Nos. 25A1207, 25A1208

IN THE

Supreme Court of the United States

DANCO LABORATORIES, LLC,
Applicant,
v.
LOUISIANA, ET AL.,
Respondents.

GENBIOPRO, INC.,
Applicant,
v.
LOUISIANA, ET AL.,
Respondents.

On Application to Stay or Vacate the Judgment of the United States Court of Appeals for the Fifth Circuit

BRIEF OF FEMINEM FOUNDATION AND AMERICAN ACADEMY OF EMERGENCY MEDICINE AS *AMICI CURIAE* IN SUPPORT OF APPLICATIONS BY DANCO LABORATORIES, L.L.C., AND GENBIOPRO, INC.

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amicus curiae FemInEM Foundation ("FemInEM") is a non-profit organization dedicated to the improvement of reproductive healthcare delivered in emergency departments across the country. FemInEM's mission is to address the disparities in outcomes for patients by equipping medical professionals with the tools, knowledge, and resources they need to deliver effective and time-sensitive care. Founded by board-certified emergency medicine physician Dara Kass in 2015, FemInEM currently has over 2,500 subscribers. FemInEM educates and provides necessary resources through its research, website, Substack, and grand round lectures and CME-accredited courses focused on reproductive health.

Amicus curiae American Academy of Emergency Medicine ("AAEM") is a professional medical organization that is dedicated to promoting fair and equitable practice environments that allow emergency physicians to deliver the highest level of patient care. Founded in 1993, AAEM has been a leader in protecting board certification in emergency medicine and confronting the harmful influence of the corporate practice of medicine. We support fair and equitable practice environments that allow emergency physicians to deliver the highest quality of patient care. AAEM's mission is AAEM fights for high-quality patient care delivered by board-certified emergency physicians and champions a fair and equitable workplace for emergency physicians through advocacy and education. AAEM currently has over

[1] Pursuant to Supreme Court Rule 37.6, counsel for the *amici* represent that they authored this brief in its entirety and that none of the parties or their counsel, nor any other person or entity other than the *amici* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

8,000 members.

Amici offer this brief to assist the Court in better understanding the role of emergency departments in medical care in the United States and illustrate the realities of what emergency department visits following medication abortion typically entail. *Amici*'s firsthand experience with women who visit the emergency department contradict the Fifth Circuit's reliance on the possibility of emergency department visits after using mifepristone to undermine the vast body of scientific research demonstrating that the drug is safe and effective with extremely low rates of serious adverse events, including when dispensed by mail and pharmacies. Respondents' "evidence" to the contrary in the lower courts misrepresents what is (and is not) actually occurring. As discussed in this submission, mifepristone is safe, effective, and critical to the practice of emergency medicine.

SUMMARY OF ARGUMENT

In December 2021, the U.S. Food and Drug Administration ("FDA") announced that it intended to permanently eliminate the requirement under the mifepristone Risk Evaluation and Mitigation Strategies ("REMS") that mifepristone be dispensed only in person at a healthcare facility, following multiple periods during which the in-person requirement was not enforced as a result of the COVID-19 public health emergency. In 2023, the agency officially modified the mifepristone REMS ("2023 REMS") to permanently remove the in-person dispensing requirement (which had already been suspended for all but a few months since July 2020) and permit dispensing by mail and through pharmacies. Its decisions to remove the in-person

dispensing requirement were based on numerous studies and real-world evidence establishing the medication's safety regardless of where it is dispensed.

Respondents suggest that mifepristone is unsafe because some patients who take mifepristone visit emergency departments. This misrepresents the role of emergency departments in the United States healthcare system. The Fifth Circuit's ruling relying on that misrepresentation will not only deny patients safe methods of accessing care but impose far reaching effects on emergency departments' ability to provide necessary healthcare.

Emergency departments are the only healthcare resource that provides healthcare to any person at any time of day regardless of their financial resources or ability to pay. One of the results of this reality is that many individuals use emergency departments for non-urgent care, including reproductive healthcare.

