United States Court of Appeals

for the

Fifth Circuit

Case No. 26-30203

STATE OF LOUISIANA, by & through its Attorney General, Liz Murrill; ROSALIE MARKEZICH,

Plaintiffs-Appellants/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; KYLE DIAMANTAS, Acting Commissioner, U.S. Food and Drug Administration; RICHARD PAZDUR, in his official capacity as Director, Center for Drug Evaluation & Research, U S Food & Drug Administration; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., Secretary, U.S. Department of Health and Human Services,

Defendants-Appellees,

GENBIOPRO, INCORPORATED,

Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellee/Cross-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA

BRIEF FOR *AMICUS CURIAE* PHYSICIANS FOR REPRODUCTIVE HEALTH IN SUPPORT OF INTERVENORS-APPELLEES/CROSS-APPELLANTS

CORINNE R. MOINI
KATHERINE S. BORCHERT
FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP
801 Seventeenth Street, N.W.
Washington, D.C. 20006

JANICE MAC AVOY
Counsel of Record
LAURA ISRAEL SINROD
ANNE S. AUFHAUSER
KATHRYN SACHS
FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP
One New York Plaza
New York, New York 10004
(212) 859-8000
janice.macavoy@friedfrank.com

Attorneys for Amicus Curiae

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CERTIFICATE OF INTERESTED PERSONS

Louisiana, et al., v. Food and Drug Administration, et al., No. 26-30203

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1, in addition to those listed in the briefs of the parties, have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Amicus Curiae:

- Physicians for Reproductive Health

Counsel for Amicus:

- Janice Mac Avoy of Fried, Frank, Harris, Shriver & Jacobson LLP
- Laure Israel Sinrod of Fried, Frank, Harris, Shriver & Jacobson LLP
- Anne S. Aufhauser of Fried, Frank, Harris, Shriver & Jacobson LLP
- Corinne R. Moini of Fried, Frank, Harris, Shriver & Jacobson LLP
- Katherine S. Borchert of Fried, Frank, Harris, Shriver & Jacobson LLP
- Kathryn K. Sachs of Fried, Frank, Harris, Shriver & Jacobson LLP

By: */s/ Janice Mac Avoy*
Janice Mac Avoy
Attorney for Amicus Curiae

Dated: July 22, 2026

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INTEREST OF AMICUS CURIAE[1]

Physicians for Reproductive Health ("PRH") is a physician-led nonprofit that seeks to assure meaningful access to comprehensive reproductive health services, including contraception and abortion. Since its founding in 1992, PRH has organized and amplified the voices of medical providers to advance reproductive health, rights, and justice. PRH's network of over 550 physicians work in forty-six states, Puerto Rico, and the District of Columbia. PRH has unique insight into the challenges physicians and patients face when confronted by laws and policies that prevent pregnant people from accessing necessary medical care and harm their ability to live freely, with dignity, safety, and security. To that end, in public discussions of reproductive health, PRH shares the physician's distinctive voice, expertise, and experience by gathering and publishing physician stories.

Requiring in-person dispensing of mifepristone directly impacts PRH physicians' ability to provide patients with a safe and effective medication that is part of the most commonly recommended medication regimen to end a pregnancy. PRH and its network can attest that mifepristone is an incredibly safe and effective drug, whether dispensed in-person or via mail or at a local pharmacy following a

[1] No counsel for any party has authored this brief in whole or in part, and no person has made any monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

telehealth visit. Indeed, PRH physicians are uniquely equipped to share the harm that they have incurred and will incur from reproductive health restrictions.

SUMMARY OF ARGUMENT

Jane Doe is a high school student who found out she was pregnant shortly after being raped. With the support of her mother and her doctors, she decided that her safest, least retraumatizing option was terminating the pregnancy using a medication regimen of mifepristone and misoprostol.[2] However, Jane could not obtain the necessary medication at a local clinic because she lives on an island where, although abortion is legal, there are zero in-person abortion providers. The closest provider is located in Honolulu, Hawai'i, which is a flight away. Jane and her family did not have the means to pay for flights and hotels, which would have been prohibitively expensive. They also wanted to avoid further disruption to Jane's life, and flying to Honolulu would have required missing school. Moreover, the delays from planning a trip to Honolulu could have narrowed Jane's medical options, potentially subjecting her to a more invasive procedure.

Thankfully, Jane had another option: she met with a telehealth provider who was able to mail the mifepristone and misoprostol prescriptions, and she safely and

[2] *See* Kristen Chalmers et al., *Abortion Experiences of Individuals with a History of Trauma(s): A Qualitative Study*, 149 Contraception 1, 5 (2025) (stating that "the invasive nature of transvaginal ultrasounds and procedures" can be "uncomfortable for some participants who related this exam to prior sexual abuse," and the ability to choose medication abortion to "do it privately and on [the patient]'s own time . . . in [the patient's] house" can help sexual assault survivors).

legally ended her pregnancy at home. The Food & Drug Administration's ("FDA") 2023 modification to the Risk Evaluation and Mitigation Strategy ("2023 REMS") allows mifepristone to be dispensed by mail or at a pharmacy. Under this framework, Jane was able to receive care despite her remote location. After receiving care through telemedicine, Jane safely (and legally) completed her medication abortion at home, surrounded by loved ones, helping her move forward from this traumatic experience in her young life.

