IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL, AND ROSALIE MARKEZICH, *Plaintiffs* v. U.S. FOOD AND DRUG ADMINISTRATION, ET AL., *Defendants*	Civil Action No.: 6:25-cv-01491 Judge David C. Joseph Magistrate Judge David J. Ayo

BRIEF OF OVER 100 REPRODUCTIVE HEALTH, RIGHTS, AND JUSTICE ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PARTIES

The undersigned counsel of record certifies that *amici curiae* are unaware of any persons with any interest in the outcome of this litigation other than the signatories to this brief and their counsel, and those identified in the party and *amicus* briefs filed in this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Except as stated below, *amici curiae* certify that they have no outstanding shares or debt securities in the hands of the public, and they have no parent companies. Except as stated below, no publicly held company has a 10% or greater ownership interest in any of the *amici curiae.*

- Endora is fiscally sponsored by Aspiration Tech. No publicly traded corporation owns 10% or more of its stock.

Dated: February 20, 2026

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INTEREST OF *AMICI*[1]

Amici are over 100 reproductive health, rights, and justice organizations, as well as other organizations with a strong interest in access to reproductive care. *Amici* have seen the importance of medication abortion to individuals' health and bodily autonomy, as well as mifepristone's efficacy and safety as a tool for achieving those goals. *Amici* have a unique window into the benefits mifepristone provides—including when prescribed via telehealth—and the immense challenges that would result if Plaintiffs obtain the relief they seek. *Amici* include, *inter alia*, healthcare organizations that provide mifepristone and would be directly impacted by an order reinstating the Food and Drug Administration's ("FDA") in-person dispensing requirement; research organizations with specialized expertise in the safety of mifepristone and the harms caused by abortion restrictions; organizations that work directly with people seeking abortion care and witness firsthand the enormous challenges they face when forced to travel for care; and organizations that advocate on behalf of people who need abortions and the clinicians who care for them. A complete list of *amici* can be found in the Appendix.

[1] *Amici curiae* certify that this brief was authored entirely by counsel for *amici* and not by counsel for any party, in whole or part; no party or counsel for any party contributed money to fund preparing or submitting this brief; and apart from *amici* and their counsel, no other person contributed money to fund preparing or submitting this brief. A motion for leave to file accompanies this brief. This brief is filed with the consent of all parties. *See* ECF No. 39.

SUMMARY OF ARGUMENT

Plaintiffs ask this Court to stay or enjoin the FDA's 2023 Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, which permanently removed the in-person dispensing requirement, permitting dispensing by mail and through certified pharmacies.[2] In seeking this extraordinary relief, Plaintiffs rely on discredited data, methodologically flawed studies, and isolated anecdotes in an effort to have this Court impose scientifically unfounded nationwide restrictions on an essential medication that has been safely used by more than 7.5 million people in the United States over more than twenty-five years. The Court should reject Plaintiffs' request.

Amici write to emphasize the overwhelming consensus of the scientific and medical community that medication abortion using mifepristone—including when prescribed via telehealth—is safe, effective, and medically necessary. The evidence confirming mifepristone's safety and efficacy has only grown more compelling since the FDA first approved it in 2000, as hundreds of high-quality studies and the experience of millions of patients have confirmed mifepristone's exceptional safety record—whether dispensed in-person or through telehealth. In seeking to enjoin the 2023 REMS, Plaintiffs rely on the same purported expert analyses and debunked studies that already have been rejected by other federal courts and the broader

[2] *See* Complaint, ECF No. 1; Pls.' Mot. for Prelim. Relief Under 5 U.S.C. § 705, ECF No. 20.

scientific community. This Court likewise should reject Plaintiffs' claims as lacking any scientific basis.

Amici also write to explain what is at stake. Granting Plaintiffs' motion would impose devastating and medically unjustified burdens on patients' access to mifepristone. Preserving patients' ability to obtain care through telehealth is critically important, particularly for people in rural areas, low-income communities, communities of color, and for survivors of intimate partner violence, who already face the steepest barriers to in-person care. If this Court reinstates the in-person dispensing requirement, it will undermine access to abortion and miscarriage care—and patients' health and autonomy—nationwide. Even people in states where abortion remains legally protected could find themselves unable to obtain mifepristone in a timely fashion, or unable to access this essential medication at all, if the court grants Plaintiffs' requested relief. Neither science nor law supports this result, and this Court should deny Plaintiffs' motion.

ARGUMENT

I. MIFEPRISTONE DISPENSED VIA TELEHEALTH IS SAFE, EFFECTIVE, AND WIDELY USED.

Mifepristone is one of two medications (along with misoprostol) in the FDA-approved regimen for medication abortion.[3] Decades of scientific evidence and real-

[3] While there are alternative regimens used for medication abortion, existing research suggests that they may be less effective and lead to more side effects than the combined regimen. *See* Elizabeth Raymond et al., *Effectiveness and Safety of Misoprostol-Only for First-Trimester*

world use by millions demonstrate that using mifepristone for medication abortion is exceptionally safe and effective, including when dispensed via telehealth. Indeed, mifepristone's safety is endorsed by, and restrictions on telehealth access to mifepristone are overwhelmingly opposed by, major medical associations such as the American Medical Association, American College of Obstetricians and Gynecologists, American Academy of Pediatrics, Society for Academic Specialists in General Obstetrics and Gynecology, Society of Family Planning, Society for Maternal-Fetal Medicine, and Society of General Internal Medicine.[4] Consistent with this scientific consensus, the FDA has repeatedly affirmed mifepristone's exceptional safety and efficacy record.[5] Plaintiffs' challenge to telehealth access does not rest on legitimate scientific evidence, but instead relies on discredited articles plagued by fundamental methodological flaws. The Court should credit the

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Medication Abortion: An Updated Systematic Review and Meta-Analysis, 127 Contraception 110 (2023); Soc'y of Family Planning, *Science Says: Misoprostol Only Is Safe and Effective* 1 (updated Aug. 21, 2023), https://societyfp.org/wp-content/uploads/2023/02/SFP_ScienceSays_misoprostol.pdf.