Using the number of women who visit an emergency room after taking mifepristone to call the drug's safety into question ignores that such visits are not indicative of serious adverse events caused by mifepristone. Nor are those numbers tied to the method of dispensing mifepristone. Research demonstrates that most of these visits involve patients seeking reassurance or observation without receiving any treatment. In fact, emergency visit data supports the conclusion that mifepristone is a safe and effective medication, whether dispensed in person or by mail or pharmacy.

In emergency departments, mifepristone is part of the standard and recommended treatment for the management of early pregnancy loss. Because

hospitals stock a fixed number of medications onsite—and health centers face particular barriers to stocking mifepristone as a result of the FDA's ongoing REMS requirements—emergency departments frequently prescribe and dispense it through retail pharmacies, as permitted by the 2023 REMS. Limiting mifepristone to in-person dispensing, and prohibiting pharmacy access, would inhibit emergency departments' ability to prescribe mifepristone as a treatment, resulting in reduced access to important reproductive healthcare and worse patient outcomes.

For these and the reasons set forth more fully below, *amici curiae* urges this Court to vacate or stay the Fifth Circuit's order.

ARGUMENT

I. THE ROLE EMERGENCY DEPARTMENTS SERVE IN THE UNITED STATES HEALTHCARE SYSTEM.

A. Emergency Departments Provide Primary Healthcare as a First Resort to Many Patients.

The emergency department is the bedrock of the United States healthcare system.[2] The emergency care system is the only component of the nation's safety net that must provide care to everyone, regardless of insurance coverage or ability to pay.[3] In 2022 alone, there were 155.4 million visits to emergency departments.[4] It is

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[2] Talia Ruxin, BA, et al., *Trends by acuity for emergency department visits and hospital admissions in California 2012 to 2022*, JAMA Network Open 1 (Dec. 18, 2023), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2812897 [doi:10.1001/jamanetworkopen.2023.48053].

[3] Institute of Medicine, Board on Health Care Services, Committee on the Future of Emergency Care in the United States Health System, *Hospital-Based Emergency Care: At the Breaking Point*, at 43 (June 3, 2007), https://doi.org/10.17226/11621.

[4] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *National Hospital Ambulatory Medical Care Survey: 2022 Emergency*

the "safety net of the safety net."[5]

Because emergency departments provide healthcare services to any person at any time regardless of ability to pay, it is common for patients to present with non-urgent healthcare needs. As a result, emergency department physicians are trained to take care of patients with any complaint at any time.[6] FemInEM COO/CLO and practicing board-certified emergency physician Dr. Kimi Chernoby explains that while emergency departments are ready to take care of the most serious—life-threatening heart attacks and strokes, gunshot wounds and mass casualties—the reality is the majority of care delivered in emergency departments is non-emergent.[7]

Indeed, patients *often* go to the emergency department for non-urgent healthcare because they have no primary care provider or know of no other option to confirm they do not need medical intervention. Dr. Chernoby has observed that patients frequently utilize the emergency department to seek assurance that they are not having a concerning healthcare issue. Some examples of the wide variety of non-emergent issues patients present: cold symptoms, expected side effects of

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Department Summary Tables, Nat'l Ctr. for Health Stat. 3 (2022), https://www.cdc.gov/nchs/data/nhamcs/web_tables/2022-nhamcs-ed-web-tables.pdf.

[5] Institute of Medicine, *supra* note 3, at 43.

[6] Kimberly Chernoby et al., *Pregnancy Complications After* Dobbs*: The Role of EMTALA*, 25 W.J. of Emergency Med., at 1 (Jan. 4, 2024), https://escholarship.org/uc/item/5j81n18f [doi:10.5811/westjem.61457].

