispensing because medication abortion presents a heightened risk for those with Rh-negative blood types[53] are also unsupported by sound science. Clinical findings from recent studies suggest that, even for people with Rh-negative blood types, the risk of adverse events associated with medication abortion at less than twelve weeks of gestation is low.[54] Moreover, imposing systematic barriers to care for the majority of patients based on a small minority of the American population that has negative Rh-type blood[55]

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[49] MA Biggs et al., *Experiences of Ectopic Pregnancy Among People Seeking Telehealth Abortion Care*, 134 CONTRACEPT. 110405 (2024).

[50] *Ectopic Pregnancy*, Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/9687-ectopic-pregnancy (last visited Feb. 19, 2026) ("Ectopic pregnancies occur in about 2% of all pregnancies.").

[51] *See* ACOG et al., FDA Citizen Petition, at 12 (Jan. 31, 2025) ("Specifically, the rates for both serious adverse events (0.25%) and ectopic pregnancy (0.14%) were 'similar to previous studies of in person medication abortion care,' published in 2013 to 2015, which had found adverse event rates of 0.2–0.5%, and ectopic pregnancy rates of 0.2%.") (citing Ushma Upadhyay et al., *Effectiveness and safety of telehealth medication abortion in the USA*, 30 NATURE MED. 1191, 1197 (2024)).

[52] *See* Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 903 (2024); *see also* MA Biggs et al., *Experiences of Ectopic Pregnancy Among People Seeking Telehealth Abortion Care*, 134 CONTRACEPT. 110405 (2024).

[53] Compl. ¶ 40. When a pregnant person with a Rh-negative blood type is carrying a Rh-positive fetus, Rh-sensitization can occur. This refers to the production of antibodies in the blood of a Rh-negative patient that may negatively impact a fetus. Society for Maternal-Fetal Medicine et al., *Society for Maternal-Fetal Medicine Statement: RhD Immune Globulin After Spontaneous or Induced Abortion at Less than 12 Weeks of Gestation*, 230 AM. J. OBSTET. GYNECOL. B1 (2024).

[54] Society for Maternal-Fetal Medicine et al., *Society for Maternal-Fetal Medicine Statement: RhD Immune Globulin After Spontaneous or Induced Abortion at Less than 12 Weeks of Gestation*, 230 AM. J. OBSTET. GYNECOL. B1 (2024); Sarah Horvath et al., *Induced Abortion and the Risk of Rh Sensitization*, 330 JAMA 12 (2023).

[55] *Rh Factor*, Cleveland Clinic (Nov. 10, 2022), https://my.clevelandclinic.org/health/diseases/21053-rh-factor (stating that "the majority of people, about 85%, are Rh-positive" so about 15% of people have Rh-negative blood type); Laura Dean, *Blood Groups and Red Cell Antigens*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (2005); *see also* Society for

would be a disproportionate response. Indeed, Rh-negative populations are so rare and risks prior to twelve weeks of gestation are so low that expert guidelines, including those published by ACOG, no longer require routine Rh testing or the prophylactic administration of Rh D immune globulin (RhIG) for abortion or pregnancy loss at less than twelve weeks of gestation; the cost of such tests and treatments—including delay and barriers to access to abortion care—outweigh their benefits.[56] FDA already has ***expressly considered and declined*** to recommend in-person Rh-testing and RhIG administration on these same bases.[57] Of course, the 2023 REMS do not prevent Rh testing and RhIG administration where appropriate based on shared decision-making.

Speculation that removing the in-person dispensing requirement from mifepristone labeling increases risk to patients smacks of fearmongering, not facts. Removing the in-person dispensing requirement has improved patient access and, in any case, has not prevented patients from being seen in person by a clinician where they choose to do so or where the provider has any concerns regarding a particular patient.

Mifepristone has been available by mail since early in the COVID-19 pandemic. Since then, *amici*'s members have observed *no significant change* in the incidence of adverse events. The drug itself is exceptionally safe, and that remains true regardless of whether patients receive mifepristone in a doctor's office, at a pharmacy, or by mail.

Maternal-Fetal Medicine et al., *Society for Maternal-Fetal Medicine Statement: RhD Immune Globulin After Spontaneous or Induced Abortion at Less than 12 Weeks of Gestation*, 230 AM. J. OBSTET. GYNECOL. B1 (2024).

