No. 26-30203

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 & 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,

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-01491)
The Honorable David C. Joseph, U.S. District Judge

BRIEF OF AMICI CURIAE 438 STATE LEGISLATORS IN SUPPORT OF DEFENDANTS-APPELLEES

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 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.

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Amici: Amici are 438 state legislators who were elected and legislate to protect their constituents' access to healthcare, including reproductive healthcare. A full list of amici curiae is in the attached Addendum.

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INTEREST OF AMICI CURIAE

Amici curiae[1] Kim Jackson, Analise Ortiz, Sara Love, *et al*. are 438 state legislators from across the United States, representing every state. They include State Senators, Representatives, and Assemblymembers representing constituents in both "red" and "blue" states and districts. A full list of amici is provided in Addendum A.

Consistent with the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), that "the authority to regulate abortion must be returned to the people and their elected representatives," amici have been legislating to address abortion access issues based on the needs, values, and desires of the constituents they were elected to represent. Some amici represent constituents in states where the provision of abortion care has been fully or partially banned. Others represent constituents in states that protect abortion access, including the provision of care via telemedicine and mail and pharmacy dispensing after the Food and Drug Administration ("FDA") issued its

[1] Amici affirm that no counsel for a party authored this brief in whole or in part and that no person or entity other than amici or their counsel made a monetary contribution to its preparation or submission. All parties have consented to this amicus curiae brief.

2023 Risk Evaluation and Mitigation Strategy ("REMS"), eliminating the in-person dispensing requirement for mifepristone, a medication that has been safely prescribed for over 25 years for abortion and miscarriage care.

Amici legislators submit this brief supporting Defendants-Appellees and Intervenors-Appellees because the relief Plaintiffs-Appellants request—a stay of the FDA's 2023 REMS—takes decisions about reproductive healthcare out of the hands of state legislators and their constituents nationwide. Reimposing a burdensome and unnecessary in-person dispensing requirement would undermine amici's constituents' ability to obtain mifepristone even in states where access to abortion is lawful and protected.

Amici ask this Court to affirm the district court's denial of Louisiana's preliminary injunction motion and thereby maintain state legislators' authority to determine reproductive healthcare policy.

INTRODUCTION

Contrary to the plaintiffs' arguments, the FDA's decision to remove the mifepristone REMS in-person dispensing requirement was sound and well-supported. It improved amici's constituents' access to reproductive healthcare—and thereby their lives.

Whether they live in rural, urban, or suburban areas, many of amici legislators' constituents have limited access to healthcare due to geography, scarcity of providers, and/or personal circumstances. The expansion of healthcare access via telemedicine and mail or pharmacy delivery has been a huge boon to amici's constituents. That is only more so when it comes to reproductive healthcare, and abortion care specifically. The in-person dispensing requirement was a significant impediment to many constituents seeking abortion care because it forced them to travel unnecessarily to obtain a safe and effective medication. Amici legislators have worked to try to reduce the barriers to obtaining reproductive and abortion care, including by legislating to facilitate the provision of such care via telemedicine and through mail or local pharmacy dispensing of mifepristone.

As legislators responsible for advocating for policies that support their constituents' health and well-being, amici have closely followed the FDA's decisions on mifepristone, and they reject the unsubstantiated suggestion that eliminating the in-person dispensing requirement was not sound and well-supported. A robust body of evidence shows that mifepristone can safely be used when dispensed by mail and at

pharmacies, after clinical evaluation and counseling via telemedicine. There is no basis for requiring patients to travel in person to a health care center to fill their prescription, rather than by mail or at a local pharmacy.

Staying FDA's 2023 decision to remove the in-person dispensing requirement would have serious harmful consequences for amici's constituents. Reimposing the in-person dispensing requirements for mifepristone would dramatically limit amici's constituents' ability to make informed choices about their bodies and lives, even in states where amici legislators have maintained or expanded abortion access. Doing so would override not only FDA's evidence-based decision, but also state legislators' decisions and their constituents' ability to access reproductive healthcare.

ARGUMENT

I. Telemedicine improves the health and well-being of amici's constituents—especially for reproductive health.

Telemedicine is essential to the health of amici's constituents. Through telemedicine, amici's constituents have the ability to consult with healthcare providers via video, telephone, or secure messaging platforms and obtain prescriptions by mail or at a local pharmacy, rather

than having to travel to an in-person appointment. In 2024, 71 percent of physicians reported using telemedicine in their practices weekly—as compared to 25 percent of physicians in 2018.[2] And 76 percent of hospitals in the U.S. currently use telemedicine—a stark increase from 35 percent a decade ago.[3]

Telemedicine does not just increase the availability of care; it increases the quality of care. Telemedicine has been found to improve patient health outcomes while simultaneously offering cost savings.[4] Better access to care, convenience, and reduced stress from trying to access in-person care also increases patient satisfaction.[5] For many of amici's constituents, increased access to healthcare—including

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[2] Tanya Albert Henry, *New data details how telehealth use varies by physician specialty*, Am. Med. Ass'n (Dec. 8, 2025), https://www.ama-assn.org/practice-management/digital-health/new-data-details-how-telehealth-use-varies-physician-specialty.

[3] *Telehealth: The Advantages and Disadvantages*, Harvard Health Publ'g, https://www.health.harvard.edu/healthy-aging-and-longevity/telehealth-the-advantages-and-disadvantages (last visited July 20, 2026).