[4] *See* Am. Coll. of Obstetricians & Gynecologists et al., *Leading Medical Organizations Call for the FDA to Permanently Remove Restrictions on Mifepristone* (June 18, 2024), https://www.acog.org/news/news-releases/2024/06/leading-medical-organizations-call-for-fda-to-permanently-remove-restrictions-on-mifepristone.

[5] *See Study: FDA Regulation of Abortion Drug Mifepristone from 2011 to 2023 Shaped by Evidence and Caution*, Johns Hopkins Bloomberg Sch. Pub. Health (Jan. 12, 2026), https://publichealth.jhu.edu/2026/study-fda-regulation-of-abortion-drug-mifepristone-from-2011-to-2023-shaped-by-evidence-and-caution; FDA Ctr. for Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 5, 14-17 (Mar. 29, 2016) ("2016 FDA Approval"), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

decades of scientific research and FDA analysis of mifepristone's safety over a handful of profoundly biased publications.

A. Mifepristone Remains Safe and Effective When Dispensed Via Telehealth.

Mifepristone is central to reproductive healthcare today. Medication abortion is the most common method of abortion in the United States, both because of its safety and efficacy and because many patients prefer it.[6] Medication abortion is approved in more than 100 countries and accounts for half of all abortions in most high-income nations.[7] In 2023, mifepristone was used in 63% of all abortions in the United States.[8]

The FDA approved mifepristone in 2000 after a thorough, nearly five-year scientific review determined it was safe for widespread use. *Hundreds* of high-quality studies conducted since that initial approval confirm mifepristone's safety. Indeed, mifepristone has been part of over 600 published clinical trials and discussed in over 900 medical reviews.[9] Mifepristone has an exceedingly low rate of serious

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[6] *See generally, e.g.*, M. Antonia Biggs et al., *A Cross-Sectional Survey of U.S. Abortion Patients' Interest in Obtaining Medication Abortion Over the Counter*, 109 Contraception 25 (2022); 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 (2024).

[7] *Mifepristone Approved List*, Gynuity Health Projects (updated May 2024), https://gynuity.org/assets/resources/mife_by_country_and_year_en.pdf.

[8] *See* Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020*, Guttmacher Inst. (Mar. 2024), https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.

[9] Based on a review of publications on PubMed.

adverse events.[10] The National Academies of Sciences, Engineering, and Medicine ("National Academies"), a highly respected nonpartisan advisory institution, concluded that the risks of medication abortion involving mifepristone are "similar in magnitude to the reported risks of serious adverse effects of commonly used prescription and over-the-counter medications."[11] Beyond medication abortion, mifepristone is regularly prescribed for the management and treatment of miscarriages, which can be life-threatening without adequate treatment.[12]

In 2016, the FDA made several changes to mifepristone's REMS and labeling to align with evolutions in evidence-based practice. This change allowed for prescription by a broader set of qualified healthcare providers and modified the conditions of use in the labeling to reflect use at a wider range of gestational durations and to remove references to multiple in-person clinic visits, consistent with the standard of care. In support of its decision, the FDA relied on updated data, including more than eighty high-quality studies analyzing outcomes for hundreds of

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[10] 2016 FDA Approval, *supra* note 5, at 14-17; Ushma Upadhyay et al., *Effectiveness and safety of telehealth medication abortion in the USA*, 30 Nature Med. 1191, 1197 (2024) [hereinafter *Effectiveness and Safety of TMAB*].

[11] Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States* 45, 56-68, 79 (2018).

[12] *See, e.g.*, Elise W. Boos et al., *Trends in the Use of Mifepristone for Medical Management of Early Pregnancy Loss From 2016 to 2020*, 330 JAMA 766 (2023), https://jamanetwork.com/journals/jama/fullarticle/2807775; Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Eng. J. Med. 2161 (2018); Justin J. Chu, et al., *Mifepristone and Misoprostol Versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso): A Randomised, Double-Blind, Placebo-Controlled Trial*, 396 Lancet 770 (2020).

thousands of patients, as well as years of real-world evidence underscoring mifepristone's safety without these impediments.[13] The FDA's 2016 decision cited a host of studies showing that the rate of major adverse events was roughly 0.3%.[14] Recent peer-reviewed research confirms that serious complications among mifepristone users remain extremely rare, and FDA data from more than twenty-five years of mandatory reporting show that the risk of death associated with mifepristone use remains infinitesimally low (less than forty recorded deaths even possibly related to mifepristone since its approval in 2000, or 0.00048%).[15]

Given its exceptional safety record, leading medical associations have long called on the FDA to lift medically unnecessary restrictions on mifepristone, including its in-person dispensing requirement.[16] After extensive review of real-world data and peer-reviewed studies, the FDA found in 2021 that mifepristone would "remain safe and effective for medication abortion if the in-person dispensing requirement is removed."[17] In 2023, the FDA permanently removed this

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[13] 2016 FDA Approval, *supra* note 5.

[14] *Id.* at 56.