[56] Free Open Access Med. Educ., *ACOG Updates Guidance on RH Testing & Prophylaxis in Early Pregnancy Loss*, (Feb. 18, 2026), https://foamed.ebmedicine.net/general-emergency-medicine/news-updates/acog-updates-guidance-on-rh-testing-prophylaxis-in-early-pregnancy-loss/; Society for Maternal-Fetal Medicine et al., *Society for Maternal-Fetal Medicine Statement: RhD Immune Globulin After Spontaneous or Induced Abortion at Less than 12 Weeks of Gestation*, 230 AM. J. OBSTET. GYNECOL. B1 (2024); ACOG Clinical Practice Update, *Rh D Immune Globulin Administration After Abortion or Pregnancy Loss at Less Than 12 Weeks of Gestation*, 144 OBSTETRICS & GYNECOLOGY 143, 144 (2024).

[57] Letter from Patrizia A. Cavazzoni, FDA, Director, Ctr. for Drug Eval. & Res., to Donna J. Harrison, Am. Ass'n of Pro-Life Obstetricians & Gynecologists et al., 18 (Dec. 16, 2021), https://downloads.regulations.gov/FDA-2019-P-1534-0016/attachment_1.pdf.

IV. FDA's Elimination of the In-Person Dispensing Requirement Is Based on Highly Credible Data and Science.

FDA's decision to remove burdensome restrictions on mifepristone reflects increased confidence in the drug's safety and efficacy, bolstered by the availability of copious additional, confirmatory data over time. 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.[58] FDA's 2011 REMS codified the restrictions that FDA put in place upon the initial approval of mifepristone.[59]

Over the extended period of time during which the drug has been in widespread use, FDA has relaxed some of the unnecessary restrictions on mifepristone—which FDA still more extensively regulates than most drugs. For example, in 2016, FDA provided a REMS update removing some of the unnecessary restrictions on mifepristone and removing references to multiple in-person visits in the mifepristone labeling. FDA's safety analysis relied on eleven independent clinical studies conducted between 2005 and 2015, covering well "over 30,000 patients";[60] randomized controlled trials;[61] and several prospective, retrospective, and observational studies,[62] which demonstrated the safety and efficacy of mifepristone under

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[58] *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."); 2000 FDA Approval Letter, Compl. Ex. 24, ECF No. 1-24; *Development & Approval Process: Drugs*, FDA (Aug. 8, 2008), https://www.fda.gov/drugs/development-approval-process-drugs.

[59] 2011 REMS for NDA 020687 Mifeprex (mifepristone) Tablets, 200 mg, (June 2011).

[60] 2016 FDA Medical Review at 62.

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

[62] *See id.* at 6, 18, 29–31, 50, 60; *see also 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

conditions of use closely resembling the proposed new 2016 conditions.[63] In particular, the change to mifepristone labeling was based on substantial evidence—including a combination of studies on almost 2,400 subjects—demonstrating that there were multiple ways to conduct follow-up visits with patients (including remote visits) and that "it appear[ed] that no single option [wa]s superior to the others."[64] Subsequent data has continued to show that there is no medical reason for all patients who have taken mifepristone to make an in-person follow-up visit to a health center afterwards.[65]

As overwhelming evidence of mifepristone's safety continued to accumulate, in 2023, FDA made a data-informed decision to adjust the REMS and remove the in-person dispensing requirement. Plaintiffs attempt to attach meaning to the fact that FDA did not remove this requirement in 2016—a decade ago.[66] However, a wealth of data undeniably shows that—even prior to the 2023 REMS change—during periods of time that FDA did not enforce the in-person dispensing requirement (including during the COVID-19 pandemic), there was no difference in safety outcomes. "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

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that medication abortion can safely and effectively be used up to at least seventy days of gestation. *See* ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (Oct. 2020, *reaff'd* 2023).

[63] *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, 249–58 (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).

[64] 2016 FDA Medical Review at 44, 64–65 (also 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").

[65] *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").

