No. 25A1207

IN THE
Supreme Court of the United States

DANCO LABORATORIES, LLC,
Applicant,
v.
LOUISIANA, et al.,
Respondents.

APPLICATION TO STAY THE JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT AND REQUEST FOR AN IMMEDIATE ADMINISTRATIVE STAY

BRIEF OF AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS AND OTHER MEDICAL SOCIETIES AS *AMICI CURIAE* IN SUPPORT OF APPLICATION BY DANCO LABORATORIES TO STAY THE FIFTH CIRCUIT'S STAY PENDING APPEAL

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INTEREST OF *AMICI CURIAE*[1]

The American College of Obstetricians & Gynecologists ("ACOG") represents more than 90% of board-certified obstetrician-gynecologists ("ob-gyns") in the United States. It is the nation's premier professional membership organization for ob-gyns 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.

In addition to ACOG, *amici curiae* include nineteen other leading medical societies: the American Medical Association; the Society of Family Planning; the Society for Maternal-Fetal Medicine; the American Academy of Nursing; the American Academy of Family Physicians; the American Academy of Pediatrics; the American College of Medical Genetics and Genomics; the American College of Physicians; the American College of Preventive Medicine; the American Gynecological and Obstetrical Society; the American Medical Women's Association; the American Society for Reproductive Medicine; the Council of University Chairs of Obstetrics & Gynecology; the Infectious Diseases Society for Obstetrics and

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

Gynecology; the North American Society for Pediatric and Adolescent Gynecology; the Society for Adolescent Health and Medicine; the Society of General Internal Medicine; the Society of Gynecologic Oncology; and the Society of Gynecologic Surgeons. 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 timely, complete, and unbiased health care that is medically and scientifically sound. For more than two decades, mifepristone has undergone rigorous scientific testing and has been found safe and effective when used for abortion care and miscarriage management, ***regardless of whether it is dispensed in person***.

In fact, the U.S. Food & Drug Administration's ("FDA") decision to finalize removal of the requirement that mifepristone be dispensed in person, issued as part of its 2023 Risk Evaluation and Mitigation Strategy ("2023 REMS"), was supported by the safety profile of the medication as demonstrated by the overwhelming weight of the medical evidence—including the substantial body of real-world data and

[2] *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).

scientific literature born out of the COVID-19 pandemic. This Court should stay or vacate the decision of the U.S. Court of Appeals for the Fifth Circuit, which adopts both Respondents' unfounded characterization of the medical evidence and Respondents' inaccurate narrative of legal and regulatory developments relating to mifepristone between July 2020 and January 2023.

Amici's members have safely prescribed mifepristone in the United States for more than twenty-five years, including by mail and at local pharmacies, 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 evidence-based science. *Amici* further have an interest in ensuring that the science surrounding mifepristone's safety, efficacy, and administration is correctly understood.

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, Applicants ask the Court to vacate or stay the Fifth Circuit's order staying the 2023 REMS under 5 U.S.C. § 705 and reinstating 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, including overwhelming data supporting the safety of mifepristone whether dispensed in person or not, *amici* ask this Court to grant Applicants' requests.

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 dispensed in person or not—and the risk of death is almost nonexistent.

For more than a quarter century, FDA has actively monitored and studied the safety of mifepristone. The results are clear: 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 access basic reproductive health care, including miscarriage management.

The Fifth Circuit's order endorses Respondents' 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, and the Fifth Circuit's endorsement thereof on an incomplete record, discount the medical community's consensus: that, based on two decades of overwhelming evidence, mifepristone is a safe and essential component of reproductive health care, including when dispensed by mail and at pharmacies. Based on its mistaken view of the scientific evidence, the Fifth Circuit ordered a ***nationwide*** return to mandatory, in-person dispensing of mifepristone—severely limiting access to mifepristone and denying medically appropriate and legal care to patients across the country. The in-person dispensing requirement has long been illogical on its face, because it dictates

only where a patient must be standing when handed a medication that she will take later at home or a location of her choice. In fact, in-person dispensing does not lead to a decrease in the rate of adverse events, which are uncommon, or improve the safety profile of the medication.

Turning back the clock to reimpose unnecessary restrictions on mifepristone will exacerbate existing inequities in maternal health for patients of color, low income, with disabilities, and/or 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 very core of individual autonomy and well-being. *Amici* urge this Court to reject the Fifth Circuit's order curtailing patient access ***throughout the country*** to an essential medication that FDA appropriately 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 used in reproductive care, with material benefits and vanishingly small risks. Mifepristone is used in combination with misoprostol to safely and effectively end pregnancy or manage miscarriage.[3]

[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).