[15] U.S. Food & Drug Admin., NDA 020687 & ANDA 091178, *Mifepristone U.S. Post-Marketing Adverse Events Study through 12/31/2024* (2025), https://www.fda.gov/media/185245/download. Not one of the infinitesimally small number of deaths can be causally attributed to mifepristone. *See* Am. Coll. of Obstetricians & Gynecologists, *Citizen Petition* (Oct. 4, 2022), https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf.

[16] Am. Coll. of Obstetricians & Gynecologists et al., *supra* note 4; Stipulation as to Facts, Purcell v. Kennedy, No. 1:17-cv-00493 (D. Haw. Nov. 27, 2019), ECF 85-4, 85-5, 85-6.

[17] U.S. Food & Drug Admin., REMS Modification Rationale Review, NDA 020687 & 91178, at 39 (Dec. 16, 2021).

requirement. Removal of the in-person dispensing requirement meaningfully increased access to mifepristone without compromising the safety or efficacy of this important medication.[18]

Telehealth, which is an increasingly common method of healthcare delivery in general, is now a standard method of care for medication abortion, both in the United States and around the world.[19] Unlike FDA's in-person dispensing requirement, which forced every patient to travel to a health center to pick up their mifepristone prescription even when there was no clinical reason for doing so, telehealth care is individually tailored to each patient's circumstances, with in-person testing or examination ordered when appropriate based on individualized

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[18] Despite this safety record, the FDA continues to unnecessarily restrict mifepristone more stringently than other drugs with similar risks. Am. Coll. of Obstetricians & Gynecologists et al., *supra* note 4; Daniel Grossman & Erica Chung, *Evidence Supports Removing Restrictions on Mifepristone*, JAMA (June 12, 2025), https://jamanetwork.com/journals/jama/article-abstract/2835287 (discussing the REMS modifications for flibanserin and PrEP regimens, reproductive health medications with similar or higher risks and incidence of adverse events). Indeed, a federal court recently found that the FDA has not justified its overly restrictive regulation of mifepristone compared to other prescription drugs under the governing statute. *See Purcell v. Kennedy*, No. CV 17-00493 JAO-RT, 2025 WL 3101785, at *2, *18 (D. Haw. Oct. 30, 2025) (citing Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57 (2022)); *see also* Reshma Ramachandran & Christopher J. Morten, *Politics, Science, and the Future of FDA Drug Regulation: FDA's Review of Mifepristone REMS as a Litmus Test*, JAMA (Jan. 12, 2026), https://jamanetwork.com/journals/jama/fullarticle/2843714 (describing HHS's and FDA's ongoing review of the mifepristone Risk Evaluation and Mitigation Strategy to determine whether modifications are necessary).

[19] Am. Coll. Obstetricians & Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, Practice Bulletin No. 225, at 35 (Oct. 2020, reaff'd 2023), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation; World Health Organization, *Abortion Care Guideline*, at 95 (Mar. 8, 2022), https://www.who.int/publications/i/item/9789240039483.

patient screening. Rigorous studies from the past several years resoundingly reinforce that patients can be screened and counseled for medication abortion via telehealth as safely and effectively as in-person screening and dispensing.[20] For instance, a study of over 6,000 telehealth patients demonstrated that telehealth-prescribed medication abortion provides statistically equivalent safe and effective results as in-person care.[21] Other studies and reviews have reached the same conclusion, further supporting that access to mifepristone via telehealth provides necessary care with the same safety levels and effective outcomes.[22]

B. Plaintiffs' Claims About Mifepristone's Risks Lack Scientific Support.

Plaintiffs' assertion that mifepristone is not safe ignores the millions of safe outcomes for people across the country that have used mifepristone since its

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[20] *See, e.g.*, Daniel Grossman et al., *Medication Abortion With Pharmacist Dispensing of Mifepristone* 137 Obstetrics & Gynecology 613 (2021); Ushma Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA INTERNAL MED. 482 (2022); Leah R. Koenig et al., *Effectiveness and Safety of Medication Abortion With vs Without Screening Ultrasonography or Pelvic Examination*, 233 Am. J. Obstetrics & Gynecology 453e1 (2025); Silpa Srinivasulu et al., *Telehealth Medication Abortion in Primary Care: A Comparison to Usual in-Clinic Care*, 37 J. Am. Bd. Fam. Med. 295 (2024); Ushma Upadhyay et al., *Effectiveness and Safety of TMAB*, *supra* note 10.

[21] Ushma Upadhyay et al., *Effectiveness and Safety of TMAB*, *supra* note 10.

[22] *See, e.g.*, Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 903 (2024); Holly A. Anger & Elizabeth G. Raymond, *Clinical and Service Delivery Outcomes Following Medication Abortion Provided With or Without Pretreatment Ultrasound or Pelvic Examination: An Updated Comparative Analysis*, 140 Contraception 1 (2024); *see also* Amanda Cleeve et al., *The Use of Telemedicine Services for Medical Abortion*, 6 Cochrane Database Syst. Rev. CD013764 (2025), (finding that "the use of telemedicine for medical abortion in early pregnancy is generally safe, effective, and acceptable;" noting that the review's findings were "consistent with the conclusions of previous work on the topic;" and reaffirming that "serious adverse events are rare").

approval in 2000; the FDA's conclusion, after thorough review of the scientific evidence, that medication abortion with mifepristone remains safe and effective whether dispensed by mail, at pharmacies, or at health centers; and the decades of reputable scientific evidence and analysis that reinforce the FDA's findings.[23] Rather than engage with the overwhelming body of evidence confirming mifepristone's exceptional safety and efficacy, including in the telehealth context, Plaintiffs rely on a smattering of deeply biased publications that have been widely discredited by the scientific community due to their grave methodological flaws.[24]

For example, several of the publications relied on by Plaintiffs mistakenly classify emergency room visits as serious adverse events. As recognized by the FDA,[25] an emergency room visit alone is not an adverse outcome. Indeed, as the FDA acknowledged in its 2021 REMS review,[26] many emergency room visits after a medication abortion involve no treatment at all; patients may seek care in the emergency room after a medication abortion to ask questions, to ensure their symptoms are normal, or to confirm that they are no longer pregnant, especially if

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[23] Ushma Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, 16 BMC MED. 1, 7-10 (2018); 2016 FDA Approval, *supra* note 5; Am. Coll. of Obstetricians & Gynecologists, *supra* note 15.