A merits decision consistent with the Fifth Circuit's May 1, 2026 order, which temporarily granted Plaintiffs-Appellants' request to stay the 2023 REMS before the Supreme Court blocked that decision, would prevent patients like Jane from receiving safe and effective abortion care or miscarriage management in this way—via mail or at a pharmacy. The result would be devastating to patients facing geographical barriers, financial constraints, intimate partner violence, and transportation limitations—among other circumstances—that make it extremely difficult to travel for in-person care. Such a decision would unnecessarily limit the options for managing pregnancy loss and abortion care, restrict patient autonomy, and constrain doctors' ability to dispense a safe and effective medication for no medically justified reason.

This brief discusses mifepristone from the perspective of physicians who provide reproductive health care, including abortion and miscarriage care, across the

United States. It centers first-person narratives from the physicians themselves.[3] The physicians' perspectives illustrate why leaving all medically sound options on the table, including dispensing mifepristone via mail or at local pharmacies, is critical.

By multiple objective measures, mifepristone—whether dispensed in-person, via mail, or at a local pharmacy—is very safe and effective. Consistent with the overwhelming medical consensus and literature, every doctor interviewed for this *amicus* brief prescribes mifepristone regularly and agrees it is a safe and effective method for terminating pregnancy or managing pregnancy loss. None had medical concerns about dispensing mifepristone remotely; in fact, numerous providers shared patient stories, like Jane's, about why remote access is essential.

Granting the relief Plaintiffs-Appellants request would severely limit access to mifepristone and block patients from receiving medically-appropriate and legal care. Indeed, requiring in-person dispensing of mifepristone will exacerbate existing inequities in abortion care and miscarriage management access, particularly for patients who already face structural barriers to care—including patients of color, low-income patients, and patients in rural areas. The inability to remotely access

[3] This *amicus* brief includes narratives from PRH providers from around the country, many of whom specialize in family medicine, complex family planning, maternal fetal medicine, and obstetrics and gynecology ("OBGYN"). These narratives were compiled from interviews conducted by the undersigned counsel, and each physician personally reviewed and approved their statements herein. The medical opinions expressed are their own and not necessarily shared by the institutions with which they are affiliated.

medication for abortion care and miscarriage management will constrain patients' autonomy in deciding where, when, and how to manage their pregnancies and pregnancy losses, and will further erode physicians' ability to provide preferred care to their patients, undermining physicians' ability to exercise their judgment and core medical ethics principles. Accordingly, this Court should deny the relief requested by Plaintiffs-Appellants.

ARGUMENT

I. Mifepristone Dispensed Remotely After Telehealth Appointments Is Safe And Effective For Medication Abortions And Miscarriage Management

In 2000, the FDA approved mifepristone, used with misoprostol, to terminate a pregnancy.[4] In the two-drug regimen for pregnancy termination, frequently referred to as medication abortion, the patient takes one dose of mifepristone followed by one or more doses of misoprostol.[5] Patients taking these medications experience bleeding and cramping when passing a pregnancy, but they face extremely low rates of complications.[6]

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

[5] *Id.*; Dr. Kristyn Brandi, *What to Know About Abortion and Miscarriages With or Without Mifepristone*, Am. Coll. Of Obstetricians and Gynecologists ("ACOG") (last reviewed Apr. 24, 2026), https://www.acog.org/womens-health/experts-and-stories/the-latest/what-to-know-about-abortion-and-miscarriages-with-or-without-mifepristone.

[6] ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (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.

When the FDA initially approved mifepristone in 2000, it required that mifepristone be dispensed only in-person at health care facilities.[7] But in July 2020, a court enjoined the in-person dispensing requirement due to the COVID-19 pandemic.[8] In April 2021, relying on significant research that mifepristone is safely dispensed outside of healthcare facilities, the FDA lifted the in-person dispensing requirement during the COVID-19 pandemic. Following a comprehensive review of evidence that showed a comparable risk of safety and efficacy for in-person versus remote dispensation of mifepristone, the FDA announced in December 2021 that it would make that change permanent, and the updated REMS took effect in January 2023.[9]

In the twenty-six years since FDA approval, more than 7.5 million people in the United States have used mifepristone for abortion and miscarriage care.[10] Medication abortion has become the most common method of abortion in the United

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7 *See* FDA Mifepristone Q&A, *supra* note 4.

8 *FDA v. Am. Coll. Of Obstetricians & Gynecologists*, 141 S. Ct. 578, 580–81 (2021).

9 FDA Mifepristone Q&A, *supra* note 4. The FDA's decision was based on "a comprehensive review of the published literature, other relevant safety and adverse event data, and information provided by advocacy groups, individuals, and the applicants," and the resulting conclusion that there "did not appear to be a difference in adverse events between periods when in-person dispensing was and was not enforced." *Id*. The FDA then "approved a REMS modification that removes the in-person dispensing requirement and adds pharmacy certification." *Id.*

10 Press Release, Planned Parenthood, *25 Years After Its FDA Approval, Mifepristone is Still Safe and Effective* (Sept. 25, 2025), https://www.plannedparenthood.org/about-us/newsroom/press-releases/25-years-after-its-fda-approval-mifepristone-is-still-safe-and-effective.