[66] Compl. ¶ 46–48.

events to the FDA Adverse Event Reporting System ("FAERS").[67] 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."[68]

Plaintiff also twists FDA's statements regarding its assessment of scientific literature, stating the literature "did not affirmatively support" the decision to eliminate the in-person dispensing requirement.[69] FDA's actual statement was that the literature was "*not inconsistent* with [FDA's] conclusion."[70] Further, Plaintiffs conveniently gloss over FDA's further statements 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.[71] Moreover, FDA considered not just scientific literature (which was robust in itself) but also "REMS assessment data, FAERS data from the time period when the in-person dispensing requirement was not being enforced, . . . and information provided by advocacy groups, individuals, the [pharmaceutical distributors of mifepristone], and the plaintiffs in the *Chelius v. Becerra* litigation."[72] In other words, FDA's literature review was not the sole relevant consideration. It was merely one component of FDA's broader, holistic assessment of the evidence, all of which supported its 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."[73]

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[67] *FDA Ctr. For Drug Eval. & Rsch., Application No. 020687Orig1s020 Summary Review*, at 48, 61 (Jan. 3, 2023) Compl. Ex. 50, ECF No. 1-50 [hereinafter "FDA 2023 Summary Review"].
[68] *Id.* at 64.
[69] Prelim. Inj. Mem. 12–13; Compl. ¶ 12 (citing to *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 249–51 (5th Cir. 2023); Pls.' Reply Mem. in Supp. of Prelim. Inj. 16–17, ECF No. 111.
[70] FDA 2023 Summary Review at 80 (emphasis added).
[71] GenBioPro's Motion at 18; FDA 2023 Summary Review at 39.
[72] FDA 2023 Summary Review at 80.
[73] *Id.* at 20, 80.

To attempt to undermine that clear absence of new safety concerns, Plaintiffs also misleadingly point to FDA's decision to eliminate "the requirement that abortion prescribers report serious adverse events other than death to the FDA" and suggest a lack of reporting was skewing the data.[74] However, contrary to Plaintiffs' suggestions, FDA's decision on prescriber reporting was neither a calculated strategy to conceal adverse events, nor did it have that effect.

First, as Intervenor GenBioPro's Motion discusses in greater detail, FDA's decision "simply brought adverse event reporting for mifepristone closer in line with the protocol applicable to virtually all other prescription drugs."[75] The decision was based on the reasoned conclusion that after fifteen years of receiving adverse event reports, mifepristone's safety profile was "well-characterized."[76] ***Second***, prescribers are not the only source of adverse event data. All applicants of new drug applications and abbreviated new drug applications—including the sponsors of the mifepristone application, Danco Laboratories, LLC and GenBioPro, Inc.—are required by law to report serious, unexpected adverse events within fifteen days, and all others on an annual basis.[77] This requirement remains in place and is unaffected by the 2016 change in REMS reporting requirements.[78] And ***third***, Plaintiffs ignore that, to inform its 2023 REMS decision, FDA specifically requested adverse event data from those other sources during the period when in-person dispensing was not enforced (as explained above).[79]

[74] Prelim. Inj. Mem. at 11; *see also* Compl. ¶¶ 12, 48 ("[T]he 2023 REMS is arbitrary and capricious, not least because it rests on FDA's unsupported determination that mifepristone is safe—a determination based on the absence of any adverse events reported *in a system FDA already gutted*.") (emphasis in original); Pls.' Reply Mem. in Supp. of Prelim. Inj. 15–16, ECF No. 111 (saying there was "lack of adequate consideration" underlying the 2023 REMS).
[75] GenBioPro's Motion at 17; *see also* FDA 2023 Summary Review at 26–28.
[76] FDA 2023 Summary Review at 15.
[77] *See* 21 C.F.R. §§ 314.80, 314.98 (2014); 2016 FDA Medical Review at 8.
[78] 2016 FDA Medical Review at 8.
[79] FDA 2023 Summary Review at 61.

Overall, FDA regulates mifepristone more stringently than nearly any other of the 20,000 drugs it regulates.[80] Unlike the 97% of prescription drugs without a REMS, mifepristone is among the tiny fraction of medications subject to such regulation, alongside highly addictive and dangerous opioids.[81] In the face of this extensive regulation, decisions to eliminate certain restrictions and requirements—including the in-person dispensing requirement—are strongly supported by and grounded in reliable science and data.