[24] UCLA Center of Reproductive Health, Law, and Policy, *Comment on Citizen Petition* (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.

[25] U.S. Food and Drug Admin., *What is a Serious Adverse Event?*, https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event (last visited Feb. 18, 2026).

[26] *See* Complaint, ECF No. 1-51 at 29 (FDA 2021 REMS Modification Review).

the emergency department is closer than the nearest abortion provider or they do not have easy access to an abortion provider.[27] And accessibility was a particular challenge in the time period analyzed by several of Plaintiffs' citations, when the COVID-19 pandemic made it more difficult to receive care from primary care physicians in general.[28] Conflating emergency room visits with serious adverse events is a major methodological flaw, and in fact contributed to the 2024 retraction of a study relied on by abortion opponents to try to distort mifepristone's safety record.[29]

Among other errors, Plaintiffs and their cited publications also mistakenly classify instances where patients receive a simple and safe follow-up procedure to complete the abortion as a "serious adverse event," notwithstanding that this is an expected outcome for a small percentage of users and an example of the treatment being ineffective rather than unsafe.[30] And Plaintiffs draw unfounded causal links

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[27] UCLA Center of Reproductive Health, Law, and Policy, *supra* note 24; Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175 (2015).

[28] G. Caleb Alexander et al., *Use and Content of Primary Care Office-Based vs Telemedicine Care Visits During the COVID-19 Pandemic in the US*, 3 JAMA Network Open e2021476 (2020).

[29] Rachel K. Jones & Kelly Baden, *Why a Flawed Study on Medication Abortion was Retracted*, The Hill (Feb. 23, 2024), https://thehill.com/opinion/healthcare/4484239-why-a-flawed-study-on-medication-abortion-was-retracted.

[30] UCLA Center of Reproductive Health, Law, and Policy, *supra* note 24, at 15–16. Treatment to complete the abortion is not a serious adverse event, as it is part of standard medical practice for the 3-5% of medication abortions that require follow-up care. Elizabeth G. Raymond et al, *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 Contraception 26, 30 (2013).

between mifepristone and infection risks, even though, as the FDA has recognized, infection is a risk whenever the pregnant uterus is emptied, whether via "miscarriage, [procedural] abortion, medical abortion, or childbirth."[31] There is no evidence that these rare complications are caused by mifepristone; in fact, according to the FDA, "the physiology of pregnancy may be a more plausible risk factor" than mifepristone for certain rare serious infections after use.[32] And Plaintiffs present no evidence at all that access to mifepristone via telehealth increases these overstated risks.

In seeking to enjoin telehealth access to mifepristone, Plaintiffs rely on a self-published paper by the Ethics & Public Policy Center ("EPPC") that was not peer-reviewed, and that lacks transparency about both the database and definitions it uses in contravention of established scientific standards. The EPPC paper artificially increases the rate of serious adverse events by classifying emergency room visits and routine follow-up care to complete the abortion as serious adverse events, which is contrary to accepted scientific practice, as discussed above.[33] Among other flaws, the paper also wrongly conflates mifepristone prescription with abortion, which does not account for the widespread use of mifepristone to treat early pregnancy loss and

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[31] U.S. FDA, *Mifeprex Prescribing Information* 15-16 (Mar. 2016).

[32] Janet Woodcock, M.D., Director, Ctr. for Drug Eval. & Res., U.S. Dep't of Health & Hum. Servs., to Donna Harrison, M.D., et al., Denying Citizen Petition Asking the FDA to Revoke Approval of Mifeprex 25-26 n.69 (Mar. 29, 2016).

[33] U.S. Food & Drug Admin., *supra* note 25.

for other obstetric care.[34] It also implies unfounded causal links between mifepristone and unrelated adverse events, such as ectopic pregnancies or pulmonary episodes.[35] Moreover, even on its own terms, the paper's analysis does nothing to support the Plaintiffs' argument that stripping telehealth access to mifepristone would improve outcomes because the insurance claims data that EPPC reviewed does not reflect whether the mifepristone was dispensed in-person or remotely. The authors' last-ditch effort to overcome this disconnect in a short "FAQ" webpage updated just days before their amicus brief was filed only underscores the sloppiness of their reasoning.[36] EPPC purports to draw safety conclusions circumstantially by comparing findings before and after July 2020, when the FDA's in-person dispensing requirement was first paused.[37] But they are forced to admit that they do not know the percentage of medication abortions provided remotely after July 2020 and, in fact, that telehealth comprised only a small fraction of medication abortion care until the very last months of their dataset, which ended in December 2023.[38] And they do not even attempt to grapple with critical confounding variables—such as the global pandemic that coincided with the elimination of

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[34] Elise W. Boos, *supra* note 12.

[35] UCLA Center of Reproductive Health, Law, and Policy, *supra* note 24.