States, accounting for 63% of all abortions performed in formal healthcare systems in 2023.[11]

A. "[Mifepristone] is completely safe."

Physicians overwhelmingly agree with the evidence confirming that mifepristone is a safe and effective abortion care and miscarriage management option. All physicians interviewed report that mifepristone-related complications are exceptionally rare, if they occur at all. For example, Dr. Aishat Olatunde, a board certified OBGYN and complex family planning specialist practicing in the Mid-Atlantic, estimates that she has prescribed mifepristone "thousands of times" since completing her medical training seven years ago, and "prescribe[s] mifepristone probably every day that [she is] in the office." She calls mifepristone "a very safe medication," and she rarely, if ever, sees complications from it.

Similarly, Dr. Avanthi Jayaweera, a family medicine physician practicing in the Mid-Atlantic, has prescribed mifepristone for thousands of patients, none of whom experienced serious adverse events as a result. Dr. Jayaweera stated she has

[11] Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Institute (Dec. 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions; Rachel K. Jones & Amy Friedrich-Karnick, *Medication Abortion Accounted for 63% of All US Abortions—An Increase from 53% in 2020*, Guttmacher Institute (Mar. 2024), https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020#:~:text=While%20there%20are%20no%20comprehensive,medication%20abortion%20are%20at%20risk.

"no concerns about using mifepristone" because it "is super safe, and I have felt very comfortable prescribing it." While Dr. Jayaweera's clinics do not dispense mifepristone remotely, in her opinion, there is "no clinical justification" for imposing remote dispensing restrictions.

Dr. Olivia Manayan, an OBGYN and complex family planning fellow who practices in Honolulu, reports the same. She says mifepristone is "incredibly safe." Further, Dr. Emma Trawick, a maternal fetal medicine fellow in the Southeast who has prescribed mifepristone hundreds of times for medication abortion and pregnancy loss believes that mifepristone is "a very, very, very safe drug" that is "a key piece of fetal loss management." Dr. Bhaskari Burra, a maternal fetal medicine physician in the Southeast, echoes this sentiment, stating that mifepristone is "bottom line, a very safe medication."

Overwhelming scientific and medical evidence supports PRH physicians' experiences. Medical and scientific research studies from the last three decades demonstrate the safety and efficacy of mifepristone (and misoprostol), both for medication abortion and miscarriage management.[12] Moreover, the risks associated

[12] "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." Brief for American College of Obstetricians & Gynecologists and Other Medical Societies as Amici Curiae Supporting Applicant Danco Laboratories at 7, *Danco Laboratories, LLC v. Louisiana*, 146 S.Ct. 1192 (No. 25A1207), https://www.acog.org/-/media/project/acog/acogorg/files/advocacy/amicus-briefs/2026/20260506_dancolabs-louisiana.pdf?rev=3e9fce70d37b4eb8b6f2a97657b73ebf; *see also* Ushma Upadhyay et al., *Reproductive Health Researchers' Comment*, ANSIRH, at 1–2 (2025) ("Decades of conclusive

with mifepristone are "exceedingly rare, generally far below 0.1% for any individual adverse event."[13] Those risks are not unique to mifepristone; rather, they arise whenever the uterus is emptied, whether through medication abortion, procedural abortion, miscarriage, or childbirth.[14] Research has not demonstrated a causal link between mifepristone and serious adverse effects.[15]

Hundreds of peer-reviewed studies on mifepristone are consistent with PRH providers' clinical experience: mifepristone is safe, and its availability makes medication abortion and pregnancy loss management safer.[16] And evidence available during the 2023 REMS decision-making process supported that conclusion.[17] Mifepristone's safety does not change when dispensed remotely.

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scientific evidence amassed through more than one hundred rigorous studies based on hundreds of thousands of patient outcomes have overwhelmingly established the safety and effectiveness of mifepristone for medication abortion and management of early pregnancy loss.") (collecting studies).

[13] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, Application No. 020687Orig1s020, Medical Review(s), at 47 (Mar. 29, 2016).

[14] Mifepristone Labeling and Medication Guide, at 16 (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf.

[15] *Id.* at 1–2, 5; U.S. Food & Drug Admin., NDA 020687 & ANDA091178, *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2024* (2025), https://www.fda.gov/media/185245/download (discussing extremely low 0.00048% fatality rate among people who took mifepristone, including deaths unrelated to abortion or pregnancy).

[16] *See, e.g.*, ANSIRH, Analysis of Medication Abortion Risk and the FDA Report "Mifepristone US Post-Marketing Adverse Events Summary Through 12/31/2022," at 2–3 (2024), https://www.ansirh.org/sites/default/files/2024-05/Analysis%20of%20MA%20Risk%20and%20FDA%20Report%20Issue%20Brief%20FINAL.pdf.

