No. 26-30203

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,
v.
U.S. FOOD AND DRUG ADMINISTRATION; KYLE DIAMANTAS, Acting Commissioner, U.S. Food and Drug Administration; MICHAEL DAVIS, in his official capacity as Acting Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., Secretary, U.S. Department of Health and Human Services,
Defendants-Appellees,
v.
GENBIOPRO, INCORPORATED,
Intervenor-Appellee/Cross-Appellant,
v.
DANCO LABORATORIES, L.L.C.,
Intervenor-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Western District of Louisiana
No. 6:25-cv-1491 (Hon. David C. Joseph)

BRIEF OF *AMICUS CURIAE* DOCTORS FOR AMERICA IN SUPPORT OF APPELLEES AND AFFIRMANCE OF DENIAL OF INTERIM RELIEF

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

1. No. 26-30203, *Louisiana, et al., v. Food & Drug Administration, et al.*

2. The undersigned counsel of record certifies that—in addition to the persons and entities listed in Appellants' and Appellees' Certificates of Interested Persons—the following listed persons or entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

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Pursuant to Fed. R. App. P. 26.1(a), the undersigned counsel certifies that Doctors for America is not a publicly held corporation, does not have a parent corporation, and no publicly held corporation owns ten percent or more of any entity listed above.

Respectfully submitted,

/s/ Thomas S. Leatherbury
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I. INTERESTS OF AMICUS CURIAE[1]

Doctors for America (DFA) is a national, non-partisan, non-profit organization that mobilizes over 40,000 doctors and medical trainees to advocate for policies that improve the health of patients and communities. Through advocacy training and action at state and federal levels, DFA works to expand access to affordable care, promote community health and prevention, and advance health justice and equity. DFA does not accept funding from pharmaceutical companies, medical device manufacturers, insurance companies, or for-profit healthcare entities, allowing us to remain fiercely independent and patient-centered in our work. DFA is the organization that puts *patients over politics* and *patients over profits*.

To support its mission, DFA formed a Food and Drug Administration (FDA) Task Force to educate, mobilize, and empower a multispecialty group of clinicians to provide unbiased expertise to evaluate and respond to the FDA regulatory process in a way that

[1] Pursuant to Fed. R. App. P. 29(a)(2), all parties consent to the filing of this brief. No party's counsel authored this brief in whole or in part; no party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief; and no other person than *Amicus*, its counsel and associated paraprofessionals made such a contribution. See Fed. R. App. P. 29(a)(4)(E).

maximizes meaningful clinical outcomes for patients. To support an FDA that puts patients first, the FDA Task Force has advocated patient-centered regulatory reform through public testimony, op-eds, educational meetings with policymakers, and more. For example, DFA's FDA Task Force has written letters, testified, and met with policymakers to advocate reforms to the Prescription Drug User Fee Act (PDUFA) to make user fee agreements more patient-centered, ensuring both timely access to drugs and biologic medicines and timely collection of data by the FDA, to prove these medicines' effectiveness and safety.[2] Some of the reforms that the DFA FDA Task Force advocated for were included in the Food and Drug Omnibus Reform Act passed at the end of 2022.[3] Recently, DFA's FDA Task Force also advocated the addition of miscarriage[4] management as an indication to mifepristone's label "[t]o

[2] Ensuring Safe and Effective Drugs and Biologics: Hearing on FDA User Fee Reauthorization Before the U.S. Comm. On Health, 117th Cong. (2022) (written testimony of Reshma Ramachandran, M.D., M.P.P., Leader, FDA Task Force, Drs. For Am.).

[3] Press Release, Kyle Shields, Doctors for America's FDA Task Force Applauds Senate End of Year Package, Drs. For Am. (Dec. 20, 2022), https://www.doctorsforamerica.org/news/press-release-doctors-for-americas-fda-task-force-applauds-senate-end-of-year-package.

[4] The terms "miscarriage" and "early pregnancy loss" are used interchangeably. *See* Am. Coll. Of Obstetricians & Gynecologists, *Practice Bulletin No. 200: Early Pregnancy Loss*, 132 Obstetrics & Gynecology e197 (2018).

ensure access to the safest and most effective treatments for miscarriage, and to preserve patient choice in miscarriage management."[5]

Amicus has a strong interest in protecting the autonomy of patients and clinicians and upholding evidence-based medical care. *Amicus* highlights the ways in which dispensing mifepristone by mail or through pharmacies supports clinicians' practices and patients' health across the United States. Modifying the 2023 federal Risk Evaluation Mitigation Strategy (2023 REMS)[6] to reinstate an in-person dispensing requirement would impose restrictions on access to mifepristone that would disrupt medical practice, including the management of early pregnancy loss (miscarriage), with no medical justification. If the FDA were to limit the ability of clinicians nationwide to safely manage miscarriage and other

[5] Citizen Petition from the Am. Coll. Of Obstetricians and Gynecologists to Lauren Roth, Assoc. Comm'r for Pol'y, FDA (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.