V. 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 Court disregards FDA's evaluations of the mifepristone REMS and grants Plaintiffs' requests for relief, it will impair access to mifepristone ***nationwide***—even in states where abortion remains legal. Moreover, the relief Plaintiffs seek would also limit mifepristone access for indications other than abortion, such as miscarriage management. This far-reaching impact would endanger pregnant patients, particularly those from vulnerable populations.

Fundamentally, mifepristone is one of the safest and most effective medications used to provide abortion care or treat early pregnancy loss and is significantly safer than pregnancy itself. To date, the empirical evidence shows that patients are significantly more likely to die during childbirth than as a result of an abortion[82] and are at an increased risk of experiencing hemorrhage, infection, and injury to other organs during pregnancy and childbirth.[83] Even under the best of

[80] ACOG et al., FDA Citizen Petition, at 12 (Jan. 31, 2025).
[81] *Id.*
[82] *See* Maria W. Steenland et al., *Pregnancy- and Abortion-Related Mortality in the US, 2018–2021*, 9 JAMA NETWORK OPEN 1, 1 (2026) (analyzing national data on annual pregnancy-related and abortion-related deaths from 2018 to 2021 and concluding that "the ratio of pregnancy- to abortion-related mortality from 2018 to 2021 ranged from 44.3 to 69.6").
[83] *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) (showing that "[t]he risk of death associated with childbirth is approximately 14 times higher than that with abortion" and that the mortality rate associated with induced abortion is "0.6 deaths per 100,00 abortions").

circumstances, pregnancy and childbirth impose significant physiological changes that can exacerbate underlying conditions and severely compromise health, sometimes permanently.[84]

The dangers of pregnancy in the United States are far greater for patients of color, patients of low-income, and/or patients living in rural areas.[85] The majority of abortion 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."[86] These populations—composed of individuals who are most likely to experience severe maternal morbidity and to die from pregnancy-related complications—are disproportionately harmed by restrictions on abortion care.[87] Pregnant people of color, in particular, are also more likely to experience early pregnancy loss or miscarriage, the treatment of which can include mifepristone.[88]

Preserving access to mifepristone and expanding access to telehealth are both crucial steps to support vulnerable populations who face structural barriers to abortion care, including patients of color, patients of lower incomes, patients who are disabled, and/or patients who are living in rural areas or health care deserts.[89] Telehealth allows such patients to avoid significant costs

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[84] *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, r*eaff'd* 2023); ACOG & Soc'y for Maternal Fetal Med. Obstetric 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).

[85] *See* Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Key Issues*, KFF (Dec. 3, 2025); Centers for Medicare & Medicaid Services, *Advancing Rural Maternal Health Equity* 1 (2022).

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

[87] *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).

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

[89] *See* 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) ("[T]elehealth 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."); M. Antonia Biggs et al., *Access to Reproductive Health Services Among People With Disabilities*, 6 JAMA NETWORK OPEN 1, 10 (2023); *cf.* March of Dimes, *Nowhere to Go: Maternity Care Deserts*

associated with travel to obtain care (such as transportation, gas, and lodging), childcare expenses, and lost wages[90]—burdens that deter and delay abortion access.[91]

Telehealth also reduces delays in obtaining care because it enables patients to avoid long wait times at physical clinics[92]—a particularly urgent concern since *Dobbs v. Jackson Women's Health Organization*, as state abortion bans have increased demand for abortion care in many states where abortion remains lawful.[93] Reinstating in-person dispensing—which would lead to even more in-person visits at clinics already at maximum capacity—would increase burdens on the health care system and impede patient access through delay. This is important because timing matters: timely access to care to end a pregnancy or manage a pregnancy loss at home can meaningfully improve patient safety and well-being. Reimposing unnecessary restrictions on mifepristone will exacerbate existing inequities and pose the greatest danger to those who already have difficulty accessing essential reproductive health care.

Moreover, there is substantial evidence demonstrating that restrictions on access that result in ***denial of*** abortion care cause 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

Across the US 24 (2024) ("[D]ata from 2021 reveals that states where abortion is prohibited had fewer OB-GYNs per 10,000 births . . . compared to states where abortion rights are upheld . . . underscoring existing disparities in physician accessibility.").