[17] *See, e.g.*, ANSIRH, *U.S. Studies on Medication Abortion Without In-Person Clinician Dispensing of Mifepristone*, at 1 (2021), https://www.ansirh.org/sites/default/files/2024-07/Issue%20Brief%20MAB%20without%20in%20person%20dispensing%207.2.24.pdf; Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine*

Indeed, researchers have confirmed that mifepristone is equally safe and effective when administered remotely, rather than in a clinic.[18]

B. Telehealth allows physicians to examine patients effectively, and physicians use their medical and professional judgment when recommending in-person care.

All physicians interviewed unequivocally agreed that they would be comfortable dispensing mifepristone via mail or at a local pharmacy following a virtual assessment. PRH physicians report that in-person and telehealth assessments for prescribing mifepristone are equally effective as physicians can date a pregnancy using the patient's last menstrual cycle, recognize ectopic pregnancy symptoms, and counsel patients about their available options via telehealth. Dr. Tal Lee, an OBGYN in New York, explains that the standard of care for dating a pregnancy is having a patient report "the first date of their last period." Dr. Olatunde agrees, explaining that providing ultrasounds for patients in-person is not a "medical necessity." Dr. Jayaweera confirms that "if [patients] meet certain clinical criteria, they don't need a physical exam" to date the pregnancy.

All physicians interviewed explained that if concerns arise during a telehealth visit regarding the patient's eligibility for a medication abortion, they recommend

Compared With In Person, 130 Obstetrics & Gynecology 778, 778–82 (2017), https://pubmed.ncbi.nlm.nih.gov/28885427/.

[18] Kristina Gemzell-Danielsson et al., *Home Use of Mifepristone for Medical Abortion: A Systemic Review*, 51 BMJ Sexual & Reprod. Health 1, 1 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12322458/pdf/bmjsrh-51-3.pdf.

that the patient be seen in-person. Dr. Manayan explains that "if [patients are] . . . pretty unsure about dating or have irregular periods, I will recommend an ultrasound prior [to confirming their eligibility for mifepristone]." Dr. Lee provided three examples where she would request an in-person visit with a patient before prescribing mifepristone: (i) if, based on the first day of their last menstrual period, the patient was too far along in their pregnancy to be eligible for medication abortion; (ii) if the patient was uncertain when their last period was, and had irregular periods, and would thus require an ultrasound to date the pregnancy; or (iii) if the patient was having symptoms of an ectopic pregnancy, such as severe abdominal pain.

An in-person dispensing requirement would require all patients travel to a healthcare center *even when there is no clinical reason to do so*, while the current model enables physicians to tailor care to individual circumstances and refer patients for in-person care *when such care is medically appropriate*.

Importantly, PRH physicians emphasize that a key diagnostic for ectopic pregnancy is the patient's description of their symptoms, which can be accomplished both via telehealth and in-person. Their experience confirms that requiring in-person screening would not improve the diagnosis of ectopic pregnancies. In Dr. Olatunde's words, "the guidance on symptoms is more helpful than the ultrasound." Moreover, Louisiana's position that prescribing mifepristone via telehealth increases

risks relating to ectopic pregnancies is not supported by the scientific research or by PRH physicians' experiences.[19] Indeed, "substantial data and current clinical … guidelines support [providing medication abortion] treatment [to] patients" seeking a medication abortion "in whom ectopic pregnancy has not been definitively excluded."[20] Prescribing mifepristone and misoprostol together for those patients therefore "is consistent with the standard of care."[21] Furthermore, patients who are too early in their pregnancy to determine pregnancy location are thoroughly counseled on when to seek care for symptoms that may indicate an ectopic pregnancy requiring monitoring.

In the extremely rare event of a ruptured ectopic pregnancy, PRH physicians confirm that recognizing its symptoms is a foundational, basic part of their training, and attest that they can easily distinguish between a miscarriage or medication abortion and a rupturing ectopic pregnancy via telehealth assessment. In fact, Dr. Lee says that the "uterine cramping" pain a patient will describe during an abortion or miscarriage is different from the pain a patient would describe during a rupturing ectopic pregnancy, which would present as "severe, diffuse abdominal pain." Similarly, Dr. Trawick explained that recognizing the symptoms of rupturing ectopic

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[19] Compl. ¶ 37, *State of Louisiana v. United States Food & Drug Admin.*, No. 6:25-CV-1491 (W.D. La. Oct. 6, 2025), ECF No. 1.

[20] Elizabeth G. Raymond et al., *Commentary: No-Test Medication Abortion: A Sample Protocol For Increasing Access During A Pandemic and Beyond*, 101 Contraception 361, 363 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7161512/pdf/main.pdf.

[21] *Id.*

pregnancies is one of the "first thing[s] you learn in residency," and emphasizes that "the symptoms of a ruptured ectopic pregnancy do not mirror the symptoms of a miscarriage. So, if someone called you with symptoms of [ruptured] ectopic pregnancy you would know." Physicians interviewed all expressed confidence that they would not miss the symptoms of a rupturing ectopic pregnancy via telehealth and would immediately help the patient access in-person, emergency care.