[7] Dr. Chernoby is the nation's only board-certified emergency physician and reproductive rights attorney. In addition to her work with FemInEM, she practices emergency medicine at George Washington University. A former Senate Health Committee fellow and National Women's Law Center counsel, she is a leading expert on the intersection of emergency medicine and reproductive health policy.

medications, joint pain, headaches, pregnancy confirmation, sunburn, bug bites, or rashes. In a study at five urban nonfederal teaching hospital emergency departments in the northeastern United States, researchers found that 50% of the 1,696 participants had non-urgent conditions.[8]

B. Patients Use Emergency Departments for Non-urgent Healthcare Because of Barriers to Accessing Other Healthcare Resources.

Many patients go to the emergency room for non-urgent care precisely because emergency departments do not require payment upfront and do not turn patients away when they present. Other healthcare resources either cannot or do not provide the same safety net feature as emergency departments. Other community-based services can restrict access based on ability to pay or otherwise, typically operate only during business hours, maintain long waiting lists, and may lack specialty and diagnostic services that are required to fully address their patients' needs.

Hospital emergency departments are the provider of first resort for millions of patients who are uninsured or otherwise lack adequate access to care in their communities.[9] For patients who are unable to obtain an appointment with their primary care provider for weeks, or have no primary care provider at all, the emergency department may be their only option, even if they do not have an "emergent" condition. In that way, the emergency department serves as many

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[8] Laura A. Petersen, MD, MPH, et al., *Nonurgent Emergency Department Visits: The Effect of Having a Regular Doctor*, 36 Med. Care 1249, 1250 (1998).

[9] Institute of Medicine, *supra* note 3, at 42.

patients' main access point for an array of care, including reproductive healthcare.[10] For example, women experiencing bleeding while pregnant may make repeated visits to the emergency department, although most will be discharged without admission.[11] Patients have also reported coming to the emergency department simply to seek reassurance.[12]

According to the Health Resources & Services Administration, about 106 million people in the United States live in a health professional shortage area for primary care.[13] And about 17 million people live in medically underserved areas identified as having a shortage of primary care health services.[14] Rural communities in particular are affected by a reduction in obstetrical services.[15] For these people, an emergency department may be the only physical location they can seek any sort of medical care.

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[10] Glenn Goodwin DO, *A national analysis of ED presentations for early pregnancy and complications: Implications for post-Roe America*, 70 Am. J. Emergency Med. 90, 91 (Aug. 2023), https://doi.org/10.1016/j.ajem.2023.05.011.

[11] *Id.* at 92.

[12] Dave Boushy, MD, et al., *Primary Care Physician and Patient Factors that Result in Patients Seeking Emergency Care in a Hospital Setting: The Patient's Perspective*, 17 J. Emergency Med. 405, 409 (1999).

[13] *Health Workforce Shortage Areas*, HRSA Data Warehouse (May 2, 2026), https://data.hrsa.gov/topics/health-workforce/shortage-areas/dashboard (defining professional shortage to include medical, dental or mental care shortages).

[14] *Id.*

[15] Usha Ranji et al., *Beyond the Numbers: Access to Reproductive Health Care for Low-Income Women in Five Communities*, Henry J Kaiser Family Foundation, at 10–11 (Nov. 2019), https://files.kff.org/attachment/Executive-Summary-Beyond-the-Numbers-Access-to-Reproductive-Health-Care-for-Low-Income-Women-in-Five-Communities.

Studies have also shown that a significant number of patients use the emergency department for non-urgent matters because of financial barriers, such as lack of funds, inability to pay upfront, or lack of insurance coverage.[16] In 2024, the total number of people ages 0–64 without health coverage increased by more than 1.3 million to 26.7 million.[17]

Many patients also use the emergency department for non-urgent matters for convenience of the primary care physician and an inability to get an appointment with their primary care provider.[18] Emergency departments essentially function as an adjunct to primary care outpatient practices.[19] Physicians across all areas of medicine routinely refer patients to emergency departments for a number of reasons, including when patients need attention after regular clinical hours or need diagnostic tests that cannot be performed in the office, and because of liability concerns.[20] Moreover, FDA drug labels often advise patients to seek care at the emergency department if certain side effects present.[21]

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[16] Institute of Medicine, *supra* note 3, at 45.