[90] *See* Andréa Becker et al., *"It Was So Easy in a Situation That's So Hard": Structural Stigma and Telehealth Abortion*, 0 J. OF HEALTH & SOC. BEHAV. 1, 2, 6–7 (2025).

[91] *See Fact Sheet Abortion in the United States*, Guttmacher Inst. (April 2025), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states (stating that "[s]ome 41% of people obtaining abortions had an income below the federal poverty level (FPL) and 30% had incomes between 100% and 199% of the FPL").

[92] Andréa Becker et al., *"It Was So Easy in a Situation That's So Hard": Structural Stigma and Telehealth Abortion*, 0 J. OF HEALTH & SOC. BEHAV. 1, 6 (2025).

[93] 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").

requested abortion care.[94] Studies have repeatedly shown that being denied an abortion undermines maternal health, exacerbates the risks inherent in pregnancy itself, and worsens patients' economic hardships.[95] These effects are not isolated; many patients seeking abortion cite the "need to focus on other children," partner-related reasons, and/or financial reasons as important factors in their decisions to have an abortion.[96] Indeed, research shows that existing children of women who are denied an abortion are more likely to live in poverty and less likely to reach developmental milestones.[97]

Restricting access to mifepristone endangers ***anyone*** who is pregnant—as well as countless others who use mifepristone for conditions like hypoglycemia and for off-label, but widely accepted, uses like treating uterine fibroids, endometriosis, inducing labor, and managing miscarriage or early pregnancy loss,[98] which account for approximately 10% to 20% of known pregnancies.[99] Untreated, the miscarriage process can take two to eight weeks to resolve,

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[94] 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. OF HEALTH ECON. 1, 1, 13 (2025) (finding that that abortion restrictions significantly increased the rate of intimate partner violence among reproductive-aged women).

[95] *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. OF PUB. HEALTH 1696, 1697 (2021) .

[96] M. Antonia Biggs et al., *Understanding Why Women Seek Abortions in the US*, 13 BMC WOMEN'S HEALTH 1, 1 (2013) (noting that 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); *see generally* Rachel K. Jones, *Medicaid's Role in Alleviating Some of the Financial Burdens of Abortion: Findings from the 2021-2022 Abortion Patient Survey*, 56 PERSPS. ON SEXUAL AND REPROD. HEALTH 244, 248 (2024) (noting that 55% of those who have an abortion have given birth at least once before).

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

[98] *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.

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

exacerbating the emotional strain of pregnancy loss.[100] *Amici*'s members frequently prescribe mifepristone (often combined with misoprostol) when a patient is experiencing early pregnancy loss because it can ease the process and lead to better health outcomes.[101] 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 they do not regret their decision, suffer from emotional distress, or experience other negative mental-health outcomes as Plaintiffs suggest.[102] In fact, patients who seek and are ***able to obtain*** abortion care experience similar or better mental health outcomes than those who seek abortion care but are denied it.[103] Study after study confirms that those who receive abortion care go on to thrive and experience direct measurable benefits from having been able to access this safe and essential form of reproductive care.[104]

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[100] 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/.

[101] *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. OF GEN. INTERNAL MED. 2398, 2400 (2020).

[102] *See* Compl. ¶ 40. Plaintiffs rely on anonymous, online blog posts about abortion, on the online forum, 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." 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, 1486–87, 1492 (2021), Compl. Ex. 18, at 3–4, 9, ECF No. 1–18.

[103] *See, e.g.*, M. Antonia Biggs et al., *Women's Mental Health and Well-Being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA PSYCHIATRY 169, 177 (2017); Frank C. Worrell, *Denying Abortions Endangers Women's Mental and Physical Health*, 113 AM. J. OF PUB. HEALTH 382, 382 (2023).

[104] *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.

Protecting patients' ability to fill their mifepristone prescriptions by mail and at pharmacies helps to ensure their ability to make decisions about their bodies and their lives, regardless of their socioeconomic background and despite barriers to accessing in-person care.

CONCLUSION

For the reasons set forth above, *amici* urge this Court to deny Plaintiffs' Motion for Preliminary Relief and grant Intervenors' Motions.

Respectfully submitted,

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