Further, physicians' medical advice on medication abortion and miscarriage management does not differ between telehealth and in-person appointments, and patients receive the same information about the potential risks and side effects of mifepristone regardless of whether the appointment is in-person.[22] Indeed, Dr. Olatunde emphasizes "the words I say are exactly the same" for in-person and telehealth abortion counseling appointments. Moreover, while physician counseling on these risks remains the same in-person and remotely, physicians also stress the importance of individualized patient care. For example, when providing counselling remotely to patients across Hawai'i's islands, Dr. Manayan "accommodate[s] for if [patients] are in a place where it is not so easy to reach us if there was a complication, like on a neighbor island, so they know the closest place to get emergency care."

[22] *See, e.g.*, *Grossman & Grindlay*, *supra* n.18 (finding that among people who received medication abortion care via telehealth, only 0.18% experienced any adverse effects, compared with 0.32% of those who received in-person care).

PRH physicians' experiences indicate that complications requiring emergency care are even rarer than statistics suggest, and that patients who do seek follow-up or emergency room care typically do so for routine, non-emergent side-effects of medication abortion, where no treatment or intervention is actually needed. Dr. Lee staffs her clinic's OBGYN emergency line and says "it's very rare" to receive calls from people who have taken mifepristone, and that, if they do call, "[u]sually [it is] because they're having expected bleeding and some people find that to be concerning. That's completely reasonable; people have different amounts of bleeding that they're comfortable with. Usually they're looking for reassurance . . . to have someone say, this is normal, you'll be okay." She has seen "no bad outcomes for medication abortions" after prescribing mifepristone and misoprostol hundreds of times. Similarly, Dr. Olatunde explains, "it's pretty uncommon" for patients to require emergency care, and "rare" for patients to "present[] with complications from their abortion or miscarriage management."

Finally, as with an in-person visit, physicians offering telehealth are always on alert for patients who are at risk of intimate partner violence, abuse, or coercion. Indeed, Dr. Manayan and others report that telehealth appointments can be the safest or only option for victims of intimate partner violence to access care. Dr. Manayan has seen telehealth patients attend appointments from work because "their partners are tracking their location" and "as long as they are at work their partner won't know

that they are getting that care." The option to terminate a pregnancy can be a lifeline for pregnant patients in abusive relationships. Indeed, Dr. Manayan describes a patient who "did not want to be tied" to an abusive partner and "feared that having a child with him would not allow for complete separation." For that patient, receiving abortion care remotely saved her from being "forced . . . to carry a pregnancy that would negatively impact her life."[23]

PRH physicians confirm that dispensing mifepristone via mail or at a local pharmacy following a telehealth visit is safe because physicians can fully assess whether the patient is a candidate for medication abortion during a virtual appointment—and in some cases, telehealth offers vulnerable patients safety advantages.

II. Removing Access To Mifepristone Via Mail Or At A Local Pharmacy Will Threaten Patients' Health And Autonomy

Removing remote access to mifepristone threatens patient health and autonomy. The physicians interviewed confirm that limiting their ability to dispense mifepristone remotely can cause medical harm when the patient is seeking a medication abortion in a life-threatening situation, especially if the patient is unable to access in-person abortion care due to geographic barriers or personal

[23] Sarah Varney & Rachel Wellford, *Transcript: Abortion Restrictions May Be Fueling A Rise in Domestic Violence, Experts Warn*, PBS News Hour (Oct. 16, 2025), https://www.pbs.org/newshour/show/abortion-restrictions-may-be-fueling-a-rise-in-domestic-violence-experts-warn.

circumstances. Physicians also worry about the ethical harm of limiting patient choice. Physicians are ethically obligated to respect patient autonomy by "acknowledg[ing] an individual's right to hold views, to make choices, and to take actions based on her own personal values and beliefs,"[24] but requiring in-person dispensing of mifepristone on a nationwide basis would undermine that obligation by removing a safe and effective option from their toolkit.

Dr. Benjamin Brown, an OBGYN and complex family planning specialist who also specializes in and researches clinical medical ethics, explains that patient autonomy is "central" to medical practice. "It's ***the*** thing that determines the plan of care" when there are multiple medically appropriate options, and "[p]recluding someone from accessing a mode of care if that restriction is not medically grounded" raises ethical concerns. Dr. Brown explains that while he is "the expert in the biomedical piece—how to interpret lab results, how to do a procedure," he is "not the expert in the needs of the person in front of [him] and their values. There's only one expert in that, and that's them." He emphasizes that when physicians "want to help the patient have the best healthcare outcome, the best treatment for them, that means making sure the plan of care is grounded in their values, needs, [and]

[24] ACOG Committee Opinion No. 390, *Ethical Decision Making in Obstetrics and Gynecology*, 110 Obstetrics & Gynecology 1479, 1481 (Dec. 2007, *reaff'd* 2016), https://journals.lww.com/greenjournal/citation/2007/12000/acog_committee_opinion_no__390__ethical_decision.53.aspx.

preferences" and that "shared decision-making" between physician and patient "is the standard of care."