[4] *See* Victor C. Ezeamii et al., *Revolutionizing Healthcare: How Telemedicine Is Improving Patient Outcomes and Expanding Access to Care*, Cureus 16(7): e63881 at 4 (July 5, 2024).

[5] *See* Shilpa N. Gajarawala & Jessica N. Pelkowski, *Telehealth Benefits and Barriers*, J. Nurse Pract. 17(2), 218-221, 218 (2020).

reproductive healthcare—through telemedicine has significantly improved their lives.

A. Telemedicine serves constituent needs in geographically and demographically diverse states.

The importance of telemedicine cannot be overstated. It has been a sea change for the better, as recognized by many states and the federal government's continued expansion of telemedicine.

For example, at the federal level, Medicare patients can now receive telemedicine services for mental health care in their homes.[6] Similarly, states like Maryland have recently passed laws such as HB 1483, which allow certain out-of-state licensed mental and behavioral health counselors to use telemedicine for continuity of care.[7]

More than 100 million Americans are "medically disenfranchised,"[8] *i.e.*, lacking access to a regular source of primary care, to say nothing of

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[6] *See* HHS, Health Res. & Servs. Admin., *Telehealth policy updates* (last updated Feb. 5, 2026), https://telehealth.hhs.gov/providers/telehealth-policy/telehealth-policy-updates.

[7] H.B. 1483, 2026 Reg. Sess. (Md.).

[8] *See* Gracy Trinoskey-Rice et al., *Closing the Primary Care Gap*, Nat'l Ass'n of Cmty. Health Ctrs. (Feb. 2023), https://www.nachc.org/wp-content/uploads/2023/06/Closing-the-Primary-Care-Gap_Full-Report_2023_digital-final.pdf.

specialists, due to a shortage of providers in their community.[9] While this population is geographically and demographically diverse, a disproportionate majority is comprised of persons who are racial and ethnic minorities, persons living in rural areas, or persons who fall in both categories.[10]

Only 20 percent of the 62 million Americans who live in rural areas have access to quality healthcare and sufficient medical facilities.[11] That disparity continues to grow as rural hospitals struggle to stay open and face constant workforce shortages.[12] Since 2010, approximately 180 rural hospitals have closed or otherwise discontinued inpatient services,[13] leaving more than three million Americans in rural communities without access to emergency rooms, inpatient care, and many other hospital

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[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] Nat'l Rural Health Ass'n, *Rural Health 101* (Dec. 3, 2024), https://www.ruralhealth.us/nationalruralhealth/media/documents/advocacy/advocacy%20leave-behinds%202024/rural-health-background-101.pdf.

services.[14] And 700 rural hospitals—one-third of all rural hospitals in the country—are at risk of closing due to financial problems, with almost 300 facing an immediate risk of closing.[15] In most states, 25 percent or more are at risk of closing.[16] In ten states, 50 percent or more of rural hospitals are at risk of closing.[17] For most of these communities, the at-risk hospital is the only place for residents to obtain primary care.[18]

The lack of reliable transportation and public transit in rural areas also poses a significant barrier to medical care for many of amici's constituents: those living in rural areas often must travel twice as far to access healthcare as those living in urban areas.[19] Thirty-three percent of American households only have one car,[20] and 45 percent of Americans

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[14] *See* Ctr. for Healthcare Quality & Payment Reform, *Rural Hospitals at Risk of Closing* (May 2026), https://chqpr.org/downloads/Rural_Hospitals_at_Risk_of_Closing.pdf.

[15] *Id.*

[16] *Id.*

[17] *Id.* (Kansas, Texas, Mississippi, Alabama, Oklahoma, Arkansas, Connecticut, Hawaii, Vermont, and Rhode Island).

[18] *Id.*

[19] *Supra* n.13, *Rural Health 101*.

[20] *See* Maya Afilalo, *Car Ownership Statistics 2026* (last updated June 10, 2026), https://www.autoinsurance.com/research/car-ownership-statistics/.

do not have access to public transportation.[21] As rural hospitals close and the availability of basic services declines, this disparity continues to grow.[22]

Declining provider access compounded with limited transportation options renders obtaining healthcare a significant draw on amici's constituents' most precious resources: time. Amici's constituents balance work (often more than one job), [23] childcare, eldercare, household responsibilities, school, and the other demands.[24] When faced with such time constraints, prioritizing one's own health often falls by the wayside.

Telemedicine enables amici's constituents to receive medical care without requesting time off work, forgoing a day's wage, travelling long

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[21] *See Public Transportation Facts*, Am. Pub. Transp. Ass'n, https://www.apta.com/news-research/about-the-industry/public-transportation-facts/ (last visited July 20, 2026).

[22] *Supra* n.14, *Center for Healthcare Quality and Payment Reform*.

[23] *See* Caroline Castrillon, *Why A Record 8.9 Million Americans Are Working Multiple Jobs*, Forbes (Mar. 24, 2025), https://www.forbes.com/sites/carolinecastrillon/2025/03/24/why-a-record-89-million-americans-are-working-multiple-jobs/.

[24] *See* HHS, Health Res. & Servs. Admin., *Why Use Telehealth?* (last updated July 29, 2025), https://telehealth.hhs.gov/patients/why-use-telehealth.

distances, or arranging for childcare,[25] making it possible for those who otherwise would forego care to receive it.[26] In this country covering 3.8 million square miles, and where 56 percent of the medically disenfranchised population lives below 200 percent of the federal poverty level, telemedicine saves lives.[27]

In short, telemedicine benefits amici's diverse constituents, their loved ones, their communities, and the health of the nation.