Under the preferred protocol in the United States, mifepristone is administered approximately twenty-four hours before misoprostol to block progesterone, which maintains the interior of the uterus, and to soften and prepare the cervix.[4] While misoprostol alone is a safe and effective regimen for medication abortion, studies have shown that use of the two drugs together maximizes efficacy and minimizes side effects.[5]

Although medication abortion causes 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. In the context of both abortion care and early pregnancy loss, research shows that mifepristone eases the process and reduces the risks it will be prolonged or incomplete.[8]

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[4] 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).

[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 CONTRACEPT. 1, 5 (2023).

[6] Respondents have mislabeled expected effects of treatment as "complications." *Compare* Compl. ¶¶ 88, 125–26, 128, *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La. Oct. 6, 2025), ECF No. 1, *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.").

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

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

Despite Respondents' assertions to the contrary in the lower courts, mifepristone has been proven safe and effective by the overwhelming weight of scientific evidence over more than two decades of use and scientific study. Mifepristone has been studied in at least 670 published clinical trials—of which 464 were randomized controlled studies, the gold standard in research design—and discussed in more than 900 medical reviews.[9] Their findings are consistent: mifepristone is exceptionally safe and effective for abortion care and miscarriage management, and even ***minor*** complications are exceedingly rare.[10]

For example, 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.[11]

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[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, the rates of "adverse events and complications remained stable" despite proportionally increased use of medication abortion); 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.,

Other studies have found that serious infection following medication abortion is also exceptionally rare, occurring in ***only 0.015%*** of patients.[12] The risk of death is ***almost non-existent***; FDA's 2024 analysis of data examining potential mifepristone-related deaths demonstrated that the mortality rate for a mifepristone user is 0.00048%.[13] Mifepristone has a lower associated mortality rate than many common medications and devices approved by FDA. For example, mifepristone has been associated with fewer deaths than over-the-counter drugs such as Tylenol.[14] Viagra has a mortality rate of 0.004%[15]—over eight times higher than the reported mifepristone-associated mortality rate referenced above.[16] Colonoscopies have a mortality rate of 0.03%—over 62 times higher than the reported mifepristone

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). 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.* (noting that fatalities were included "regardless of causal attribution to mifepristone").

[14] 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").

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

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

mortality rate referenced above.[17] 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 Its Dispensing Method.

Mifepristone is safe, whether it is dispensed in a health care facility, by mail or through a certified pharmacy following a telehealth consultation. Since April 2021, FDA has permitted patients to fill mifepristone prescriptions at pharmacies or by mail after clinical evaluation and counselling, either via telehealth or in person at a health center. After completing the medication regimen, patients are instructed to confirm their treatment was effective with an at-home pregnancy test or blood test at a local lab. The patient is directed to seek in-person care for certain clinical indications like heavy bleeding or signs of infection. Reproductive health clinics and providers—just 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 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.[18] Patients are evaluated by a qualified health care provider—just as they would be in person. They

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

[18] *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).

are asked about symptoms and 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.[19]

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 published rates of in-person medication abortion care."[20] 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.[21] 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.[22] In a survey of 1,600 patients who received abortion care through telemedicine, "[n]early all participants were very

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[19] 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 (June 2020).

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

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

[22] *Id.* at 902–03.

satisfied with telehealth abortion."[23] 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.[24] Indeed, in-person dispensing does not lead to a decrease in the rate of adverse events or an increase in safety.

In the lower courts, Respondents attempted to obscure this reality with statistically unsupported anecdotes[25] that do not speak directly to mifepristone's overall safety, or its safety through dispensing via mail or pharmacy. These anecdotes do not provide any information about how the drug was obtained or any comparison to the number of patients who used the drug without complications. To the extent Respondents 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.[26] Reproductive health care should be treated no differently.

Speculation that remote prescribing and dispensing by mail or pharmacy increases the likelihood of serious adverse events is alarmist, not factual. Removing

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[23] 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).

[24] *Id.* at 247–248.

[25] Compl. ¶ 125, *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La. Oct. 6, 2025), ECF No. 1; 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. Unless otherwise noted, "ECF" refers to the District Court's electronic docket, *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La. 2025).

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

the in-person dispensing requirement has improved patient access while maintaining safety and has not prevented patients from seeking in-person care when they so choose, or when providers determine it is appropriate.