Other PRH physicians agree. Dr. Olatunde explains that "it should be patients deciding how they want their care to be provided. It's our job to facilitate and to guide and to provide recommendations based on their personal and individualized scenario and medical situations and outline the options. . . we are the *facilitators* of their care. *Not the deciders, the facilitators*." Dr. Trawick emphasizes that among medically supported options, patient choice is essential; it is "really important for patients to have all options available to them," including the ability to obtain medication via mail or at a local pharmacy. Dr. Lee notes that patients often choose medication abortion so "[t]hey can choose where and when they pass the pregnancy, so they can be maybe in their pajamas surrounded by loved ones if they want. There is no reason to [only] give [mifepristone] in the clinic. It's all about what's best for the patient." Dr. Rachel Jensen, a board-certified OB/GYN and specialist in complex family planning practicing in the D.C. area, emphasizes that "[t]elehealth is an incredible way to increase patient-centeredness, and to have more of these conversations in a setting where patients are more comfortable."

As the below accounts demonstrate, requiring in-person dispensing of mifepristone not only presents risks to a patient's health or life, but also erodes patient autonomy.

A. "She could have avoided a trip that put her life at risk."

Many patients seeking abortion care suffer from medical conditions that make traveling to a clinic medically dangerous, and the ability to receive mifepristone via mail or at a local pharmacy can be life-saving.[25] For example, Dr. Jayaweera described a patient in the early stages of her second pregnancy who was suffering from hyperemesis gravidarum ("HG"), typically a self-limiting[26] condition of nausea and vomiting of early pregnancy that is often "associated with short-term and long-term adverse outcomes for the mother and her offspring."[27] Dr. Jayaweera's patient had an unusually severe and prolonged presentation that became debilitating and life-threatening. She required multiple hospitalizations, IV fluids, and extensive monitoring given severe electrolyte imbalance, dehydration, and profound weight loss, leaving her "unable to eat, unable to function," and unable to care for her toddler. Dr. Jayaweera became especially worried when the patient lost a significant amount of weight, a symptom Dr. Jayaweera describes as "very concerning for someone who is pregnant." According to Dr. Jayaweera, HG put both the pregnancy

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[25] *See, e.g.*, Ushma D. Upadhyay et al., *Distance Traveled for an Abortion and Source of Care After Abortion*, 130 Obstetrics & Gynecology 616, 616–17 (2017), https://journals.lww.com/greenjournal/abstract/2017/09000/distance_traveled_for_an_abortion_and_source_of.17.aspx ("For most patients, greater distance traveled for abortion was associated with increased likelihood of seeking subsequent care at an ED.")

[26] *See* Julia Kathrin Juekstock et al., *Managing Hyperemesis Gravidarum: A Multimodal Challenge*, 8 BMC Med. 1, 1 (2010), https://link.springer.com/article/10.1186/1741-7015-8-46#auth-JK-Jueckstock-Aff1 (as a self-limiting condition, HG symptoms resolve without medical intervention for most patients).

[27] *Id*.

and the patient's life at risk, and the patient risked serious heart complications from abnormalities in electrolyte levels, as well as severe dehydration and malnourishment. While the patient desperately wanted a second child and had suffered through two early miscarriages, she ultimately made the difficult decision to end the pregnancy for the sake of her health and her existing child, with the support of her partner.

There were no abortion providers in the patient's area, however, and Dr. Jayaweera's clinic only dispenses mifepristone in-person. The patient was forced to drive for hours to seek the care that she needed: a medication abortion using mifepristone and misoprostol. Dr. Jayaweera believes that this patient would have been an excellent candidate to receive mifepristone by mail following a telehealth visit because her condition was so severe that it was unsafe for her to travel:

> Subjecting someone very ill to that type of travel . . . put her life at risk. I would have not recommended that any patients with these symptoms go on an extended travel like this. But given the state of reproductive healthcare access, she had no other option. Had this patient been able to receive a mifepristone prescription via telehealth, she could have avoided a trip that put her life at risk.

Indeed, the patient was so medically unstable that she received IV fluids directly before the drive. As a result of this harrowing experience, the patient disclosed that while she had previously been firmly "pro-life," the experience shifted her perspective. She realized "I couldn't go through with this pregnancy without risking

my life or the family's wellbeing." From Dr. Jayaweera's perspective, the lesson here is that "you never think you need an abortion until you need one, and that is why it is so important to allow people to take the lead on their own healthcare."

Another pregnant patient Dr. Jayaweera treated was suffering from a severe mental health crisis that made her "acutely suicidal." Recognizing that her pregnancy was a reason for her severe depression and suicidal ideation, the patient decided to get an abortion.[28] Dr. Jayaweera explained that when the patient first decided that she needed an abortion, she was eligible for a medication abortion, but by the time she had arranged travel and accessed care, her pregnancy had advanced and procedural abortion became the only option.