B. Telemedicine is critical to reproductive health.

Telemedicine also plays an especially critical role in the context of reproductive health, which is often time sensitive. That is why many amici have advanced legislation seeking to expand access to reproductive

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[25] Sixty percent of rural communities are classified as childcare deserts. *Rural Health 101*, *supra* n.13.

[26] *See How TeleHealth Expands Access to Quality Care for Busy Families and Rural Communities*, New Freedom Fam. Med. & Aesthetics (May 4, 2026), https://www.newfreedomfamilymed.com/blogs/how-telehealth-expands-access-to-quality-care-for-busy-families-and-rural-communities.

[27] G. Trinoskey-Rice et al., *supra* n.8.

healthcare, including through protection of and increased access to telemedicine.[28]

The ability to manage one's reproductive health through telemedicine enables timely care for a wider geographic, demographic, and socioeconomic range of constituents.[29] Delays of even a few days or weeks in obtaining reproductive healthcare have been shown to make people less likely to seek out or continue their care.[30] The barriers to accessing reproductive healthcare in person, combined with the often time-sensitive nature of such care, make telemedicine a clinical and

[28] *See, e.g.*, HB 2464, 57th Leg., 1st Reg. Sess. (Ariz. 2025); HB 360, 68th Leg., Reg. Sess. (Idaho 2025); SB 782, 2026 Leg., Reg. Sess. (Fla. 2026); SB 837, Gen. Assemb., 2025 Sess. (Pa. 2025); HB 3472, 2023 Leg., 2023 Reg. Sess. (W. Va. 2023); HB 2093, 55th Leg., 2nd Reg. Sess. (Ariz. 2022); HB 2868, 55th Leg., Reg. Sess. (Ariz. 2021); HB 2332, 54th Leg., 1st Reg. Sess. (Ariz. 2019).

[29] *See* Victor C. Ezeamii et al., *supra* n.4.

[30] *See* Alex Schulte et al., *relationship between experiencing a challenge or delay accessing contraception and contraceptive self-efficacy: Data from a 2022 nationally representative online survey*, Reprod. Health (2025); Alia Cornell, MPH et al., *Seeking Abortion Care Across State Lines After the Dobbs Decision*, JAMA Network Open (Mar. 9, 2026).

practical necessity for millions of Americans seeking reproductive healthcare of all types.[31]

1. Many of amici's constituents have difficulty accessing in-person reproductive healthcare.

Many of the same challenges discussed above impact the ability of amici's constituents to access in-person reproductive care.

Geographic barriers are the most reported barrier.[32] Patients in rural or medically disenfranchised communities face higher degrees of geographic isolation, limiting reproductive care access.[33] Young people

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[31] *See* Elizabeth A. Pleasants, Alice F. Cartwright, & Ushma D. Upadhya, *Association Between Distance to an Abortion Facility and Abortion or Pregnancy Outcome Among a Prospective Cohort of People Seeking Abortion Online*, JAMA Network Open Vol. 5. No. 5 (May 13, 2022) ("greater travel distance to reach an abortion facility was associated with delays in access and prevention of access to wanted abortion care" "innovative approaches to abortion provision . . . including use of telehealth . . . should be prioritized for improving abortion access").

[32] *See* Rebecca J. Kreitzer et al., *Affordable but Inaccessible? Contraception Deserts in the US States*, Duke Univ. Press, J. of Health Politics, Policy & Law (Apr. 1, 2021) (between 17 percent and 53 percent of a state's population lived in a contraception desert, and "low-income people and people of color are more likely to live in certain types of contraception deserts").

[33] *See* Amanda Mackay, Selina Taylor, & Beverley Glass, *Inequity of Access: Scoping the Barriers to Assisted Reproductive Technologies* (Jan. 16, 2023).

are another group disproportionately affected by geographic barriers, as they often lack reliable access to transportation.[34]

Reproductive healthcare providers frequently face significant regulatory hurdles and burdens, such as onerous facility requirements, mandatory licensing schemes, and inspection regimes. [35] These requirements often go well beyond what is required of comparable outpatient medical providers and threaten an already thin provider network.[36]

Telemedicine offers an evidence-based alternative to the millions of amici's constituents who live in reproductive healthcare deserts. Reproductive healthcare encompasses a wide range of care: a college

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[34] Bronte K. Johnston et al., *Barriers to contraception access and use among youth: A scoping review in high-income countries*, Int'l J. Gynecology Obstetrics 173:74-86, 81 (Nov. 14, 2025) ("Transportation challenges were mentioned in five articles. Large travel distances were challenging, particularly for those accessing care without parents knowing and from rural communities.").

[35] *See* Jessica Arons, *The Last Clinics Standing*, ACLU (Oct. 9, 2018), https://www.aclu.org/news/reproductive-freedom/the-last-clinics-standing.

[36] *See* Emily Olsen, *Planned Parenthood clinics close amid funding restrictions: KFF* (June 10, 2026), https://www.healthcaredive.com/news/planned-parenthood-closures-medicaid-title-x-funding-kff/822294/.

student going to her first gynecologist's appointment; a couple hoping to conceive; a woman freezing her eggs because her cancer treatment regime will impact her fertility; a mother dealing with a difficult or medically dangerous pregnancy; or a person seeking an abortion to ensure they can continue providing for their existing children or pursuing their education. The message amici legislators hear from their constituents is clear: women of every background, socioeconomic status, and location need easy and affordable access to all forms of reproductive healthcare. Telemedicine makes that access possible for many.