Mifepristone has been available by mail since early in the COVID-19 pandemic. Since then, *amici* have not observed ***any increase*** in the incidence of adverse events. The Fifth Circuit's assertion to the contrary is based entirely on a speculative increase in emergency department or urgent-care "visits" associated with dispensing of mifepristone by mail or pharmacy.[27] However, as FDA observed in discussing that very evidence, emergency department visits frequently do not involve any serious adverse event or any medical treatment ***at all***.[28] It is not uncommon for patients—especially those in rural areas—to seek reassurance or monitoring at emergency departments even in the absence of any medical complication requiring clinical intervention.[29] The Court should not endorse an approach that would allow

[27] *See Louisiana ex rel. Murrill v. FDA*, No. 26-30203, slip op. at 11 (5th Cir. May 1, 2026) (citing 2021 FDA Letter AAPLOG and Am. Coll. of Pediatricians denying in part and granting in part 2016 Citizen Petition, Docket No. FDA-2019-P-1534 (Dec. 16, 2021) Compl. Ex. 10, ECF No. 1-10 DC Dkt. No. 1-10, at 35).

[28] *See* 2021 FDA Letter AAPLOG and Am. Coll. of Pediatricians denying in part and granting in part 2016 Citizen Petition, Docket No. FDA-2019-P-1534 (Dec. 16, 2021) Compl. Ex. 10, ECF No. 1-10 DC Dkt. No. 1-10, at 32 ("half of the ED/urgent care visits did not entail any medical treatment.").

[29] *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 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).

the Fifth Circuit to override FDA's strongly supported scientific judgment with an unsupported interpretation of the medical evidence.

IV. The Fifth Circuit Materially Distorted the Regulatory Timeline of FDA's Elimination of the In-Person Dispensing Requirement.

FDA's decisions to remove burdensome restrictions on mifepristone have been grounded in copious data confirming mifepristone's safety and efficacy, including its decision to remove the in-person dispensing requirement.

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.[30]

Over the extended period 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 evidence-based practice. FDA's safety analysis relied on eleven independent clinical studies conducted between 2005 and 2015, covering well "over 30,000 patients";[31] randomized controlled trials;[32] and several prospective, retrospective, and observational

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[30] *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.

[31] 2016 FDA Medical Review at 62.

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

studies,[33] which demonstrated the safety and efficacy of mifepristone under conditions of use closely resembling the proposed new 2016 conditions.[34] Subsequent data has continued to confirm these conclusions.[35]

As overwhelming evidence of mifepristone's safety continued to accumulate, including when dispensed through mail and pharmacies, FDA made two data-informed decisions in 2021, first to suspend, and then to announce its intent to permanently lift, the in-person dispensing requirement. Respondents argued below that FDA's decision to remove the in-person dispensing mandate was a political effort to circumvent state abortion bans after *Dobbs v. Jackson Women's Health Organization* overturned *Roe v. Wade* in June 2022.[36] The Fifth Circuit endorsed

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

[34] *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").

[35] *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").

[36] *See, e.g.,* Mot. for § 705 Stay or Inj. Pending Appeal at 23, *Louisiana ex rel Murrill v. FDA*, No. 26-30202 (5th Cir. Apr. 17, 2026) (ECF No. 12-1); *see also* Reply in Supp. of Mot. for § 705 Stay or Inj.

that theory based on a single citation to an executive order generically directing federal agencies to expand access to abortion care, which was dated more than six months ***after*** FDA announced its intention to permanently modify the mifepristone REMS.[37]

The regulatory history unequivocally shows that the 2021 REMS change was based on scientific evidence and legal developments long predating *Dobbs*. For years before *Dobbs*, *amici* and other medical experts argued that FDA should lift the mifepristone REMS altogether, because FDA's unique restrictions on mifepristone reduced patient access with no safety benefit.[38] During the COVID-19 pandemic, it became clear that FDA's medically unnecessary in-person dispensing requirement was exposing patients to needless and deadly viral risks. As a result, *amici* ACOG and Council of Chairs of Obstetrics and Gynecology ("CUCOG")—whose members represent the departments of obstetrics and gynecology at nearly 150 schools of medicine across the United States—brought legal action seeking preliminary and permanent injunctive relief from the in-person dispensing requirement for the duration of the COVID-19 pandemic. *Amici* won the requested preliminary

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Pending Appeal at 2, 12, *Louisiana ex rel Murrill v. FDA*, No. 26-30202 (5th Cir. Apr. 24, 2026) (ECF No. 89).

[37] *See Louisiana ex rel. Murrill v. FDA*, No. 26-30203, slip op.at 9 (5th Cir. May 1, 2026).