[6] U.S. Food & Drug Admin., Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation (current as of Jan 1, 2025, approved Jan. 3, 2023, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation; U.S. Food & Drug Admin., Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, (current as of April 8, 2026), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

common obstetric conditions, DFA clinicians would be unable to provide their patients with the most up-to-date, evidence-based care. DFA respectfully ask the Court to affirm the denial of interim relief and not to stay the 2023 REMS.

II. SUMMARY OF ARGUMENT

Clinicians across the country wish to express their concerns about staying the 2023 REMS for mifepristone to reimpose an in-person dispensing requirement. Any reimposition of the in-person dispensing requirement would obstruct safe and effective care to patients in need and consequently threaten public health. *Amicus* emphasizes the profound harms to American health care that would flow if the Court rewrites the 2023 REMS.

Reinstating an in-person dispensing requirement for mifepristone would preclude certified clinicians from mailing the medication or prescribing it through a certified pharmacy, greatly diminishing patients' ability to access medical care involving mifepristone via telehealth.[7] Instead, mifepristone would be dispensable only in person in specific healthcare settings, a particularly burdensome requirement for patients

[7] U.S. Food & Drug Admin., Information about Mifepristone, *supra* note 6.

in rural America. Limiting access to mifepristone would do more than inconvenience patients with medically unnecessary and burdensome barriers to care; it would force them to choose either more invasive procedures or less common protocols. Limiting access to mifepristone thus inhibits clinicians' ability to provide treatment that is grounded in robust scientific data proving safety and efficacy, whether dispensed at home or in a doctor's office.

This brief contains firsthand accounts from clinicians across practice areas and across the country about the safety of mifepristone and the harms that medically unnecessary restrictions on mifepristone access would cause.[8] In the narratives that follow, clinicians explain that the in-person dispensing requirement for mifepristone would negatively impact miscarriage management and abortion care, particularly for patients in rural areas that are obstetric care deserts. These accounts, in clinicians' own words, describe how restricting access to mifepristone could jeopardize their ability to provide safe and effective health care, undermine the patient-clinician relationship, and interfere with

[8] All of the clinicians herein are members of Doctors for America. DFA counsel interviewed them in conjunction with this case or in connection with *All. for Hippocratic Med. v. United States FDA*, 668 F. Supp. 3d 507 (N.D. Tex. 2023).

clinicians' ethical obligations to their patients by restricting access to an evidence-based protocol.

III. ARGUMENT

A. Clinicians emphasize that mifepristone is safe and effective for both abortion care and managing early pregnancy loss.

Medical research has consistently demonstrated that mifepristone is safe and effective, and that significant adverse events and outcomes are exceedingly rare, occurring in less than a fraction of 1% of cases.[9] Adverse event data tracked by the FDA since the approval of mifepristone reveals that mifepristone has an exceptionally low mortality rate: 0.48 deaths per 100,000 cases.[10] Mifepristone has a lower mortality rate than other common medications like sildenafil (Viagra), which has a mortality rate roughly six times greater than mifepristone, and penicillin, which has a mortality rate three times greater than

[9] Kelly Cleland et al., Significant Adverse Events and Outcomes After Medical Abortion, 121 Obstetrics & Gynecology, 166, 166 (2013); *see also Safety and Effectiveness of First-trimester Medication Abortion in the United States*, Advancing New Standards in Reprod. Health (May 3, 2021), https://www.ansirh.org/sites/default/files/2021-06/medicationabortion-safety_2021_FINAL.pdf.

[10] Analysis of Medication "Abortion Risk and the FDA Report" Mifepristone US Post-Marketing Adverse Events Summary through 12/31/2024," Advancing Standards in Reproductive. Health (May 2025), https://www.ansirh.org/sites/default/files/2025-05/Issue%20Brief%20MAB%20SAEs-May2025%20Final_0.pdf.

mifepristone.[11] Neither sildenafil nor penicillin is subject to any Risk Evaluation Mitigation Strategy,[12] and both are available via telehealth subject to state regulation.

These statistics are not abstractions. They are borne out by the daily experience of the certified clinicians who prescribe and monitor mifepristone use among their patients. Dr. Beth Oller is a family medicine physician who received her MD from the University of Kansas School of Medicine. She is a co-owner of a family medicine practice in Stockton and practices at Rooks County Health Center, a critical care facility in rural, northwestern Kansas. Dr. Oller describes why, despite its strong safety profile, data may show an increase in emergency room visits after taking mifepristone:

> When I advise my patients of the risks, we've always quoted something like 3 to 5% follow up in the emergency room. If you look at actual data, and I just looked it up in my patient data base, 5% would be the highest number of patients who visit the emergency room after taking mifepristone.
>
> But guess what? Most are not actual medical emergencies. I am not faulting patients for going to the emergency room. If a

[11] *Id.*

[12] Neither medication is on the FDA's list of Approved Risk Evaluation and Mitigation Strategies. U.S. Food & Drug Admin., *Approved Risk Evaluation and Mitigation Strategies*, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (last visited July 11, 2026).