[36] *See* Hall & Anderson, Frequently Asked Questions About the Largest Study on Chemical Abortion, Resp. 9 (updated Feb. 9, 2026), https://eppc.org/publication/frequently-asked-questions-about-the-largest-study-on-chemical-abortion/.

[37] *See id.*

[38] *See id.*

FDA's in-person dispensing requirement—that dramatically reduced healthcare access and generally increased morbidity and mortality.[39] In short, this back-of-the envelope calculation is as flimsy as the rest of EPPC's paper, particularly when contrasted with the wealth of peer-reviewed, statistically-powered studies that directly examine the safety of care provided through telehealth and confirm that serious adverse events remain exceptionally low.[40]

These concerning misrepresentations and deep methodological flaws make the paper wholly unreliable. It would be error for this Court to credit the EPPC paper to grant Plaintiffs the relief they seek, particularly since Plaintiffs' own expert, Dr. Christina Francis, has admitted that it is "not a study in the traditional sense" and "not conclusive proof of anything."[41] The other publications on which Plaintiffs rely contain similarly glaring methodological flaws.[42]

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[39] *See, e.g.*, Jose Villar et al., *Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection*, 175 JAMA Pediatrics 817 (2021).

[40] *See* sources cited *supra* notes 18-23.

[41] Alice Miranda Ollstein, '*Rolling Thunder': Inside Conservatives' Strategy to Curb Abortion Pill Access*, Politico (May 7, 2025), https://www.politico.com/news/2025/05/07/anti-abortion-pill-gameplan-rolling-thunder-00331933.

[42] *See, e.g.*, UCLA Center of Reproductive Health, Law, and Policy, *supra* note 24, at 19-23 (identifying methodological flaws in J. Studnicki et al., *Determining the Period Prevalence and Acuity of Emergency Department Visits Following Induced Abortion Mistakenly Identified as Spontaneous Abortion: An Analytic Observational Prospective Cohort Study,* Family Medicine and Primary Care: Open Access 9 (282) (2025)); Brief of Amici Curiae American Civil Liberties Union, Center for Reproductive Rights, and Lawyering Project in Support of Petitioners, *U.S. Food & Drug Administration v. Alliance for Hippocratic Medicine* and *Danco Laboratories, L.L.C. v. Alliance for Hippocratic Medicine*, Nos. 23-235, 23-236 (filed Jan. 30, 2024).

II. REMOVING TELEHEALTH ACCESS TO MIFEPRISTONE WILL ENDANGER MANY COMMUNITIES' HEALTH AND AUTONOMY.

If this Court grants Plaintiffs' motion and enjoins the prescription of mifepristone through telehealth, it would result in immediate and irreparable harm across the country. Telehealth is critical for access to medication abortion, particularly for certain populations that are especially vulnerable and often most in need of access to medication abortion for their health and autonomy. Restricting access to medication abortion via telehealth will undermine public health.

A. Telehealth Provides Essential Access to Abortion Care.

Telehealth is indispensable to legal abortion care. Medication abortion now accounts for 63% of all abortions in the United States, and more than one in four abortions is obtained via telehealth services.[43] In certain states, the reliance on telehealth is even more pronounced. For example, 40% of abortions in Delaware and 34% of abortions in Nevada were obtained through telehealth in 2024.[44] Telehealth is not a peripheral convenience but is in fact essential for many patients to access the care they need. Disrupting this key component of the nation's abortion care infrastructure would reduce access for vulnerable populations across the country.

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[43] Jones & Friedrich-Karnik, *supra* note 8; Soc'y of Family Planning, *#WeCount Report, April 2022 to December 2024* (June 23, 2025), https://societyfp.org/research/wecount/wecount-december-2024-data/.

[44] Soc'y of Family Planning, *#WeCount Report, April 2022 to December 2024*, *supra* note 43.

Telehealth has been particularly essential for meeting dramatically increased demand in states that still protect abortion access in the wake of the Supreme Court's decision in *Dobbs*.[45] Abortion bans have placed extraordinary strain on the remaining providers in states that support abortion access, who face an influx of appointments from patients forced to travel across state lines for care. Telehealth enables providers in those states with access to care to absorb this surge in patients even without a proportional increase in brick-and-mortar clinics, and helps mitigate long appointment wait times that would otherwise delay care.[46] Indeed, because of telehealth, some states that share a border with one or more states where abortion is banned have been able to absorb the additional patients with little or no increase in the number of physical clinic locations between 2020 and March 2024.[47]

Even setting aside the increased demand from out-of-state patients traveling for care, telehealth is crucial in states with protected abortion access to overcome the significant geographic barriers that can make it difficult to serve residents in need of medical care. The average American now lives 86 or more miles from an abortion provider, making in-person access to time-sensitive care logistically difficult or

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[45] 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 e45671 (2023).
[46] 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.
[47] *Id.*

impossible for many patients.[48] Telehealth plays a key role in promoting equitable access by reaching patients who might otherwise be unable to travel to a clinic in time to access care.[49] And mounting concerns around a national shortage of obstetrician-gynecologists and rising rates of maternal-healthcare-deserts further emphasize the importance of telehealth as a means of ensuring that patients can access reproductive healthcare when and where they need it.[50]

B. Eliminating Mifepristone Dispensing Via Telehealth Will Impact Already Vulnerable Communities the Most.

Telehealth is especially crucial to protect abortion access for particularly vulnerable communities, including people living in poverty, people living in rural areas, people subject to intimate partner violence, and people of color. If mifepristone can no longer be distributed via telehealth, people in these already marginalized groups are the most likely to suffer.