[38] *See, e.g.*, *Purcell v. Kennedy*, No. 1:17-cv-00493-JAO-RT, D. Haw. (Oct. 30, 2025), at *24–*27 (discussing letters to FDA from amici and others in 2015–2016); ACOG Position Statement, *Improving Access to* Abortion (June 2018, *reaff'd* 2021); Elizabeth G. Raymond et al., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 New Eng. J, Med. 790, 793 (2017); Kelly Cleland & Nicole Smith, *Aligning Mifepristone Regulation with Evidence: Driving Policy Change Using 15 Years of Excellent Safety Data*, 92 CONTRACEPT. 179, 180 (2015).

injunction,[39] and during the six-month period when in-person dispensing was enjoined by court order, FDA observed ***no increase*** in serious adverse events.[40] Based on that real-world evidence, as well as multiple domestic and international research studies conducted during the pandemic reinforcing mifepristone's safety when dispensed by mail, in April 2021, FDA issued guidance suspending the in-person dispensing requirement for mifepristone for the duration of the public health emergency.[41] Then, in December 2021, based on additional real-world evidence and research showing no reduction in safety under the nonenforcement policy, FDA announced that it would make that REMS change permanent.[42] The *Dobbs* decision was not issued until ***over six months later***, in June 2022. Plainly, FDA's decision to remove the in-person dispensing requirement was not a political reaction to *Dobbs*—it was a confirmation of FDA's earlier 2021 nonenforcement decision,

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

[40] U.S. Food & Drug Admin., 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS (Apr. 12, 2021) Compl. Ex. 3, ECF No. 1-3.

[41] *Id.* These findings were confirmed in FDA 2023 Summary Review. *See FDA Ctr. For Drug Eval. & Rsch., Application No. 020687Orig1s020 Summary Review*, at 61 (Jan. 3, 2023) Compl. Ex. 50, ECF No. 1-50 [hereinafter "FDA 2023 Summary Review"] ("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." *Id.* at 64.

[42] U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last visited May 4, 2026).

reinforced by the wealth of new COVID-era evidence showing that in-person dispensing was not necessary to ensure safety when dispensing mifepristone.[43]

The Fifth Circuit also mischaracterized FDA's statements regarding its assessment of scientific literature, repeating an earlier inaccurate finding in *Alliance for Hippocratic Medicine v. FDA* that the literature "did not affirmatively support" the decision to eliminate the in-person dispensing requirement.[44] FDA's actual statement was that the literature was "***not inconsistent*** with [FDA's] conclusion."[45] Further, the Fifth Circuit and Respondents glossed over FDA's additional 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.[46] 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."[47] In other words, FDA's literature

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[43] Further, the Fifth Circuit's theory that "ensuring out-of-state medical providers could prescribe mifepristone to women in states that restrict abortion was a goal of the regulation", *Louisiana ex rel. Murrill v. FDA*, No. 26-30203, slip op. at 10 (5th Cir. May 1, 2026), is not only factually unsupported, but also irrelevant to the work and role of FDA.

[44] *Louisiana ex rel. Murrill v. FDA*, No. 26-30203, slip op. at 13 (5th Cir. May 1, 2026) (quoting *All. for Hippocratic Med. v. FDA,* 78 F.4th 210, 250 (5th Cir. 2023), *rev'd and remanded sub nom.*, *FDA. v. All. for Hippocratic Med.*, 602 U.S. 367 (2024)).

[45] FDA 2023 Summary Review at 80 (emphasis added).

[46] GenBioPro's Motion at 18; FDA 2023 Summary Review at 39.

[47] FDA 2023 Summary Review at 80.

review was not the sole relevant consideration. It was merely one component of FDA's holistic assessment of the evidence, 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."[48]

To undermine that clear absence of new safety concerns, the Fifth Circuit's stay decision, echoing its errors in *Alliance*, misleadingly points to FDA's decision to eliminate "the requirement to report mifepristone's adverse events" and suggests a lack of reporting was skewing the data.[49]

FDA's decision on prescriber reporting was neither a calculated strategy to conceal adverse events, nor did it have that effect. ***First***, FDA's decision aligned adverse event reporting for mifepristone with the protocol applicable to other prescription drugs. The agency's decision was based on the reasoned conclusion that after fifteen years of analyzing adverse event reports, mifepristone's safety profile was "well-characterized."[50] ***Second***, prescribers are not the only source of adverse event data. All applicants of new drug applications and abbreviated new drug applications—including mifepristone applicants Danco Laboratories, LLC and

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[48] *Id.* at 20, 80.

[49] *Louisiana ex rel. Murrill v. FDA*, No. 26-30203, slip op. at 13 (5th Cir. May 1, 2026); *see also* Compl. ¶¶ 12, 48, ECF No. 1 ("[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).

[50] FDA 2023 Summary Review at 15.