> patient calls us, especially after hours, and they say: "I feel like I'm bleeding a ton. I am super worried about this." What are you going to say? "Do what you need to do. And if you need to go into the emergency room, do it."
>
> Most of the time, it's reassurance in the emergency room. Most of the time, they look at your hemoglobin to make sure it's okay and monitor your bleeding for a couple hours. And most of the time, everything is okay.
>
> I had a natural miscarriage. I'm a doctor who's done this a long time. I was shocked at how much I bled. I can remember taking a bath to feel better and looking down and being like, the water is red and thinking, I'm going to call my OBGYN friend to see if this is okay. I am a doctor, and I was worried about the amount of bleeding.
>
> So, the majority of the time, when patients who take mifepristone go into the ER, it's because they're anxious about it and they get there and nothing ends up needing to be done.
>
> And you know when that also happens? When people are naturally miscarrying.
>
> Most are not going into the ER with severe medical emergencies or with something that needs to be done. You've got to differentiate why are they there.

Dr. Kristin Lyerly is an OB/GYN who practiced for most of her career in northeast Wisconsin and most recently as a locum tenum in northern Minnesota. She earned her MD and Master of Public Health degrees from the University of Wisconsin, where she also completed her residency in obstetrics and gynecology. Dr. Lyerly echoes Dr. Oller's

comments about the safety of mifepristone, showing again that the medication is safe, and that its use does not lead to a meaningful increase in actual emergencies:

> We have 25 years of data, evidence, and experience in the United States that tells us that mifepristone is safe and effective. And there's much more data internationally. We know this is safe.
>
> But I'll tell you, as a physician, if my patient calls me and says, "I'm worried, I think I'm bleeding too much", I'm going to say go in and get evaluated.
>
> And, often, as the doctor who receives these patients in emergency rooms, all I offer is reassurance. Yes, some patients need a dilation and curettage (D&C) to get rid of all retained products. And some patients need an extra dose of the medication. But, most of the time, patients who have taken medication for early pregnancy loss just need reassurance that everything's going to be okay.
>
> People are so afraid because there is so much misinformation out there, and this negative information is trying to perpetuate fear that mifepristone is unsafe. Of course, if you're taking it, you're going to feel somewhat concerned about it. And sometimes you do just need somebody who you feel like you can trust, who can evaluate you and say, "Nope, everything's okay. You're going to be okay." But my favorite thing to do is say, "If you're not okay, if you go home and something changes, I'm going to be right here. So just come on back."

Simply counting emergency room visits by those who have taken mifepristone does not equate to actual emergencies caused by the

medication. That reality, confirmed by the physicians who prescribe mifepristone and staff the emergency rooms, underscores a conclusion twenty-five years of data already compel: Mifepristone is safe and effective.

B. Clinicians underscore that mifepristone is a standard treatment option not only for abortion care but also for early pregnancy loss.

Miscarriage is not a rare misfortune. Rather, it is one of the most common experiences in reproductive medicine. Every year in the United States, more than a million women—approximately one in ten—lose a clinically recognized pregnancy.[13] A significant percentage of those miscarriages occur in the first trimester, clinically referred to as "early pregnancy loss."[14]

When a miscarriage is diagnosed and the body does not expel all of the tissue, the clinical question is how to complete the pregnancy loss safely, promptly, and in a way that the patient prefers. At this point, the pregnancy has ended, and treatment involves one or more of the

[13] Am. Coll. of Obstetricians & Gynecologists, *Improving Access to Mifepristone for Reproductive Health Indications* (June 2018), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.

[14] Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 200, supra* note 4.

following: expectant management (waiting for the body to expel the pregnancy naturally, a process that can take days or weeks and carries some risk of heavy bleeding or infection due to the tissue remaining in the body); surgical management (otherwise known as a uterine aspiration, or a D&C, a process that requires a clinical facility with a procedure/operating room, trained personnel, and anesthesia or sedation); and medical management (medication to help the woman's body complete the miscarriage on a more predictable timeline and usually at home).[15]

The most effective treatment option for medication management of early pregnancy loss (miscarriage) is mifepristone taken in combination with misoprostol.[16] For successful management of early pregnancy loss, mifepristone followed by treatment with misoprostol is over 83% effective versus 67% for misoprostol alone, and mifepristone followed by

[15] *Id.*

[16] Honor Macnaughton, Melissa Nothnagle & Jessica Early, *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 Am. Fam. Physician 473, 473–74 (2021).

misoprostol reduces the need for follow-on surgical uterine aspiration from 23.5% to 8.8%.[17]

As the following clinicians' accounts affirm, if medically unnecessary restrictions were imposed on access to mifepristone, these restrictions would not make treatment safer. As these clinicians describe, restricting mifepristone would undermine their ability to safely and effectively manage early pregnancy loss. This, in turn, would likely heighten the physical and emotional trauma already associated with miscarriage.