[17] Jennifer Tolbert et al., *Key Facts about the Uninsured Population*, KFF (Apr. 9, 2026), https://www.kff.org/uninsured/key-facts-about-the-uninsured-population/?entry=executive-summary-introduction.

[18] Boushy, MD, et al., *supra* note 12, at 406.

[19] Kristen A. Matteson, M.D., M.P.H., et al., *Accessing Care: Use of a Specialized Women's Emergency Care Facility for Nonemergent Problems*, 17 J. Women's Health 269, 275 (Nov. 2, 2008).

[20] Institute of Medicine, *supra* note 3, at 46.

[21] *See, e.g.*, FDA Label Viagra Tablet, at 1 (2014), https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/20895s039s042lbl.pdf.

For example, Dr. Kimi Chernoby has observed that patients frequently utilize the emergency department to be evaluated for effects of common medications such as headache after new blood pressure medications, or rash after antibiotics. While these potential side effects may be disclosed to patients in advance as part of informed consent counseling, cautiousness often leads the patient to present to an emergency department. It is therefore not surprising that patients who experience bleeding after taking mifepristone find themselves going to emergency departments to have their bleeding evaluated, even though that bleeding is expected and discussed with patients in advance. Nor is this kind of use of the emergency department unique to abortion care. Instead, it reflects the typical pattern of patients' use of emergency departments generally to receive non-urgent care.

C. Women Often Visit Emergency Departments for Reproductive Healthcare Because of Limited Access to Medical Care.

The emergency department is, and has long been, a critical access point for all aspects of pregnancy-related care in the United States.[22] Pregnancy complications are the fifth most common reason women between the ages of fifteen and sixty-four visit emergency departments nationally, and as many as 84% of pregnant individuals visit an emergency department at some point while pregnant.[23] Emergency department visits related to early pregnancy complications, including miscarriage and ectopic pregnancy, represent approximately 3% of all visits among females of

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[22] Margaret E. Samuels-Kalow et al., *Post-Roe Emergency Medicine: Policy, Clinical, Training, and Individual Implications for Emergency Clinicians*, 29(12) Acad. Emergency Med. 1414, 1414 (2022).

[23] Chernoby, *supra* note 6, at 1.

reproductive age, amounting to about one million annual visits nationally.[24]

The emergency department functions as a default provider of reproductive healthcare for millions of women not because of any particular medication or procedure, but because of the structural inadequacies of the American healthcare system. Research shows that only 45% of pregnant women who visit the emergency department do so because they believe they are experiencing a true emergency and 13% of visits are attributable to difficulty accessing a primary obstetric provider.[25] In another study, 36% of women presented to an obstetrics and gynecology emergency department because they felt they were having a true emergency, yet only 7% were admitted.[26]

A significant proportion of pregnancy-related visits are non-urgent. Among pregnant women who visited the emergency department, 35% had at least one non-urgent visit,[27] which was strongly associated with lack of private insurance. Uninsured women had more than five times the odds of non-urgent emergency

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[24] Emily E. Ager, MD, MPH, et al., *Preliminary Post-Dobbs Trends in Emergency Department Use for Early Pregnancy Complications*, 27 W.J. Emergency Med. 85, 87 (2026); *see also* Lyndsey S. Benson et al., *Early pregnancy loss in the emergency department, 2006–2016*, 2 J. Am. Coll. Emergency Physicians Open, at 1 (2021), https://onlinelibrary.wiley.com/doi/epdf/10.1002/emp2.12549 [doi:10.1002/emp2.12549].

[25] Kimberly A. Kilfoyle, MD, MSCR, et al., *Non-Urgent and Urgent Emergency Department Use During Pregnancy: An Observational Study*, 216 Am. J. Obstetrics & Gynecology

, at 5 (2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5290191/ [doi:10.1016/j.ajog.2016.10.013].