GenBioPro, Inc.—are required by law to report serious, unexpected adverse events within fifteen days, and all others on an annual basis.[51] This requirement remains in place and is unaffected by the 2016 change in REMS reporting requirements.[52] And ***third***, to inform its 2023 REMS decision, FDA specifically requested adverse event data from those other sources from the period in-person dispensing was not enforced (as explained above).[53]

The Fifth Circuit's misleading portrayal of FDA's decision-making process in 2021 to 2023 also obscures a key reality: 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.[54] Indeed, as a federal district court found in October 2025 in *Purcell v. Kennedy*, 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.[55]

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[51] *See* 21 C.F.R. §§ 314.80, 314.98 (2014); 2016 FDA Medical Review at 8. The Fifth Circuit notes this point but does not acknowledge that its reasoning would call into question FDA's reliance on the same adverse-event reporting system it uses for virtually all prescription drugs. *See Louisiana ex rel. Murrill v. FDA*, No. 26-30203, slip op. at 13 n.7 (5th Cir. May 1, 2026).

[52] 2016 FDA Medical Review at 8.

[53] FDA 2023 Summary Review at 61.

[54] 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).

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

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

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

Mifepristone is an extremely safe and effective medication for abortion care and to treat early pregnancy loss. It is markedly safer than pregnancy itself. Patients are significantly more likely to die during childbirth than as a result of an abortion[56] and are at an increased risk of experiencing hemorrhage, infection, and injury to other organs during pregnancy and childbirth.[57] Pregnancy and childbirth impose significant physiological changes that can exacerbate underlying conditions and severely compromise health, sometimes permanently.[58]

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[56] *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").

[57] *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) ("[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 100,000 abortions").

[58] *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.

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 health care deserts.[59] 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."[60] 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.[61] Pregnant people of color are also more likely to experience early pregnancy loss or miscarriage, the treatment of which can include mifepristone.[62] Telehealth allows such patients to avoid significant costs associated with travel to obtain care (such as

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).

[59] *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); 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).

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

[61] *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 Issue*s, KFF (Dec. 3, 2025).

[62] *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).

transportation, gas, and lodging), childcare expenses, and lost wages[63]—burdens that deter and delay abortion care access.[64]

Telehealth also enables patients to avoid long wait times at physical clinics[65]—a particularly urgent concern since the *Dobbs* decision, as state abortion bans have increased demand for abortion care in many states where abortion remains lawful.[66] Reinstating in-person dispensing would increase burdens on the health care system and impede patient access through delay. Timely access to care to end a pregnancy or manage a pregnancy loss 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 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

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[63] *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).

[64] *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").

[65] 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).

[66] 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.[67] Being denied abortion care undermines maternal health, exacerbates the risks inherent in pregnancy itself, and worsens patients' economic hardships.[68] In addition, existing children of women denied an abortion are more likely to live in poverty and less likely to reach developmental milestones.[69]

Restricting access to mifepristone endangers ***anyone*** who is pregnant—including patients managing miscarriage or early pregnancy loss,[70] which account for approximately 10% to 20% of known pregnancies.[71] Untreated, the miscarriage process can take two to eight weeks to resolve, exacerbating the emotional strain of pregnancy loss.[72] *Amici*'s members frequently prescribe mifepristone (often

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[67] 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).

[68] *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) .

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

[70] *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.

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

[72] 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-

combined with misoprostol) when a patient is experiencing early pregnancy loss because it can ease the process and lead to better health outcomes.[73] 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 an abortion is relief and that they do not regret their decision, suffer from emotional distress, or experience other negative mental-health outcomes.[74] 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 access.[75] Study after study confirms that those who receive abortion care experience

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and-mifepristone-as-controlled-substances-implications-for-the-management-of-non-abortion-related-conditions/.

[73] *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).

[74] *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 that relief was the most commonly felt emotion at all time points across the five-year study period and that the "overwhelming majority of women felt that the abortion was the right decision for them"). *Contra* Compl. ¶ 40, ECF No. 1. Respondents 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." 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.

[75] *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

direct measurable benefits from having been able to access this safe and essential form of reproductive care.[76]

Protecting patients' ability to fill 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 grant Applicants' requested relief.

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[76] *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.

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In the
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DANCO LABORATORIES, LLC,
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v.
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CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2026, one copy of the BRIEF FOR AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS AND OTHER MEDICAL SOCIETIES AS *AMICI CURIAE* IN SUPPORT OF APPLICATION BY DANCO LABORATORIES TO STAY THE FIFTH CIRCUIT'S STAY PENDING APPEAL in the above-captioned cases was served by electronic mail and first-class U.S. mail, postage prepaid, as required by U.S. Supreme Court Rule 29.3, to the following counsel:

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