Dr. Cynthia Davis is an OB/GYN in South Dakota. She attended medical school at the University of Florida and completed her residency at the University of Colorado. Dr. Davis underscores the importance of mifepristone for treating early pregnancy loss and the significant medical and ethical difficulties that she already observes due to limited access to mifepristone in her state:

> I speak from the experience of an obstetrician-gynecologist in a state where it has always been very difficult to obtain mifepristone due to stigma as well as the physician and

[17] Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Eng. J. Med. 2161, 2161 (2018). While the mifepristone-misoprostol protocol is more effective at managing early pregnancy loss, a misoprostol-only regimen remains within the standard of care. Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 200, supra* note 4.

pharmacy certification requirements. I am not an abortion provider, but I can tell you that the difficulty of obtaining this drug in treating pregnancy loss has significantly harmed many of my patients.

Given how common first-trimester pregnancy loss is, this treatment delay, often resulting in significant bleeding, infection, and psychological trauma, is devastating. I have seen this result in women requiring blood transfusions and surgeries they otherwise would not have needed had they been able to access mifepristone earlier in the process. I have seen women avoid any future pregnancies for fear of similar recurring trauma.

Of course, other options exist to treat the clinical situations mentioned above. However, expectant management can result in acute bleeding episodes, increased risk of infection, anxiety, and depression, which I have witnessed in multiple patients over the years. Surgical management is extremely safe but, as with any medical procedure, there are still risks, including bleeding, infection, uterine scarring resulting in infertility, and uterine perforation with possible damage to the bowel, bladder, or blood vessels. In addition, the costs associated with surgical management are often more than the family can absorb. And although there can be complications related to any medication, I have found mifepristone to be effective and safe in my many years of experience (over 30 years).

It is heartbreaking to watch a family go through the difficulties related to pregnancy loss and, more so, to watch harm come to our patients. Interference in the doctor-patient relationship by making mifepristone less accessible disrespects the sacred relationship between doctor and patient, not to mention the expertise in a physician's medical training.

Dr. Amy Kaleka is a family medicine clinician in Wisconsin. She attended medical school at Central America Health Sciences University and completed her residency in family medicine at Virginia Tech Carilion School of Medicine. Dr. Kaleka explains how restricted access to mifepristone would impede management of early miscarriage:

> Imposing unnecessary restrictions on mifepristone could prevent me from being able to safely manage miscarriages in early pregnancy.
>
> Mifepristone is vital to providing safe care for early pregnancy loss. Increasing restrictions on medications that can improve safety outcomes of pregnant patients will inevitably lead to worse maternal outcomes. As providers, we do our best to perform safe and high-quality care to prevent complications. The availability of mifepristone allows me to provide safe and high-quality miscarriage management care to patients, reducing their likelihood of complications which ultimately reduces health care costs by avoiding hospitalizations. The use of this medicine is vital for medication management of miscarriages per the latest medical guidelines. I hope to continue to provide safe obstetric care, which involves mifepristone as an option for pregnant patients for both miscarriage and abortion care.

Dr. Cheryl Hamlin is an OB/GYN who practices in Massachusetts. She attended medical school at the University of Illinois and completed her residency at Boston Medical Center. Dr. Hamlin provides a firsthand account of mifepristone's ability to expand access to care:

> The mifepristone/misoprostol regimen is our preferred course of care for early pregnancy loss. Mifepristone is widely used both as a medication used to terminate pregnancy as well as for medical management of a miscarriage. Patients who wish to avoid a D&C have the option of medical management for both miscarriage and termination of pregnancy. Imposition of unnecessary limits on access to mifepristone would significantly affect the options, and therefore the health, of those in need of this treatment.
>
> Yes, misoprostol alone may be safely used for both induced abortions and miscarriages, but the addition of mifepristone is more effective, reducing the risk of potential complications from an incomplete miscarriage.
>
> Not having the full range of options to offer my patients would adversely affect my patients, potentially delaying care, causing them to require more invasive procedures and subjecting them to the associated risks. Mifepristone must remain widely accessible to those for whom the best option is a medication procedure.

Dr. Jane Doe I is a family medicine clinician practicing on the West Coast who has asked to remain anonymous. Dr. Doe I highlights the importance of the safety of the mifepristone/misoprostol regimen and the risks associated for patients who are unable to access mifepristone.