Abortion patients are disproportionately poor: nearly half of all abortion patients live below the federal poverty line.[51] When abortion restrictions prevent

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[48] Selena Simmons-Duffin & Shelly Cheng, *How Many Miles Do You Have to Travel to Get Abortion Care? One Professor Maps It*, NPR (June 21, 2023), https://www.npr.org/sections/health-shots/2023/06/21/1183248911/abortion-access-distance-to-care-travel-miles#:~:text=Just%20a%20year%20ago%2C%20%22less,large%20cities%20in%20the%20South.

[49] 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 e45671 (2023).

[50] Katherine J. Kramer et al., *Trends and Evolution in Women's Health Workforce in the First Quarter of the 21st Century*, 5 World J. Gynecology & Women's Health 622 (2022), https://pubmed.ncbi.nlm.nih.gov/35601601/.

[51] Liza Fuentes, *Inequity in US Abortion Rights and Access: The End of Roe Is Deepening Existing Divides*, Guttmacher Inst. (Jan. 2023).

patients from being able to access the care they seek, a variety of harms ensues. For patients living in or near poverty, being denied an abortion deepens the very economic hardship that already constrains their access to care. Women denied abortions are nearly four times more likely to be living in poverty six months after being denied care than women who were able to access abortions.[52] They also have more than three times greater odds of being unemployed and are more likely to be enrolled in public safety net programs than woman who were able to access abortion.[53] Being denied an abortion also increases women's debt and negative public financial records, including bankruptcies and evictions.[54]

Telehealth is uniquely positioned to prevent these outcomes because it directly addresses many of the barriers to healthcare that poverty creates. Nearly 20% of abortion patients report postponing purchasing food to cover costs associated with their abortion—costs that include not only the cost of the abortion itself but transportation, missed wages, and childcare.[55] Households below 200% of the federal poverty line are far more likely to lack vehicle access (19%), making travel

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[52] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 112 Am. J. Pub. Health 1290 (2022).
[53] *Id.*
[54] Sarah Miller, Laura R. Wherry & Diana Greene Foster, *The Economic Consequences of Being Denied an Abortion*, 15 Am. Econ. J.: Econ. Pol'y 394 (2023).
[55] Samuel Dickman et al., *Financial Hardships Caused by Out-of-Pocket Abortion Costs in Texas, 2018*, 112 Am. J. Pub. Health 758, 759 (2022).

to a clinic logistically impossible for many.[56] Telehealth eliminates or reduces these secondary costs by allowing patients to seek care without traveling, missing work, or securing childcare.[57] Research confirms that telehealth reduces missed appointments and improves continuity of care—outcomes that are particularly vital for working-class and low-income patients whose access to paid leave, reliable transportation, and flexible schedules is limited.[58]

Restricting telehealth would also disproportionately harm rural and geographically isolated communities. More than one-third of women of reproductive age live more than an hour away from their nearest abortion facility.[59] Research confirms the concrete consequences of these distance barriers: an increase in travel distance from 0–50 miles to 50–100 miles has been found to reduce abortion rates by 16%.[60] And telehealth is particularly vital for Indigenous communities, who face

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[56] *See* Comment of The Boston University School of Law's Program on Reproductive Justice (BUPRJ), Immigrants' Rights and Human Trafficking Program (IRHTP), and the Racial Justice and Movement Lawyering Clinic (RJMLC) on FDA-2025-P-3287-0001, at 9 (Oct. 11, 2025), https://www.regulations.gov/comment/FDA-2025-P-3287-0060.

[57] *See id.* at 8.

[58] *Id.*

[59] Benjamin Rader et al., *Estimated Travel Time and Spatial Access to Abortion Facilities in the US Before and After the* Dobbs v. Jackson Women's Health *Decision*, 328 JAMA 2041 (Nov. 1, 2022), https://jamanetwork.com/journals/jama/fullarticle/2798215?guestAccessKey=70c1bc40-5cc0-4bcf-a73d-a5b9b26ccf01&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=110122.

[60] Jason M. Lindo et al., *How Far Is Too Far?: New Evidence on Abortion Clinic Closures, Access, and Abortions*, 55 J. Hum. Res. 1137 (2020).

severe barriers due to federal law restrictions on Indian Health Service facilities and geographic isolation on Tribal lands.[61]

Congress expressly limited the FDA's authority to impose REMS restrictions that result in these kinds of harms. The REMS statute requires that FDA-imposed restrictions on approved drugs shall "not be unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing healthcare (such as patients in rural or medically underserved areas)."[62] A court order mandating that every mifepristone patient in the country travel in-person to a hospital, clinic, or medical office to be handed their prescription would impose exactly this kind of burden on patients.

While Plaintiffs claim that restricting access to mifepristone helps survivors,[63] the evidence overwhelmingly demonstrates the opposite: cutting off telehealth access to mifepristone will place survivors of intimate partner violence at much higher risk. Nearly half of women in the United States have been affected by intimate partner violence, and women of color, women living in rural areas, women in poverty, and noncitizens are disproportionately impacted.[64] Abusers routinely exert

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[61] Lauren Van Schilfgaarde et al., *Tribal Nations and Abortion Access: A Path Forward*, 46 Harv. J.L. & Gender 1 (2023).

[62] 21 U.S.C. § 355-1(f)(2)(C).

[63] *See* Compl. ¶¶ 150–158, *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La. Oct. 6, 2025), ECF No. 1.