Access to reproductive healthcare through telemedicine saves lives. For example, mifepristone is often prescribed when a patient experiences early pregnancy loss, but the miscarriage does not complete without medical assistance.[37] The ability to consult a provider virtually to receive immediate advice and then fill prescriptions by mail or at a local

[37] *See* ACOG Practice Bulletin No. 200, Early Pregnancy Loss (Nov. 2018, reaff'd 2025); *see also* Honor MacNaughton et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 Am. Fam. Physician 473-480, 475 (Apr. 15, 2021); Mara Gordon & Sarah McCammon, *A Drug That Eases Miscarriages Is Difficult for Women to Get*, NPR (Jan. 10, 2019), https://www.npr.org/sections/healthshots/2019/01/10/666957368/adrug-that-eases-miscarriages-isdifficult-for-women-to-get.

pharmacy can make the difference in accessing timely care—and thereby avoiding immediate harm to health and fertility.

2. Many constituents have limited or no physical access to abortion care.

Even in places where amici legislators have voted to protect or expand the right to terminate a pregnancy, in-person access to abortion care is often constrained,[38] making telemedicine (including mail or pharmacy dispensing of mifepristone) critical to receiving such care.

Abortion care is concentrated in urban centers, leaving patients in rural counties, small towns, and suburban communities with little practical ability to obtain in-person care within the gestational window in which medication abortion is available.[39] These geographical and logistical barriers can render abortion practically inaccessible for many of amici's constituents. Telemedicine helps amici's constituents access abortion care without sacrificing employment and caregiving

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[38] *See* Soc'y of Fam. Plan., *#WeCount report, April 2022 through December 2025* (June 10, 2026), https://societyfp.org/wp-content/uploads/2026/05/WeCount-Report-11-Dec-2025-data.pdf.

[39] *See* Jonathan M Bearak, Kristen Lagasse Burke, & Rachel K Jones, *Disparities and change over time in distance women would need to travel to have an abortion in the USA: a spatial analysis*, The Lancet Pub. Health (Oct. 3, 2017).

responsibilities, and without unnecessary delays that may have detrimental impacts on their health.

Telemedicine plays an important and increasingly common role in abortion access, accounting for 27 percent of abortions in 2025 as compared to only 5 percent in 2022.[40] Medication abortions now account for more than 60 percent of all abortions in the country, up from 53 percent in 2020.[41] Evidence shows that medication abortion remains safe and effective when delivered via telemedicine and mail or pharmacy delivery.[42]

Reinstating the in-person dispensing requirement for mifepristone would fall hardest on those of amici's constituents who already face the greatest barriers to obtaining reproductive healthcare, including patients in rural areas, those unable to travel, those juggling caregiving

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[40] *See* Society of Family Planning, *#WeCount report, April 2022 through June 2025* (Dec. 9, 2025), https://societyfp.org/research/wecount/wecount-june-2025-data/.

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

[42] *See* Roopan Gill, Wendy V. Norman, *Telemedicine and medical abortion: dispelling safety myths, with facts*, mHealth (Feb. 1, 2018).

responsibility (for children or parents) and/or work, and those with limited financial resources. Amici, as elected representatives, have a direct interest in ensuring their constituents can access lawful healthcare in their states without facing unnecessary and burdensome barriers.

II. The FDA's decision to lift the in-person dispensing requirement was sound and supported.

Most amici legislators are not scientists—but one does not need to be a scientist to see that plaintiffs are trying to circumvent the FDA's evidence-based decision to lift the in-person dispensing requirement. Claims that FDA's decision to permanently remove the in-person dispensing requirement was unsupported and unsound could not be farther from the truth.

FDA's decision to eliminate the in-person dispensing requirement was supported by decades of research and a robust body of evidence demonstrating the efficacy and safety of mifepristone. FDA first approved mifepristone for the termination of pregnancy in 2000, with multiple restrictions.[43] FDA has appropriately eased some of those

[43] *See* FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Apr. 8, 2026), https://www.fda.gov/drugs/postmarket-drug-safety-information-
(Continued…)

restrictions over the past twenty-five years as mifepristone's safety and efficacy have been proven time and again through millions of uses and more than 100 studies.

In 2011, the extant restrictions became part of a REMS.[44] In 2016, consistent with 15 years of data demonstrating mifepristone's proven track record of safe use across more than 2.5 million patients, FDA announced modifications to the REMS including permitting qualified advanced-practice clinicians to be certified prescribers of mifepristone and removing certain heightened reporting requirements (while continuing to impose other reporting requirements that are still more onerous than those for the vast majority of other FDA-approved medications). *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 375–76

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patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation ("The FDA approved Mifeprex more than 20 years ago based on a thorough and comprehensive review of the scientific evidence presented and determined that it was safe and effective for its indicated use.").

[44] *See Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007*, 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008).