> As a family medicine physician, I frequently work with patients during their early pregnancy. Unfortunately, some of my patients' pregnancies end in miscarriage. When this is the case, I use a combination of the medications mifepristone and misoprostol to treat my patients.
>
> A mifepristone/misoprostol treatment regimen is the gold standard in the medical management of a missed miscarriage,

> also known as a silent miscarriage, where parts of the products of conception have not passed and remain in the uterus. The addition of mifepristone improves the likelihood of a successful passage of products of conception. When patients take mifepristone and misoprostol, the combination imposes less risk of prolonged bleeding, infection, and the need for surgical procedures.
>
> Personally, I was unable to access mifepristone as a patient suffering from a silent miscarriage. I have had repeated pregnancy loss and had to use medications to complete the passage of the products of conception. Restrictions on medication, such as mifepristone, put my patients and me at risk of adverse outcomes.

As these clinicians highlight, mifepristone is critical for managing early pregnancy loss (miscarriage) safely and effectively, and minimizing the need for subsequent procedures. Requiring that mifepristone be dispensed in person, as opposed to by mail or at a certified pharmacy, could effectively result in misoprostol being the only medication option for management of early pregnancy loss. Such a prospect is not in patients' best interests.

Medicine is practiced as a shared decision-making process between the clinician and patient.[18] For certain patients, offering misoprostol

[18] Am. Coll. of Obstetricians and Gynecologists, Comm. Opinion No. 819, *Informed Consent and Shared Decision Making in Obstetrics and Gynecology*, 137(2), e34-e41, Obstetrics. & Gynecology (Feb. 2021).

alone or pursuing expectant or surgical management might be the indicated course of care that a clinician and their patient agree upon. But other patients determine in consultation with their clinician that mifepristone and misoprostol is the preferred option based on their individual therapeutic and psychological needs. Imposing unnecessary restrictions on access to mifepristone could limit clinicians' ability to help their patients make the choices that are safest and best for them, worsening maternal outcomes.[19]

C. Clinicians highlight how an in-person dispensing requirement would diminish mifepristone access for rural patients, as well as those suffering from abuse and trafficking, threatening their health and safety.

As several clinicians have highlighted, for patients suffering an early pregnancy loss and an incomplete miscarriage, a combined

[19] Soc'y for Maternal-Fetal Med. et al, *Leading Medical Organizations Respond to Recent Court Decisions on Access to Mifepristone*, Soc'y for Maternal-Fetal Med. (May 6, 2026) https://www.smfm.org/news/leading-medical-organizations-respond-to-recent-court-decisions-on-access-to-mifepristone ("In-person fulfillment requirements for mifepristone do nothing to enhance or ensure the safety of a drug already deemed safe. Rather, they impose medically unnecessary burdens, lead to delays in care, and worsen health inequities for patients across the country."); Jack Resneck, Jr., *Reducing Access to Mifepristone Would Harm Patients*, Am. Med. Assoc. (Mar. 25, 2024) https://www.ama-assn.org/about/leadership/reducing-access-mifepristone-would-harm-patients ("Reimposing unnecessary limits on mifepristone, which is used in the two-drug protocol for medication abortion and miscarriage management, will jeopardize public health and significantly worsen inequities in maternal health for people of color, those with low incomes and those living in underserved communities.").

mifepristone/misoprostol regimen is the best option.[20] An in-person dispensing requirement will burden patients.

Patients may need to access medication through the mail or at a pharmacy for various reasons, some intensely personal, including privacy, time constraints, financial pressures, transportation, or other practical concerns.[21] Many rural patients prefer the relative accessibility of medical care through a telehealth provider and medication via mail. Consider the vast expanses of Nevada and New Mexico, or those rural Michiganders or Minnesotans near the Canadian border. Over a third of all counties in the United States are maternity care deserts, meaning the county has no hospital or birthing center that offers obstetric care and also has no obstetric clinicians,[22] and over half of U.S. counties lack a

[20] Schreiber, *supra* note 17; Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 200*, *supra* note 4.

[21] Melissa Quinn & Joe Walsh, *Supreme Court Upholds Mail Access to Abortion Pill Mifepristone for Now*, CBS News (May 14, 2026, 6:13 PM ET) https://www.cbsnews.com/news/supreme-court-abortion-pill-mifepristone-ruling; The Assoc. Press, *Court Restricts Abortion Access Across the U.S. by Blocking the Mailing of Mifepristone*, NPR (May 2, 2026, 3:58 PM ET) https://www.npr.org/2026/05/01/nx-s1-5808328/court-restricts-abortion-access-mailing-mifepristone.