[64] M.C. Black et al., *National Intimate Partner and Sexual Violence Survey: 2010 Summary Report*, Ctr. for Disease Control & Prevention 48 (2011).

coercive control over survivors' reproductive choices, including through birth control sabotage and forced pregnancies. Research from the Center for Disease Control ("CDC") shows that nearly 10.3 million women have experienced a partner trying to force pregnancy or refusing to use contraception, and survivors of intimate partner violence are nearly three times more likely to conceal an abortion from their partners due to safety concerns.[65] For these survivors, the ability to access abortion care discreetly and without an abuser's knowledge is a lifeline.

Telehealth serves that function precisely because it offers survivors privacy, autonomy, and a way to access care that can escape an abuser's surveillance. Restricting telehealth access to mifepristone would force survivors to navigate the very barriers that abusers exploit: the need to travel to a clinic, arrange childcare, take time off work, and explain absences to a controlling partner. Research has found that the privacy afforded by telehealth may better facilitate patients' disclosure of coercion, enabling survivors to speak more openly with providers about their experiences in settings where an abusive partner is less likely to monitor or control the interaction.[66] As advocates have warned, restricting access to mifepristone will cause particularly grave harm to survivors of intimate partner violence by limiting

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[65] Yvonne Lindgren, *The Doctor Requirement: Griswold, Privacy, and At-Home Reproductive Care*, 32 Const. Comment. 341, 373 (2017).

[66] Elizabeth C. Romanis et al., *Safeguarding and Teleconsultation for Abortion*, 398 Lancet 555, 556 (2021).

their ability to access abortion care, thus increasing their risk of health complications, violence, and homicide.[67] These harms fall hardest on survivors in marginalized communities who already face the steepest barriers to in-person care.

Along with the myriad harms discussed above, restricting telehealth access to mifepristone would disproportionately harm Black, Brown, and immigrant communities who already face greater barriers to accessing healthcare, including abortion. Black and Brown women account for a majority of those seeking abortion care.[68] Factors such as time, travel, and the general costs associated with accessing abortion care already prohibit many women of color from accessing mifepristone in a timely manner.[69] Telehealth addresses many of these barriers by eliminating the need for long-distance travel and reducing the secondary costs—missed wages, childcare, transportation—that fall most heavily on communities of color.

The same is true for immigrant communities. Immigrants are generally less likely to drive than their native-born counterparts, making travel to in-person appointments particularly difficult.[70] And telehealth addresses not only logistical

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[67] *See* Comment of Legal Voice et al. on FDA-2025-P-3287 (Nov. 27, 2025), https://www.regulations.gov/comment/FDA-2025-P-3287-0068.

[68] Jillian McKoy, *Travel Times to Abortion Facilities Have Increased Drastically in Post-*Roe *Era*, Bos. Univ. Sch. of Pub. Health (Nov. 23, 2022).

[69] Ushma D. Upadhyay et al., *Sociodemographic Characteristics of Women Able to Obtain Medication Abortion Before and After Ohio's Law Requiring Use of the Food and Drug Administration Protocol*, 2 Health Equity 122 (2018).

[70] Alexa Delbosc & Rahman Shafi, *What Do We Know About Immigrants' Travel Behaviour? A Systematic Literature Review and Proposed Conceptual Framework*, 43 Transport Revs. 914 (2023).

barriers but also linguistic ones: approximately 20% of asylum-seeking patients do not pursue medical care due to fear of miscommunication or not understanding their provider.[71] Telehealth can help bridge this gap by connecting patients with language-concordant providers who may not be available in their immediate geographic area. For communities already navigating the intersection of immigration status, poverty, and limited English proficiency, telehealth is often the only realistic path to timely reproductive care. Eliminating it risks leaving these patients with nowhere to turn.

C. Restricting Abortion Access Worsens Public Health Outcomes.

Telehealth for abortion, like abortion more generally, is essential to public health. Contrary to Plaintiffs' claims that restricting mifepristone access would save families from harm,[72] it is the restriction of abortion access—not its availability—that endangers lives. Access to safe, legal abortion is a critical component of the broader healthcare system, and curtailing it through telehealth restrictions would produce the very harms Plaintiffs claim to oppose.

The historical record is unambiguous on this point. The gradual legalization of abortion in the years leading up to *Roe v. Wade* reduced maternal mortality among

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[71] *See* Comment of The Boston University School of Law's Program on Reproductive Justice (BUPRJ), *supra* note 56.

[72] *See* Compl. ¶¶ 120–131, *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La. Oct. 6, 2025), ECF No. 1 (asserting quasi-sovereign harms to Louisiana women from mifepristone); Pls.' Mem. in Supp. of § 705 Stay at 15, ECF No. 20-26 (arguing that "the public interest is disserved by a drug that does not afford adequate protections to its users" (quotation marks omitted)).

people of color by 30–40%.[73] Research since *Dobbs* confirms that this pattern is now reversing. The racial dimensions of these harms are particularly stark. Black women are already two to four times more likely than white women to experience maternal mortality or morbidity.[74] Abortion bans in fourteen states have also increased infant mortality, with an estimated 478 additional infant deaths above what would have been expected.[75] Research following Texas's 2021 abortion ban estimated a 6–13% increase in infant mortality.[76] Black infants have been hit hardest, dying at a rate 11% higher than expected following abortion bans.[77] These are not abstract projections. They are documented consequences of restricting access to care.