(2024). FDA also approved GenBioPro's generic mifepristone for use in 2019. *Id.*

Since its approval, an estimated 7.5 million people in the U.S. have safely used mifepristone to terminate a pregnancy,[45] and data shows that complications are rare, "occurring in no more than a fraction of a percent of patients."[46] FDA has recognized that mifepristone's "well-characterized" safety record "has not changed over the period of [its] surveillance," which is now well over two decades.[47]

At the onset of the COVID-19 pandemic, FDA suspended the in-person dispensing requirements for most drugs, "including certain controlled substances," and "powerful opioids" to avoid subjecting patients to viral exposure. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Sotomayor, J., dissenting). Yet, FDA initially treated mifepristone differently, leaving in-person

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[45] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024*, https://www.fda.gov/media/185245/download (last visited July 20, 2026).

[46] Nat'l Acads. of Scis., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 55, Nat'l Academies Press (2018).

[47] Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 020687, 91178 REMS Modification Rationale Review 15* (Dec. 16, 2021).

dispensing requirements in place. *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 191-97 (D. Md. 2020). In July 2020, a court injunction permitted patients to access the drug by mail for six months before the Supreme Court issued a stay of that injunction in January of 2021. *Id.* at 233; *Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578.[48]

In April 2021, FDA announced that it would not enforce the in-person dispensing requirement during the COVID-19 pandemic, allowing mifepristone to be dispensed "through the mail . . . or through a mail-order pharmacy."[49] In December 2021, the agency announced that it would modify the REMS to permanently remove the in-person dispensing requirement, which it formalized in the 2023 REMS. *See All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 226 (5th Cir. 2023), *rev'd on other grounds*, 602 U.S. 367 (2024).[50]

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[48] Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 020687Orig1s025 Mifepristone Summary Review 14* (Jan. 3, 2023); *accord* Compl., Ex. 50, *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La., filed Oct. 6, 2025), ECF No. 1-50.

[49] *Id.*

[50] FDA, *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG* (Jan. 2023),
(Continued…)

FDA's decision to remove the in-person dispensing requirement was supported by evidence that the requirement was "unduly burdensome on patient access." *See* 21 U.S.C. § 355-1(f)(1), (f)(2)(C), (g)(4)(B). It was also based on years of scientific data and literature demonstrating mifepristone's safety, including FDA's review of data from the more than a year when the in-person dispensing requirement was not enforced,[51] where FDA found *no* difference in adverse outcomes between periods when the requirement was enforced and was not enforced. FDA also conducted a "comprehensive review of the published literature," which "support[ed] that dispensing by mail is safe and effective." *Id.* at 45, 67–75. FDA soundly concluded that this extensive body of evidence collectively showed the "benefits of" lifting the in-person dispensing requirement "outweigh[ed] the risks." *Id.* at 11. And evidence post-dating FDA's 2023 REMS decision affirms that mifepristone remains safe and effective without the in-person dispensing requirement. A 2024 study

https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

[51] *See, e.g.*, Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 020687, 91178 REMS Modification Rationale Review 15* (Dec. 16, 2021), 24–36(reviewing studies).

found that over 99% of patients who receive abortion care via telehealth experience no adverse effects.[52]

FDA's decision to remove the in-person dispensing requirement was consistent with its statutory obligation to lower barriers to medication access. *See* 21 U.S.C. § 355-1(f)(1)(A), (f)(2)(C) (REMS requirements may "not be unduly burdensome on patient access," "considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)"); *see also Purcell v. Kennedy*, Civ. No. 17-00493, 2025 WL 3101785, at *14, 17 (D. Haw. Oct. 30, 2025) (noting that these factors apply to a REMS modification). Studies show that telehealth abortion care is "as effective, timelier, and potentially more accessible than in-clinic care[.]"[53] And data shows that receiving

[52] *See* Ushma D. Upadhyay et al., *Effectiveness and safety of telehealth medication abortion in the USA*, 30 Nature Med. 1191–98 (Feb. 15, 2024).

[53] Silpa Srinivasulu et al., *Telehealth Medication Abortion in Primary Care: A Comparison to Usual in-Clinic Care*, 37 J. Am. Bd. Fam. Med. 295, 299 (2024).

abortion medication via telehealth is nearly two-thirds less expensive than doing so in-person.[54]

Staying the 2023 REMS thus would actively cut against FDA's statutory mandate by imposing unnecessary barriers to medication access. And it would interfere with amici legislators' reliance on that FDA action when legislating to maintain or expand abortion access, undermining a core premise of *Dobbs*: that the decision of whether and how residents may access abortion care is for each state to make.

III. Staying the 2023 REMS nationwide would cause immediate and serious harms.

Staying the 2023 REMS would cause real, immediate and serious harms to those seeking access to mifepristone for abortion and miscarriage care,[55] including in states that have chosen to protect and expand access to abortion care after *Dobbs*.

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[54] Ushma D. Upadhyay et al., *Pricing of medication abortion in the United States, 2021-2023*, 56 Persps. on Sexual & Reprod. Health 282-294, 282 (2024).