[22] March of Dimes, *Nowhere to Go: Maternity Care Deserts Across the US* (Report No. 4) (2024), https://www.marchofdimes.org/peristats/assets/s3/reports/2024-Maternity-Care-Report.pdf, at 8.

hospital that provides obstetric care.[23] The majority of these counties are rural.

Rural families often live far from the nearest pharmacy or clinician's office. For many patients, the only practical option is to obtain mifepristone through the mail. Requiring that mifepristone be dispensed in-person in certain health care settings effectively mandates that this country's rural patients overcome travel obstacles and incur burdensome expense to receive the care they need.

Clinicians underscore that it is medically unnecessary that patients be physically present in certain healthcare settings to safely receive mifepristone. They recount that ability to physically travel to a doctor's office to fill their mifepristone prescription is a significant hurdle for many patients who are poor or lack access to transportation or live in a growing number of maternity care deserts. Dr. Hamlin noted that, even in states where access to care is widely available, there can be vast areas where in-person care is non-existent. For example, Cape Cod and the Islands in Massachusetts represent an underserved area, where driving to Boston—or taking a ferry—adds, at times, insurmountable barriers.

[23] *Id.* at 16.

In those and other underserved areas, further limitations on mifepristone access, including requiring in-person dispensing and precluding people from receiving their medication by mail or at a local pharmacy, would burden patients with an arduous, additional journey.

Dr. Maria Phillis is a maternal fetal medicine physician in Cleveland, Ohio. She attended medical school at Johns Hopkins University and completed her residency in OB/GYN at University Hospitals Cleveland Medical Center. Drawing on that expertise, Dr. Phillis is unequivocal that access to mifepristone when it is prescribed via telemedicine and dispensed by mail or pharmacy is not a convenience but a medical necessity for patients facing barriers to in-person care.

> Mifepristone is an incredibly safe drug and medication; there are more side effects from a variety of other medications, some of which are over the counter, and some of which are easily prescribed via telehealth without any restrictions or REMS. Doctors have been safely prescribing mifepristone in the United States for years, and even longer in some European countries. Based on my experience, we have not seen a sudden increase in people coming into the emergency room because they had an adverse effect from mifepristone.
>
> The medical field recognizes that patients may have significant barriers to accessing care in general, not just abortion care, and that makes access to mifepristone via telehealth all the more important. People may have difficulty obtaining transportation to a clinic, finding childcare, paying for a doctor's visit, or any number of other difficulties that

> may keep them from seeing a doctor. When someone experiences these difficulties, it delays the care we are able to provide them and exposes them to greater risk.
>
> It is incredibly important that mifepristone remain accessible through telehealth. Telehealth access may be the only access a patient has to mifepristone, and there is no detriment a patient would suffer from accessing care via telehealth compared with an in-person clinic.

One OB/GYN practicing in Western New York who wishes to remain anonymous, Dr. Jane Doe II, describes how requiring in-person visits for care that can be safely provided through telehealth and mail or pharmacy dispensing imposes significant burdens on patients, particularly those facing geographic, financial or caregiving barriers.

> Mifepristone is an incredibly safe medication. An in-person requirement for dispensing mifepristone provides only additional barriers to care without benefits. As a provider in Western New York, I have had patients travel multiple hours to receive in-person care that could have easily gotten care through telemedicine. An in-person requirement creates a huge barrier to patients who don't have easy access to transportation, or who have financial or childcare restrictions that limit their ability to travel.

Dr. Oller describes the valuable role telehealth and mail or pharmacy dispensing plays in managing patients' early pregnancy loss without adding undue burden or strain, especially on patients who face barriers like transportation limitations, travel distance, work

obligations, childcare responsibilities, or provider and facility shortages, all of which affect patients' ability to access care.

> Many of my patients drive an hour to see me, and in the in between, they are getting an ultrasound, getting initial hCG levels tested,[24] figuring out if indeed this is a miscarriage. Having that patient come in for every single touch is just not feasible, but telehealth allows you to look at them and to make sure that they are understanding your instructions. When somebody is bleeding and cramping heavily and going through a pregnancy loss, telehealth allows you to visit with them, to talk them through what's going on or do a follow-up check-in, without the patient having to come into the office.
>
> Pregnancy loss is painful enough without missing several days of work and without driving back and forth to doctors at great distance. And now add that I'm really not very comfortable because I'm not feeling great because I am going through this pregnancy loss process. Why do I have to come in?
>
> That ability to do telemedicine in between can be absolutely crucial. I have had patients that have said, "I'm not going to be able to get into your office for a couple of days. I will not be able to get there. I don't have transportation. I don't have childcare. I have to work." I don't want you to have to wait. All the time we're waiting, we're increasing the risk of sepsis.