Abortion restrictions have also been shown to increase disparities in premature birth and low birthweight between Black and white infants by 3–6%.[78] And state-level abortion restrictions enacted prior to 2022 were associated with increases in intimate partner violence–related homicides of women and girls.[79] Restricting telehealth access to mifepristone would compound each of these

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[73] Sherajum Monira Farin et al., *The Impact of Legal Abortion on Maternal Mortality*, 16 Am. Econ. J.: Econ. Pol'y 174 (2022), https://www.aeaweb.org/articles?id=10.1257/pol.20220208.

[74] Alexis A. Creanga et al., *Racial and Ethnic Disparities in Severe Maternal Morbidity: A Multistate Analysis, 2008–2010*, 210 Am. J. Obstetrics & Gynecology 435.e1 (2014).

[75] Alison Gemmill et al., *US Abortion Bans and Infant Mortality*, 333 JAMA 1315 (2025).

[76] Alison Gemmill et al., *Infant Deaths After Texas' 2021 Ban on Abortion in Early Pregnancy*, 331 JAMA 1609 (2024).

[77] *Id.*

[78] Graham Gardner, *The Maternal and Infant Health Consequences of Restricted Access to Abortion in the United States*, 98 J. Health Econ. 102938 (2024).

[79] Maeve E. Wallace et al., *States' Abortion Laws Associated with Intimate Partner Violence–Related Homicide of Women and Girls in the US, 2014–20*, 43 Health Aff. 682 (2024).

outcomes by erecting additional barriers for the very communities that already bear the greatest burden.

Plaintiffs seek nationwide restrictions on mifepristone access that would cause profound harm. Abortion access saves lives, reduces maternal and infant mortality, narrows racial health disparities, and protects survivors of violence. Telehealth is the mechanism through which millions of patients access that care. Restricting it would not protect anyone; it would cause the gravest harm to those who can least afford it.

CONCLUSION

For the foregoing reasons, *Amici* urge this Court to deny Plaintiffs' motion.

February 20, 2026

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2026, I presented the foregoing to the Clerk of Court by filing and uploading to the CM/ECF system, which will send notification of such filing to all parties.

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APPENDIX

List of *Amici Curiae*

Center for Reproductive Rights

American Civil Liberties Union Foundation

Planned Parenthood Federation of America

10,000 Women Louisiana

A Woman's Choice Clinics: Jacksonville, FL; Charlotte, NC; Greensboro, NC; Raleigh, NC; Danville, VA

Abortion Coalition for Telemedicine

Abortion Forward (f/k/a Pro-Choice Ohio)

Access Health Center Ltd

Alamo Women's Clinic of Albuquerque

Alamo Women's Clinic of Illinois

All Families Healthcare

Alyssa Rodriguez Center for Gender Justice

American College of Nurse-Midwives, Oregon Affiliate

Americans United for Separation of Church and State

Ancient Song, Inc.

Avow Texas

Bread and Roses/Gainesville Woman Care

Brevard NOW

California Women Lawyers

Cambridge Reproductive Health Consultants

Carolina Abortion Fund

Catholics for Choice

Cedar River Clinics

Center for Women's Health

Chicago Abortion Fund

CHOICES Center for Reproductive Health

Cobalt Advocates

Collective Power for Reproductive Justice

Desert Star Institute for Family Planning

Desiree Alliance

Doctors for America

El Pueblo

Endora

Equal Rights Advocates

Essential Access Health

Every Mother Counts

Faith Choice Ohio

Family Planning Associates Medical Group

Feminist Center for Reproductive Liberation

FL National Organization for Women

Frontera Fund

Fund Texas Choice

Gender Justice

Gender Justice League

Greater Orlando National Organization for Women

Greenville Women's Clinic PA

GSBA, Washington's LGBTQ+ Chamber of Commerce

Guttmacher Institute

Health Imperatives Inc.

Ibis Reproductive Health

If/When/How: Lawyering for Reproductive Justice

Indigenous Women Rising

International Action Network for Gender Equality & Law (IANGEL)

Ipas US

Jane's Due Process

Juniper Midwifery

Just The Pill

Justice and Joy National Collaborative

Lawyering Project

Legal Momentum, The Women's Legal Defense and Education Fund

Maine Family Planning

Michigan Chamber for Reproductive Justice

Michigan Voices

Midwest Access Coalition

Miscarriage and Abortion Hotline

National Abortion Federation

National Council of Jewish Women

National Health Law Program

National Network of Abortion Funds

National Organization for Women, Jacksonville Chapter

National Perinatal Association

National Women's Law Center

National Women's Political Caucus

New York Abortion Access Fund (NYAAF)

New York Midwives

NOISE FOR NOW

Northland Family Planning Centers

Northwest Health Law Advocates

Nurses for Sexual Reproductive Health

Oklahoma Call for Reproductive Justice

Partners in Abortion Care

Pasco County National Organization for Women, Inc.

People Power United

Physicians for Reproductive Health

Pinellas County National Organization for Women

Plan C

Power to Decide

Pro-Choice North Carolina

Protect Our Care, a fiscally sponsored project of New Venture Fund

Reclaim, Inc.

Red River Women's Clinic

Reproaction

Reproductive Equity Now Foundation

Reproductive Freedom for All

Reproductive Freedom Fund of New Hampshire

Reproductive Health Access Project

Rhia Ventures

Robbinsdale clinic, PA

SHERo Mississippi

Southwestern Women's Options

Tennessee Freedom Circle

Texas Equal Access Fund

The Brigid Alliance

The Jane Network

Truth Pregnancy Resource Center

Ubuntu Black Family Wellness Collective

URGE: Unite for Reproductive & Gender Equality

Virginia Affiliate of the American College of Nurse-Midwives

Wavelength Psychological Services

Women Lawyers On Guard Inc.

Women's Law Project