[26] Matteson, *supra* note 19, at 271–72.

[27] Kilfoyle, *supra* note 25, at 4.

department use as privately insured patients.[28] This data demonstrates a pattern: pregnant women seek reassurance at emergency departments for non-urgent symptoms, largely due to limited access to timely outpatient care.

The majority of emergency department visits following an abortion are similarly non-urgent. In data from the California Medicaid program following 54,911 patients undergoing abortion, roughly 6.4% of these abortions were followed by an emergency department visit within 6 weeks.[29] However, the composition of this statistic matters here: 49.8% of those visits were for other health concerns completely *unrelated* to the abortion, and another 9.4% involved unrelated but concurrent conditions.[30] Only 40.5% were abortion-related, and of those, 66.6% involved patients who presented with symptoms ***but received no treatment*** from emergency department clinicians.[31] The rate of visits that actually resulted in a diagnosis or treatment for an abortion-related issue was a mere 0.87%, and the rate of major complications following medication abortion specifically was just 0.31%.[32]

D. Reliance on Emergency Departments for Reproductive Healthcare Is Even Greater in Rural Communities.

Reliance on emergency departments for reproductive healthcare is especially

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[28] *Id.* at 5. (finding that uninsured women experienced an odds ratio of 5.55 for non-urgent emergency department use compared to privately insured patients).

[29] Ushma D. Upadhyay, PhD, MPH, et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 183 (2015).

[30] *Id.* at 181.

[31] *Id.*

[32] *Id.*

pronounced in rural America, where access to obstetric providers and birthing facilities has been in precipitous decline. Today, only 41% of rural hospitals in the United States provide labor and delivery services.[33] In twelve states, less than one third of hospitals offer such services.[34] More than 35% of all counties in the United States are now classified as "maternity care deserts," defined as counties without a single birthing facility or obstetric clinician.[35] These counties are home to more than 2.3 million women of reproductive age.[36]

The crisis only continues to deepen. In the last thirteen years, 217 rural hospitals have closed their labor and delivery units.[37] Since the end of 2020, 133 rural hospitals have ended deliveries or planned to do so before the end of 2026.[38] Thirty labor and delivery units at rural hospitals shuttered in 2025 alone, surpassing the twenty-one closures recorded the prior year.[39] "This means that an increasing number of emergency physicians are responsible for managing pregnancy complications, including discharging and transferring patients appropriately, without the support of an in-house [obstetrician]."[40]

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[33] *Stopping the Loss of Rural Maternity Care*, Center for Healthcare Quality & Payment Reform (Mar. 2026), https://ruralhospitals.chqpr.org/Maternity_Care.html.

[34] *Id.*

[35] *Nowhere to Go: Maternity Care Deserts Across the U.S.*, March of Dimes (2024), https://www.marchofdimes.org/maternity-care-deserts-report.

[36] *Id.*

[37] Chernoby, *supra* note 6, at 1.

[38] *Stopping the Loss*, *supra* note 33.

[39] *Id.*

[40] Chernoby, *supra* note 6, at 1.

The downstream effects of these closures on emergency departments are predictable and well-documented. When obstetric units close, patients do not stop requiring care. Instead, the emergency department becomes their primary—and often only—point of access for reproductive healthcare.[41]

II. EMERGENCY DEPARTMENT VISITS BY PATIENTS FOLLOWING USE OF MIFEPRISTONE IS NOT INDICATIVE OF SERIOUS ADVERSE EVENTS RELATED TO MIFEPRISTONE.

A. Patients Use the Emergency Department After Medication Abortion for a Variety of Reasons Unrelated to the Safety of Mifepristone.

As discussed above, patients present to the emergency department for a myriad of reasons, including a desire for reassurance or evaluation of a non-urgent condition, or a lack of accessible alternatives.[42] Characterizing emergency department visits following mifepristone use as evidence of the medication's danger is unsupported by the medical literature and reflects a fundamental misunderstanding of how and why Americans use emergency departments.