[24] Human chorionic gonadotropin (hCG) is a hormone produced after implantation; it becomes detectable within days of implantation and, in a normally developing intrauterine pregnancy, rises at a predictable rate during the first trimester. *See* Danielle Betz & Kathleen Fane, *Human Chorionic Gonadotropin*, StatPearls Pub. (Apr. 27, 2025), https://www.ncbi.nlm.nih.gov/books/NBK532950. Clinicians measure hCG to help distinguish among a viable intrauterine pregnancy, a failing or completed miscarriage, and an ectopic pregnancy, particularly where ultrasonography is nondiagnostic or unavailable. *See* Betz & Fane, *supra*; Linda W. Prine & Honor MacNaughton, *Office Management of Early Pregnancy Loss*, 84 Am. Fam. Physician 75, 77–78 (2011).

> We're increasing the risk that something can happen. And so telehealth and dispensing through a pharmacy has been the difference between I can get in with you in two or three days and I can get in with you now.
>
> Life happens even in big cities. But you add in the rural dimension, and you add in the socioeconomic stressors of gas, reliable transportation, jobs that often don't offer a lot of sick days or time off, difficulty with childcare and rearranging schedules. Telehealth is the difference between delaying care and increasing the risk of complications and being able to treat the patient safely and effectively right away.

Dr. Andrea Palmer is an OB/GYN who practices in Ontario, Canada, and formerly practiced in Fort Worth, Texas. She graduated from the University of Oklahoma College of Medicine and completed her residency in OB/GYN at OU Health Sciences Center. Dr. Palmer describes the difference remote dispensing of mifepristone could have made for her patients while they dealt with the grief of losing a pregnancy and the anxiety that comes with making difficult health decisions:

> If I would have been able to do something like telehealth with my Texas patients, that would have made a difference. When I see a miscarriage patient in person, a lot of women want to think about what they're going to do. They're busy grieving the loss of the pregnancy. And so making a decision like how you're going to treat the miscarriage is more than a lot of patients have the emotional room for.
>
> It's hard to make a good decision when you're grieving. And so I would let them go home. My nurses would call them a day or two later to check in. Have they made a decision? Do they

> want to come back for another ultrasound? That was always an evolving conversation. But if telehealth were an option for those patients who did live far away, and I would have been able to prescribe mifepristone in that situation, I 100% would have done it.

Dr. Andrea Contreras graduated from Baylor College of Medicine and completed her residency training in Texas. She is completing her fellowship in Complex Family Planning. Dr. Contreras recounted the experience of a patient diagnosed with an early pregnancy loss who, after learning of her treatment options, needed time to process the diagnosis before deciding how to proceed. When she later chose medication management with mifepristone, difficulties in accessing mifepristone obstructed Dr. Contreras's patient in obtaining the prescribed treatment, delaying care during an already painful and emotionally overwhelming experience.

> We had a patient that was diagnosed with an early pregnancy loss. This was a very desired pregnancy for her. We had done multiple ultrasounds over a six-to-eight week time frame. And, most of the time that's usually our limit on expectant management, where most people pass the pregnancy by the eight-week mark.
>
> At eight weeks this patient had some persistent spotting and a little bit of cramping. She was still reluctant to take the medications. And because we know that people are competent and are able to take medications, we offered to send her home with them since we were able to dispense them at our clinic.

She wasn't ready. Two days later, she called us and she said that she wanted the medication (the mifepristone and misoprostol regimen).

That's when we went down this whole rabbit hole trying to find a pharmacy that would be able to dispense mifepristone because, even under the current regulations, mifepristone is not readily available in many places.[25] We sent the prescription to one pharmacy to fill. After the pharmacist had agreed to fill the prescription, the management of the chain pharmacy declined. So, then we had to go to a different pharmacy. I was a lot of yes, no, with different people within the same pharmacies giving us different answers. But at least the patient was able to get the prescription filled from a pharmacy that was closer to her, which would not be available to her if the in-person dispensing requirement is re-instated. …

Sometimes when patients have an early pregnancy loss (also known as a missed abortion), their body might try to pass the pregnancy. They might have cramping and bleeding that can be persistent. That bleeding can get pretty heavy. And depending on the patient and their wishes, they might not be able to go to the hospital. Others may just be bleeding enough that they don't need to go to the hospital, but over time it accumulates. They can have significant amounts of blood loss, anemia, and they might become symptomatic and need iron supplementation or blood transfusions. Or they can have very heavy bleeding and require emergency surgery and transfusions, etc. Whereas if the patient had received the medication promptly, yes, it would have caused bleeding and cramping, but it would have been in a more controlled manner where they might have passed a pregnancy sooner and not

[25] Even under the existing 2023 REMS, only certified health care providers may prescribe mifepristone, and it "may only be dispensed by or under the supervision of a certified prescriber, or by a certified pharmacy on a prescription issued by a certified prescriber." U.S. Food & Drug Admin., Information about Mifepristone, *supra* note 6.