[55] Abortion restrictions are associated with significant changes in the medication management of miscarriages. In a recent study, researchers found that between 2018 to 2024 the rate of active management (either procedural or medication) for miscarriages declined in ban states and during that same time, access states dramatically increased the use of mifepristone for miscarriage management, but its use for that purpose (Continued…)

Reinstating the in-person dispensing requirement would prevent people from obtaining a safe and effective medication through the mail or pharmacies, instead requiring people nationwide to travel in person just to pick up their mifepristone. For some individuals, this barrier would make obtaining mifepristone impossible due to lack of access to transportation, inability to secure time off from work or other responsibilities, or other reasons that disproportionately affect lower-income individuals.[56]

Staying the 2023 REMS would also harm those seeking an in-clinic abortion by increasing wait times at already overwhelmed clinics serving both in-state patients and out-of-state patients from jurisdictions that have restricted or prohibited abortion access[57]—even though timely

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in ban states increased much more modestly. Maria I. Rodriguez, Megan Fuerst, & Kaitlin Schrote, *Management of Spontaneous Abortion Among Commercially Insured Individuals in the United States After Dobbs v Jackson*, 336 Women's Health 48, 52 (May 18, 2026).

[56] Nat'l Acads. of Sci., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States*, 78 (2018) ("Financial burdens and difficulty obtaining insurance are frequently cited by women as reasons for delay in obtaining an abortion.").

[57] *See* Alyssa Goldberg, *People are flocking out-of-state for abortion care. Clinics are fighting to keep up*, USA Today (Mar. 18, 2025, at 11:59 AM).

access to abortion care is critical.[58] This is all the more true given the overall decline in the number of brick-and-mortar abortion clinics.[59] And these barriers say nothing of the attendant costs of being required to travel to obtain medication in person, such as the need to obtain a means of transportation, childcare, and/or time off of work.

Reinstating the in-person dispensing requirement would also impede other forms of critical healthcare. The same facilities that provide abortion care often offer essential services such as contraception, prenatal care, family planning, cancer screening, and treatment for sexually transmitted infections.[60] Increased demand for in-person abortion appointments for patients who are unable to access mifepristone

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[58] *See, e.g.*, Rachel K. Jones & Jenna Jerman, *Time to Appointment and Delays in Accessing Care Among U.S. Abortion Patients*, Guttmacher Inst. (Aug. 2016).

[59] *See* Rachel K. Jones, Ava Braccia & Emma Stoskopf-Ehrlich, *Number of Brick-And-Mortar Abortion Clinics Declined Slightly Between 2024 and 2025*, Guttmacher Inst. (Feb. 2026).

[60] *See* Katherine M Mahoney et al., *Health services provided at the time of abortion in the US: a scoping review of the qualitative and quantitative evidence*, medRxiv (Jan. 23, 2024), https://www.medrxiv.org/content/10.1101/2024.01.22.24301627v1; Planned Parenthood, *Our Services*, https://www.plannedparenthood.org/get-care/our-services (last visited July 20, 2026).

by mail or pharmacy delivery would delay access to all forms of care at those facilities, worsening overall health outcomes.[61]

There are also obvious cost impacts from staying the 2023 REMS—which, again, will fall heaviest on those least able to bear them. Access to medication via mail-order pharmacies has significantly decreased

[61] Jennifer Mueller et al., *Effects of the Dobbs decision on abortion and related service provision among sexual and reproductive health clinics in the United States: results from a qualitative study*, Sexual and Reproductive Health Matters 9-10 (Sep. 2025) ("[W]e found clinics in less restrictive/ protective states struggling to balance the provision of abortion and other [sexual and reproductive health] services in the face of this increased demand. Our participants discussed how wait times for other types of [sexual and reproductive health] care have increased due to the prioritisation of abortion appointments."), https://pmc.ncbi.nlm.nih.gov/articles/PMC12462416/pdf/ZRHM_33_2557074.pdf; *see also* Julia Strasser et al., *Penalizing Abortion Providers Will Have Ripple Effects Across Pregnancy Care*, Health Affs. (May 3, 2022) ("[R]outine outpatient care for pregnancy services may also shrink as abortion restrictions grow.").

costs for patients,[62] and this is no less true for medication abortions.[63] Staying the 2023 REMS would harm individuals in all states by increasing the out-of-pocket expenses necessary to access a safe and effective medication.

Reimposing these barriers and costs increases the same harms that mifepristone access via telemedicine has been reducing.[64] Studies predict that increased abortion restrictions will result in increased maternal mortality,[65] and other studies demonstrate that increased abortion

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[62] Julie A Schmittdiel et al., *Opportunities to encourage mail order pharmacy delivery service use for diabetes prescriptions: a qualitative study*, 19 BMC Health Servs. Rsch. 422, at 2 (2019) ("Mail order pharmacy use is also associated with better health care outcomes and decreased health care utilization and costs."); Junyi Ma & Li Wang, *Characteristics of Mail-Order Pharmacy Users: Results from the Medical Expenditures Panel Survey*, 33 J. Pharm. Prac. 293, 293 (Oct. 2, 2018).

[63] *Pricing of Medication Abortion in the United States, 2021-2023*, at 282, supra n.54 (finding that "medications provided by virtual clinics were notably lower in price than in-person care and this difference widened over time").

[64] *See* Andréa Becker et al., *"It Was So Easy in a Situation That's So Hard": Structural Stigma and Telehealth Abortion*, 67 J. of Health & Soc. Behavior 120, 125-129 (2025) (discussing structural barriers to receiving care that were mitigated by telemedicine).