Many people go to an emergency room after a medication abortion for reassurance or evaluation of non-urgent symptoms such as nausea, diarrhea, or the

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[41] Liana R. Woskie, PhD, MSc, et al., *Obstetric-Related Emergency Medical Treatment and Labor Act Violations and No Health Exception Bans*, 6 JAMA Health F. (Dec. 5, 2025), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2842295 [doi:10.1001/jamahealthforum.2025.4726].

[42] Upadhyay, *supra* note 29, at 183; Ushma D. Upadhyay et al., *Distance Traveled for an Abortion and Source of Care After Abortion*, 130 Obstetrics & Gynecology 616, 624 (2017) [hereinafter *Distance Traveled*]; Ushma D. Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, 16 BMC Med., at 1 (2018), https://doi.org/10.1186/s12916-018-1072-0 [hereinafter *Abortion-Related ED Visits*].

bleeding and cramping that is an expected and necessary part of the abortion; to ask questions; or to confirm they are no longer pregnant.[43] A national study found that more than 50% of emergency department visits after abortion involve observational care only, in other words, no treatment.[44] A small number present for a safe and simple outpatient procedure to complete the abortion, which is expected in approximately 3-5% of women who have a medication abortion and is not an adverse event.[45]

Emergency department visits following medication abortion sometimes occur when there are no accessible alternatives, such as when a patient lives far from the abortion provider.[46] Emergency department visits are also common among individuals with Medicaid coverage, many of whom lack a primary care provider.[47] Studies have consistently shown that Medicaid enrollees have more fragmented care and higher rates of emergency department use across all conditions, not just those related to medication abortion.[48] These findings directly implicate systemic

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[43] UCLA Law Ctr. for Reproductive Health, Law, & Policy and UCSF Advancing New Standards in Reproductive Health, Comment on FDA Docket No. FDA-2025-P-0377-0001, FDA-2025-P-1576-0001, and FDA-2025-P-2162-0001, at 13 (Aug. 27, 2025), https://law.ucla.edu/reproductive-health-researchers-comment-letter-fda.

[44] *Abortion-Related ED Visits*, *supra* note 42, at 1.

[45] Ushma D. Upadhyay et al., *Deception by obfuscation: Studnicki et al.'s retracted longitudinal cohort study of emergency room utilization following abortion*, 134 Contraception 1, at 2 (2024), https://doi.org/10.1016/j.contraception.2024.110417.

[46] *Distance Traveled*, *supra* note 42, at 624.

[47] Karoline Mortensen & Paula H. Song, *Minding the Gap: A Decomposition of Emergency Department Use by Medicaid Enrollees and the Uninsured*, 46 Med. Care 1099, 1099–1100 (2008).

[48] Upadhyay, *supra* note 45, at 2.

healthcare access barriers rather than medication safety.

B. Studies Show That Emergency Department Visits After Mifepristone Use Are Not Indicative of Safety Concerns.

The FDA itself recognizes, in guidance applicable to all drugs, that emergency room visits, standing alone, do not constitute and are not evidence of serious adverse events.[49] While Respondents emphasize that the "FDA's own mifepristone label warns that roughly 1 in 25 (or 4% of) women who take mifepristone *as directed* will end up in the emergency room,"[50] given the common use of emergency departments for non-urgent matters, and read in context with the FDA's safety findings and the peer-reviewed literature, this data does nothing to negate the evidence that mifepristone use, regardless of where the drug is dispensed to patients, is extremely safe.

To start, Louisiana's blind reliance on the label's emergency room statistic ignores that the very same label separately reports that serious adverse reactions occurred in fewer than 0.5% of women.[51] Thus, the label itself distinguishes between where patients went (emergency departments) and whether anything serious

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[49] U.S. Food & Drug Admin., *What is a Serious Adverse Event?* (2023), https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.