> required the transfusion, the emergency room visit, or the surgery.

Meanwhile, patients who are victims of abuse, including rape or incest, may prefer medication abortion prescribed through telehealth and dispensed by mail or at a pharmacy to procedural abortion in a clinic for another reason: the minimal invasiveness of medication abortion can lower the risk of re-traumatization.[26] Providing them with the option of medication abortion through telehealth and mail or pharmacy dispensing is essential to respect their autonomy.[27] Additionally, receiving medication by mail or pharmacy permits privacy that can be critically important in evading the control of a trafficker or abuser. Dr. Davis

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[26] Resneck, Jr., *supra* note 19 ("Forced pregnancy and denial of abortion care have been shown to lead to worse health and economic outcomes for women and increased exposure to intimate partner violence."); *See also* Decl. Of Katherine B. Glaser, M.D., Ex. 7, at 6, *All. For Hippocratic Med. V. FDA*, No. 2:22-cv-00223 (N.D. Tex. Jan. 13, 2023).

[27] *Understanding Domestic Violence and Abortion Access,* Connections for Abused Women and their Children (July 7, 2023), https://www.cawc.org/news/understanding-domestic-violence-and-abortion-access; Elizabeth Tobin-Tyler et al., Restricting Access to Medication Abortion Will Not Help Survivors of Intimate Partner Violence, Health Affairs (Feb. 26, 2026), https://www.healthaffairs.org/content/forefront/restricting-access-medication-abortion-not-help-survivors-intimate-partner-violence; Sarah Varney & Rachel Wellford, *Abortion Restrictions may be Fueling a Rise in Domestic Violence, Experts Warn*, PBS News (Oct. 16, 2026, 6:25 PM ET), https://www.pbs.org/newshour/show/abortion-restrictions-may-be-fueling-a-rise-in-domestic-violence-experts-warn.

shares her experience with a patient facing pregnancy loss after being trafficked and lacking the ability to get proper care or help:

> Access to miscarriage care is essential medicine, and in many cases, access via telemedicine is critical. I work in the middle of South Dakota, a maternity desert. I serve a diverse population including Native Americans, farmers and ranchers, Hutterites, and more. Some women face challenges of physically coming in for care because of sheer distance, lack of transportation, and poverty. Weather challenges in South Dakota can include impassable roads during our snowy winters which often make transferring very sick patients to our high-level care hospital virtually impossible.
>
> But others face more complicated challenges related to abuse and trafficking. I had a patient who was picked up by strangers while simply walking along a road outdoors. She was trafficked to the nearest larger city for a weekend and became pregnant. The traffickers threatened her life, as well as the lives of her family, if she spoke to anyone about the circumstances of her pregnancy. And she lived quite a distance from any in-person clinic without ready access to transportation and without financial resources to pay for care. Consequently, she did not seek medical help for her first-trimester pregnancy loss and did not come in for an evaluation until the situation had mushroomed into an emergency. I saw her for the first time when she arrived by ambulance with concerns about late first trimester excessive bleeding, requiring a blood transfusion and an emergency D&C.
>
> This could have been avoided if she had a safe way to contact the local OB/GYN (me). In this case, access to telemedicine with the option of remote medical management of her pregnancy loss could have prevented this horrible outcome. We likely could have avoided the medical complications as well as the trauma all of this put my patient through.

Dr. Alisha Miller, a board-certified family medicine physician who graduated from Virginia Commonwealth University School of Medicine and completed her residency at the University of South Florida Morsani College of Medicine, and practices in western Pennsylvania, succinctly captured the indispensable role telehealth plays in delivering patient care: "Six years ago, before the pandemic, we didn't know how to do it, and now we could not practice medicine without it." Patients experiencing early pregnancy loss may simply have no other option to obtain mifepristone except through a telehealth provider and medication delivered via mail or picked up at a pharmacy.

IV. CONCLUSION

For the foregoing reasons, DFA respectfully asks the Court affirm the denial of all requested interim relief.

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Respectfully submitted,[28]

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[28] Counsel thanks University of Tulsa law students Melody Reed and Eli Feck for their invaluable work on this brief.

CERTIFICATES OF SERVICE AND ECF COMPLIANCE

I hereby certify that on July 21, 2026, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system. I also certify that: 1) All required privacy redactions have been made in compliance with 5th Cir.R.25.2.13; 2) The electronic submission is an exact copy of any paper document generated in this matter in compliance with 5th Cir.R.25.2.1.; and 3) The document has been scanned for viruses with the most recent version of Microsoft Defender for Endpoint and CrowdStrike Falcon and is free of viruses.

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CERTIFICATE OF COMPLIANCE

This brief contains 6,499 words, as determined by the word-count function of Microsoft Word, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface in Century Schoolbook font size 14 with footnotes in font size 12.

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