For this patient, "the abortion was life-saving." And if she had had access to a medication abortion remotely, "she would have been able to get an abortion much earlier in pregnancy, address her severe mental health symptoms and become medically stable a lot sooner." Dr. Jayaweera says that she has "had people tell me, 'I'd rather be dead than move forward with this pregnancy.' Sometimes the way they present is very concerning, and if I'd been able to reach them via telehealth I would have said, 'we need to get you care and we need to get you care now.' This is better than making an [in-person] appointment, which can lead to additional,

[28] *Cf.* Kathleen Chin et al., *Suicide and Maternal Mortality*, 24 Springer Nature 239, 239 (2022), https://link.springer.com/article/10.1007/s11920-022-01334-3 ("Suicide is a leading cause of death in the perinatal period (pregnancy and 1 year postpartum).").

unnecessary delays, especially if they are traveling far or have other barriers to access care."

Both of Dr. Jayaweera's patients had the time, financial means, and job flexibility to travel to access abortion care. But other patients facing life-threatening pregnancy conditions may not have those privileges. A stay of the 2023 REMS risks forcing critically ill patients to travel to obtain mifepristone or to forego it altogether.

B. "They would have to fly to get abortion care."

Medical emergencies are not the only reason patients benefit from the availability of remote abortion care and miscarriage management, as many patients face other obstacles to accessing care in-person: distance to a clinic, work constraints, disability, intimate partner violence, childcare concerns, and countless other barriers. For example, of Hawai'i's eight islands, there are abortion providers on only three islands. For this reason, Dr. Manayan reports that telehealth is essential for Hawai'ian patients because "if an off-island patient was unable to attend their appointment virtually and get their medication mailed to them, they would have to fly to get abortion care." As with Jane Doe, flying is simply not an option for many patients, especially among patients facing historic healthcare inequities, like Native Hawai'ian and Pacific Islander populations who are less likely to have a primary healthcare provider, or for those who may simply choose to forgo care due to the

high costs.[29] Restricting the remote dispensation of mifepristone will only exacerbate these existing inequities by further increasing the cost of care. Dispensing mifepristone remotely "gives patients the opportunity to have control over their body and their life" without facing additional hurdles.

Patients in states with large rural areas face similar challenges in accessing mifepristone for abortion care and miscarriage management. Dr. Burra works at one of the only clinics in the western region of her state that provides specialized care for high-risk pregnancies, and many of her patients live in rural areas that are two to three hours away from her clinic. She has historically prescribed mifepristone via telehealth for pick-up at a local pharmacy for patients experiencing a miscarriage or pregnancy loss. By prescribing mifepristone over telehealth for at-home management, Dr. Burra is "trying to save patients from having to drive several hours" for an in-person appointment while experiencing the trauma of a miscarriage or pregnancy loss. Dr. Burra reports that patients who live far from the clinic also face logistical barriers to care, such as access to transportation or gas money, childcare, and time off work to travel to appointments.[30] The ability to dispense mifepristone remotely via telehealth safely eliminates these burdens.

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[29] Shannon Schumacher et al., *Health Care Experiences of Native Hawaiian or Pacific Islander Adults*, KFF (Dec. 3, 2024), https://www.kff.org/racial-equity-and-health-policy/health-care-experiences-of-native-hawaiian-or-pacific-islander-adults/.

[30] *See, e.g.*, Maleeha Aziz, *Abortion is Essential: Stories of Liberation*, American Civil Liberties Union, https://www.aclu.org/abortion-stories/maleeha-aziz (last accessed Apr. 24, 2026)

The patient populations facing these access barriers typically already face systemic healthcare inequities, and a stay of the 2023 REMS would exacerbate existing racial and economic disparities in maternal health. Indeed, studies show that Black and Indigenous patients already "face greater distances to reach an abortion provider," a disparity that could be lessened by easier access to mifepristone via telehealth and mailed or locally filled prescriptions.[31] Additional medically unnecessary restrictions on mifepristone access will ultimately worsen maternal health outcomes overall because patients will be "compelled to continue a pregnancy against [their] will, even when serious health threats exist."[32] Tragically, the United States has the highest maternal mortality rate among developed countries, and Black women "experienc[e] higher rates of maternal death than any other demographic group."[33] And without accessible abortion care, maternal mortality rates in the United States could further increase by 24% across all populations, and by a staggering 39% for Black women specifically.[34]

(describing financial and emotional cost of traveling to another state in the wake of abortion restrictions and misinformation).

31 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 2 (2023), https://publichealth.jmir.org/2023/1/e45671/PDF.

32 Elyssa Spitzer et al., *Abortion Bans Will Result in More Women Dying*, Center for American Progress (Nov. 2, 2022), https://www.americanprogress.org/article/abortion-bans-will-result-in-more-women-dying/.

33 *Id.*

34 *Id.*

Further, reducing remote access to abortion medication would increase risks to patient populations who may hesitate to attend an in-person clinic. For example, Dr. Trawick emphasizes that some immigrant patients do not feel comfortable seeking care at a hospital, and that remote access is "routine[ly]" the only way they receive care.[35] For each population, access to abortion care and miscarriage management via mail or at a local pharmacy mitigates inequities, fosters empowerment and respect for patient autonomy, and could improve overall maternal health outcomes.