[50] Plaintiffs' Memorandum of Law in Support of their Motion for Preliminary Relief under 5 U.S.C. § 705, *Louisiana v. U.S. Food & Drug Admin.*, No. 6:25-cv-01491-DCJ-DJA, 2026 WL 936958 (W.D. La. Apr. 7, 2026), 2025 WL 4103394 (emphasis in original); *Louisiana v. U.S. Food & Drug Admin.*, No. 26-30203, 2026 WL 1194924, at *5 (5th Cir. May 1, 2026).

[51] FDA Label Mifepristone Tablet, at 7 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

happened (rarely). The "1 in 25" statistic addresses only the former and, crucially, not the latter.

Time and time again, the FDA has found complications and serious adverse events associated with mifepristone to be exceptionally rare.[52] In 2016, the FDA concluded that medication abortion's "efficacy and safety have become well-established,"[53] and that "serious complications have proven to be extremely rare,"[54] with serious adverse events described as "exceedingly rare."[55]

The FDA's 2024 Post-Marketing Adverse Events Summary (through December 31, 2024) reaches the same conclusion.[56] It noted no established causal relationship between *any* serious adverse events and mifepristone.[57] A Cochrane Library systematic review likewise found serious adverse events to be rare.[58]

The medical literature reports mifepristone's continued safety. Major

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[52] U.S. Food and Drug Administration, Center for Drug Evaluation and Research ("FDA/CDER"), Application No. 020687Orig1s020 Medical Review(s), at 12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (hereinafter "FDA/CDER 2016").

[53] *Id.*

[54] *Id.*

[55] *Id.* at 47.

[56] FDA, Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024, at 1 (2024), https://www.fda.gov/media/185245/download (discussing rarity of serious adverse events and that there is no established causal relationship between those events and medication abortion).

[57] *Id.*

[58] Jing Zhang, *Medical methods for first trimester abortion*, Cochrane Library, at 35 (May 24, 2022), https://doi.org/10.1002/14651858.CD002855.pub5.

complications requiring hospitalization or blood transfusion occur in fewer than 0.4% of patients.[59] Emergency department clinicians have found that severe complications like hemorrhage are exceedingly rare, inherent to pregnancy, and never proven to be caused by mifepristone.[60]

Further, a study examining emergency department visits from 2009 to 2013 found that abortion-related visits across the board accounted for just 0.01% of all visits among women aged 15 to 49.[61] A majority of those—over 51%—involved observation care only.[62] And for the small minority of patients where medications were administered in the emergency department for abortion-related care—16.1% of visits—the most common were pain and anti-nausea medications.[63] Such medication is considered routine supportive care and not treatment for serious or life-threatening complications.

As discussed in Section I.C. *supra*, research shows that only 0.87% of patients visit the emergency room for an abortion-related complication.[64] In a large study of telehealth medication abortions, only 1.3% were followed by a known emergency

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[59] Upadhyay, *supra* note 29, at 181 (study of nearly 55,000 abortions found a major complications rate of 0.31% for medication abortion).

[60] Haleigh P. Ferro, BS, et al., *Disproportionate impact of abortion restriction: Implications for emergency department clinicians*, 69 Am. J. Emergency Med. 160, 161 (2023); FDA Label Mifepristone Tablet, *supra* note 51, at 2, 5–6.

[61] *Abortion-Related ED Visits*, *supra* note 42, at 7.

[62] *Id.* at 8.

[63] *Id.* at 6.

[64] Upadhyay, supra note 29, at 181.

department visit, 38.3% of which resulted in no treatment.[65] This further illustrates why headline emergency department visit numbers, including those referenced by Louisiana, are misleading.

The findings of these studies underscore that the numbers linked with emergency department visits capture patient behavior, not clinical harm. It is reasonable for a patient who undergoes a medication abortion, regardless of where the medication is dispensed, to consult with a provider for reassurance or observation; depending on the patient's circumstances, that provider may be in the emergency department. The consistently low numbers of patients discharged without receiving any treatment at all, let alone treatment for a serious complication, contradict Louisiana's attempts to misrepresent these visits as evidence of serious complications.