[65] *See, e.g.*, Amanda Jean Stevenson, *The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant*, 58 Demography 2019 (Continued…)

restrictions cause increased infant mortality rates.[66] These harms fall disproportionately on under-resourced populations, including women of color, who already face higher incidences of maternal mortality and pregnancy complications. Moreover, denial of access to abortion care is also associated with poor health outcomes, higher rates of poverty, lower educational attainment for parents and children,[67] and increases in intimate partner violence.[68]

(2021); Dovile Vilda et al., *State Abortion Policies and Maternal Death in the United States*, *2015-2018*, 111 Am. J. Pub. Health 1696 (Sep. 2021); Amanda Jean Stevenson & Kate Coleman-Minahan, *Estimated Increase in Severe Maternal Morbidity Due to a Total Abortion Ban*, 127 Contraception 21, 21 (Nov. 2023).

[66] *See, e.g.*, Parvati Singh & Maria F. Gallo, *National Trends in Infant Mortality in the US After Dobbs*, 178 JAMA Pediatrics 1364 (2024); Roman Pabayo et al., *Laws Restricting Access to Abortion Services and Infant Mortality Risk in the United States*, 17 Int'l J. Env't Rsch. Pub. Health 3773 (May 26, 2020); Alison Gemmill et al., *US Abortion Bans and Infant Mortality*, 333 JAMA 1315-1323 (2025).

[67] *See, e.g.*, Diana Greene Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2020); Diana Greene Foster et al., *Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children*, 205 J. Pediatrics 183, 187-88 (Feb. 2019); Heidi D. Nelson et al., *Associations of Unintended Pregnancy with Maternal and Infant Health Outcomes: A Systematic Review and Meta-Analysis*, 328 JAMA 1714, 1727-29 (Nov. 1, 2022).

[68] Dhaval M. Dave et al., *Abortion Restrictions and Intimate Partner Violence in the Dobbs Era*, Nat'l Bureau of Econ. Rsch., Working Paper No. 33916 (Oct. 2025).

Requiring travel to an in-person provider also imposes stigmatic and privacy harms. Abortion stigma remains a pervasive obstacle that delays care, suppresses information-seeking, and prevents individuals from asking for support.[69] Increased privacy concerns regarding abortion are a key reason for choosing telemedicine, and for many, accessing care from home is a precondition for accessing care at all. Forcing people to travel to a health center harms those who depend on the confidentiality and privacy afforded by receiving mifepristone via mail or at a pharmacy.

Staying the 2023 REMS also imposes immediate and substantial harm on specific populations among amici's constituents. These include survivors of intimate partner violence ("IPV"), as a group of organizations that serve IPV survivors explained to the Supreme Court when urging it to overturn this Court's stay.[70] Survivors of IPV are three times more

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[69] *See* Annik Mahalia Sorhaindo & Antonella Francheska Lavelanet, *Why does abortion stigma matter? A scoping review and hybrid analysis of qualitative evidence illustrating the role of stigma in the quality of abortion care*, 311 Soc. Sci. & Med. 3 (Aug. 24, 2022); *see also* M. Antonia Biggs et al., *Unwanted abortion disclosure and social support in the abortion decision and mental health symptoms: a cross-sectional survey*, Contraception (Oct. 2022).

[70] *See* Brief of Legal Voice, the National Domestic Violence Hotline, et al. as amici supporting Applicants, No. 25A1208 (U.S. May 7, 2026) ("Legal Voice Amicus").

likely to conceal their abortion from their partner.[71] Abusers commonly restrict access to transportation, medical care, and financial resources, making in-person clinic visits dangerous or impossible for many IPV survivors.[72] For many of these constituents, in-home medication abortion obtained by mail or at a local pharmacy after a telemedicine appointment is the only feasible means of accessing care.[73] Reinstating the in-person dispensing requirement would jeopardize survivors' ability to access abortion care privately and safely, with potentially life-threatening consequences.[74]

Reinstating the in-person dispensing requirement would likewise impose severe and disproportionate burdens on amici's constituents with disabilities, as the Disability Rights Education and Defense Fund

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[71] *See* Megan Hall et al., *Associations between Intimate Partner Violence and Termination of Pregnancy: A Systemic Review and Meta-Analysis*, PLoS Med. 11(1): e1001581, 25 (Jan. 2014).

[72] *See* Nat Stern et al., *Unheard Voices of Domestic Violence Victims: A Call to Remedy Physician Neglect*, 15 Geo. J. Gender & L. 613, 633 (2013); *see also* Legal Voice Amicus Br. at 13.

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

[74] *See* Legal Voice Amicus Br. at 17.

explained in its amicus brief before the Supreme Court.[75] An estimated 25.5 million people in the United States have travel-limiting disabilities, and 3.6 million are housebound.[76] At the same time, people with disabilities face dramatically higher risks of severe pregnancy-related complications and mortality.[77] Congress recognized these concerns when it amended the REMS framework to require explicit consideration of burdens on "patients with functional limitations." 21 U.S.C. § 355-1(f)(2)(C)(iii). Reinstating the in-person requirement would contravene this statutory mandate and re-erect precisely the type of exclusionary structural barrier that federal disability law has long sought to dismantle.[78]

The harms of enjoining the 2023 REMS further extend to the nation's military readiness, as a group of former military officials and

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[75] *See* Brief of Amici Curiae of Disability Rights Education and Defense Fund et al., No. 25A1208 (U.S. May 5, 2026) ("DREDF Amicus Br.").

[76] Stephen Brumbaugh, *Travel Patterns of American Adults with Disabilities*, U.S. Dep't of Transp., Bureau of Transp. Statistics (Sep. 2018), https://rosap.ntl.bts.gov/view/dot/37593.