C. Restrictions on dispensing mifepristone can "compound the grief patients are already experiencing."

Even when patients do not face clear geographical, transportation, time, or health barriers, longstanding medical ethics guidelines require fostering patient autonomy as part of the standard of care.[36] As Dr. Brown emphasizes, those ethical requirements mean that patients should be able to choose the manner in which they experience the end of their pregnancy, whether due to an abortion, miscarriage, or

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[35] Physicians in places that have experienced recent immigration crackdowns report that immigrant patients have canceled, missed, or postponed critical appointments because they fear being targeted at medical facilities. *See, e.g.*, Josh Marcus, *Planned Parenthood's No-show Rates in Minnesota Spike as Pregnant Women Avoid ICE, Report Says*, Independent (Feb. 2026), https://www.independent.co.uk/news/world/americas/us-politics/minnesota-ice-planned-parenthood-pregnancy-b2922306.html (no-show rates at a clinic in Minnesota spiked 8% in February 2026); *Bovino Defends Immigration Surge Tactics, Deflects Questions of Abuse*, MPR News (Jan. 2026), https://www.mprnews.org/story/2026/01/20/ice-enforcement-minneapolis-minnesota-latest-updates (patients have missed, canceled, or postponed appointments "due to the fear of being targeted by immigration officials at medical facilities.").

[36] *See generally* Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* (9th Ed. 2026).

pregnancy loss, to the greatest extent medicine permits. Dr. Olatunde sums up what all of the physicians interviewed repeatedly emphasized: the care they provide is "not one-size-fits-all," and every patient's needs "are specific to them, and it's not going to be the same for every person." According to Dr. Brown, providing physicians with "a broad toolkit" is "the most important way to make sure the [patient] can get the care they need," and taking remote abortion care or miscarriage management "out of my toolkit could prevent me from caring for a patient in the right way for that person."

Forcing all patients across the country to travel to a health center to fill their mifepristone prescription defies these basic principles of patient autonomy. For example, Dr. Trawick recalls the story of a patient who experienced a devastating fetal loss. Dr. Trawick confirmed that at-home management of this pregnancy loss was completely safe for the patient, and that "the patient desperately just wanted it to be managed at home." But there was no mifepristone available in her area, and her state does not allow physicians to mail mifepristone. Dr. Trawick explained:

> Instead of being able to receive mifepristone in the mail, which would have been perfectly safe and less disruptive to the patient and her family, the patient had to drive about 5 hours to a clinic for a procedural abortion . . . .This situation was not medically complicated, but the legal complexity only makes [physicians'] jobs harder and compounds the grief patients are already experiencing . . . . It just stinks to not be able to meet patients with the options that are medically safe for them because of regulations.

The ever-growing restrictions on reproductive health also undermine physicians' ability to provide care they know is safe and consistent with their ethical obligations. Physicians nationwide can no longer focus on managing safe, effective, patient-centered care. Instead, as Dr. Jensen reflects, reproductive health restrictions "impede[] our ability to use our medical judgment." She says that clinicians working in reproductive health have "the knowledge, the tools and the technology" to provide mifepristone remotely where appropriate without requiring medically unnecessary travel, but may be legally prevented from doing so. Dr. Brown echoes this sentiment, emphasizing that "there's just no way for policy to anticipate all of the contours of what's going on in one individual's life such that it can be written out in the law to anticipate every need for every Jane Doe patient." Dr. Trawick similarly states that the increased restrictions "[m]ake[] me constantly feel like I'm not able to provide the care for patients that they deserve and need. . . .[It] makes me feel like I'm participating in these restrictive regulations, saying you can't have this procedure here . . .that makes me feel complicit."

Requiring in-person dispensing of mifepristone on a nationwide basis would only further limit patient autonomy and physicians' ability to offer safe and effective treatment for patients ending their pregnancy or managing a pregnancy loss.

CONCLUSION

For all of the reasons set forth herein, PRH respectfully asks that this Court affirm the denial of Plaintiffs-Appellants' motion.

Dated: July 22, 2026

Respectfully submitted,

/s/ Janice Mac Avoy

Janice Mac Avoy
Counsel of Record
Laura Israel Sinrod
Anne S. Aufhauser
Kathryn Sachs
FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP
One New York Plaza
New York, New York 10004
(212) 859-8000
janice.macavoy@friedfrank.com

Corinne R. Moini
Katherine S. Borchert
FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP
801 Seventeenth Street, N.W.,
Washington, D.C. 20006

CERTIFICATE OF SERVICE

I, Janice Mac Avoy, an attorney of record in this matter, certify that on this day the foregoing *Amicus Curiae* Brief was served electronically on all parties via CM/ECF.

Dated: July 22, 2026

/s/ Janice Mac Avoy
Janice Mac Avoy
Counsel of Record

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/s/ Janice Mac Avoy
Janice Mac Avoy
Counsel of Record

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

July 23, 2026

Ms. Janice Mac Avoy
Fried, Frank, Harris, Shriver & Jacobson, L.L.P.
1 New York Plaza
New York, NY 10004

No. 26-30203 State of Louisiana v. FDA
USDC No. 6:25-CV-1491

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