[77] Jessica L. Gleason et al., *Risk of Adverse Maternal Outcomes in Pregnant Women with Disabilities*, 4(12) *JAMA Network Open* (Dec. 15, 2021).

[78] *See* DREDF Amicus Br. at 9-13.

civilian national security leaders explained to the Supreme Court when imploring it to stay this Court's stay.[79] Those amici explained that, when access to reproductive care via telemedicine is restricted, servicemembers—who generally do not choose where they serve and operate within rigid schedules, rules, and command structures—face delays in their ability to access care, extended absences, and other harms that directly impair their ability to serve.[80] Because federal law prevents the Department of Defense from funding most abortions,[81] while recent policy changes have rescinded transportation allowances for reproductive care,[82] telemedicine access to mifepristone is one of the few remaining pathways for servicemembers stationed in states that permit such care to obtain it without extended absences that interfere with their ability to

[79] *See* Brief of Former Military Officials, Former Civilian National Security Leaders, and Vet Voice Foundation as Amici Curiae in Support of [Applicants], No. 25A1208 (U.S. May 7, 2026) ("Former Military Officials' Amicus").

[80] *See id.* at 4.

[81] *See* 10 U.S.C. § 1093(a).

[82] Dep't of Def., Def. Travel Mgmt. Off., Memorandum, UTD for MAP 04-25(S) (Jan. 29, 2025).

serve and harm their reputations, ability to progress up the chain of command, and units' readiness.[83]

Staying the 2023 REMS also would disproportionately harm parents, who make up 59% of abortion patients[84] and who rely on telemedicine to access care without sacrificing employment or existing caregiving responsibilities.[85] For these patients, the ability to obtain care at home—rather than traveling to a clinic—is often essential to remaining present and dependable for the children who rely on them.

All of these harms would impact persons in states that have expanded abortion access post-*Dobbs*, including those from which many amici hail. There is no way to limit the harms of *nationally* enjoining the 2023 REMS to only those states which have chosen to limit abortion access. The grant of such relief to one state—Louisiana—would thus have the consequence of impacting abortion policy in every other state,

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[83] Former Military Officials' Amicus at 16-17.

[84] Usha Ranji et al., *Key Facts on Abortion in the United States*, KFF (Jan. 7, 2026), https://www.kff.org/womens-health-policy/key-facts-on-abortion-in-the-united-states/.

[85] *See* Kathleen Morrison et al., *Understanding the use of telehealth in the context of the Family Nurse Partnership and other early years home visiting programmes: A rapid review*, 8 Digital Health 1-13 (2022).

territory, and the District of Columbia. Such encroachment runs contrary to *Dobbs*' recognition that "various States may evaluate" the countervailing interests central to abortion issues "differently," and that "ordered liberty does not prevent the people's elected representatives from deciding how abortion should be regulated." 597 U.S. at 217-18. State laws protecting access to abortion in amici's states[86] in no way preclude Louisiana or other similarly situated states from enforcing their own abortion laws within their borders. But staying the 2023 REMS would impose the in-person dispensing requirement in all states, trammeling the interests that elected representatives of many states have lawfully sought to protect and advance.

In sum, staying the 2023 REMS would force amici's constituents to navigate medically unnecessary barriers to timely access safe and effective abortion care—including in states where amici have legislated

[86] Such efforts have occurred and are ongoing in many amici legislators' states. *E.g.*, Md. Const. art. 48 (Maryland's Constitutional codification of the right to reproductive freedom); SB 0848, Gen. Assemb., 447th Sess. (Md. 2025) (enacted) (Public Health Abortion Grant Program – Establishment); HB 2464, 57th Leg., 1st Reg. Sess. (Ariz. 2025) (legislation to repeal existing regulations on mailing of abortion medication); SB 837, 2025-2026 Reg. Sess. (Pa. 2025) (Reproductive Freedom Act).

to protect and expand access to reproductive healthcare. It would reimpose barriers to care that fall hardest on the most vulnerable populations. It would increase costs, and delay access to critical healthcare services beyond abortion. And it would undermine the federalism principles on which *Dobbs* was predicated.

The 2023 REMS reflects FDA's evidence-based judgment that the in-person dispensing requirement is not necessary to ensure safe use of mifepristone. Amici urge this Court not to disturb that well-founded determination.

CONCLUSION

This Court should affirm the district court's decision declining to grant a preliminary injunction motion.

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I hereby certify that on July 22, 2006, I electronically filed the foregoing brief with the Clerk of the Court of the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE

The undersigned counsel certifies that this brief:

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Dated: July 22, 2026

/s/ Amanda Shafer Berman
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United States Court of Appeals

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July 23, 2026

Ms. Amanda Shafer Berman
Crowell & Moring, L.L.P.
600 5th Street, N.W.
Suite 8000
Washington, DC 20001

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

Dear Ms. Berman,

You must submit the 6 paper copies of your brief required by 5th Cir. R. 31.1 within 5 days of the date of this notice pursuant to 5th Cir. ECF Filing Standard E.1.

If your brief was insufficient and required corrections, the paper copies of your brief must **not** contain a header noting "RESTRICTED". Therefore, please be sure that you print your paper copies **from this notice of docket activity** and not the proposed sufficient brief filed event so that it will contain the proper filing header. Alternatively, you may print the sufficient brief directly from your original file without any header.

Sincerely,

LYLE W. CAYCE, Clerk

Christy Combel

By: _____
Christy M. Combel, Deputy Clerk
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