C. Expected Mifepristone Side Effects and Adverse Events Unrelated to Mifepristone Should Not Be Considered Serious Adverse Events Caused by Mifepristone.

Patients visit the emergency room after a medication abortion for cramping, vaginal bleeding, or uncertainty about whether the abortion is complete. These are all expected outcomes that "can be managed according to best-practice recommendations" by emergency department clinicians and should not be conflated with serious adverse events.[66]

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[65] Ushma D. Upadhyay et al., *Effectiveness and safety of telehealth medication abortion in the USA*, 30 Nature Med. 1191, 1193 (2024), https://doi.org/10.1038/s41591-024-02834-w.

[66] Ferro, *supra* note 60, at 161.

i. *Heavy Bleeding Is Expected, Yet Often Misclassified*

Like any means by which the pregnant uterus is emptied—including childbirth, miscarriage, or procedural abortion—a successful medication abortion always involves vaginal bleeding.[67] A patient who arrives at the emergency room with such bleeding after taking mifepristone is very likely to be experiencing the expected physiological response to the medication and not a complication.[68] Truly excessive bleeding is defined by soaking through two pads per hour for at least two consecutive hours, and bleeding below that threshold is not considered a "complication."[69] Several researchers have warned that the term hemorrhage is often misused and captures many cases of normal post-medication-abortion bleeding, mischaracterizing them as a complication.[70]

ii. *Treatment for Incomplete Abortion Is Not a Serious Adverse Event.*

An incomplete medication abortion—where a patient presents with retained products of conception—can be treated with a repeat dose of misoprostol, uterine

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[67] Alice F. Cartwright, *Measurement of medication abortion-related bleeding: A systematic scoping review*, Contraception, at 1 (2026), https://doi.org/10.1016/j.contraception.2026.111432i; FDA Label Mifepristone Tablet, at 16 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (indicating bleeding is an expected part of ending a pregnancy).

[68] *Id.*; Ferro, *supra* note 60, at 161.

[69] Jennifer L. Kerns, *Society of Family Planning Clinical Recommendation: Management of hemorrhage at the time of abortion*, 129 Contraception, at 4 (2024), https://doi.org/10.1016/j.contraception.2023.110292.

[70] *Id.* at 1–2, 9.

aspiration, or expectant management.[71] An additional dose of misoprostol is usually the next step.[72] As an alternative, patients can undergo a uterine aspiration, which is the exact same treatment as a procedural abortion. Studies have shown that between 3% and 5% of patients who undergo a medication abortion will need an outpatient uterine aspiration procedure.[73] This is a known and expected outcome for a small minority of patients.[74] The subsequent treatment is safe and is not indicative of a dangerous event. Attempts to classify anticipated follow-up care as "serious adverse events" misrepresent the clinical reality of abortion care.

iii. *Adverse Events from a Miscarriage or a Pre-Existing Condition Should Be Distinguished from Adverse Events Caused by Mifepristone.*

Similarly, in the context of miscarriage care, it is crucial for any valid safety analysis of mifepristone to distinguish adverse events arising from the underlying pregnancy loss from those caused by mifepristone itself.[75] Studies that fail to make this distinction improperly attribute the complications of a miscarriage to the medication used to manage it. When a patient is having a miscarriage, there is necessarily bleeding. It is thus illogical to say that the mifepristone and misoprostol,

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[71] *Medication Abortion Up to 70 Days of Gestation*, American College of Obstetricians & Gynecologists (Oct. 2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

[72] *Id.*

[73] Upadhyay, *supra* note 45, at 2.

[74] *Id.*

[75] *Id.*

when prescribed to treat a miscarriage, caused the bleeding that is inherent to the miscarriage process.

The same logic applies to patients who present with pre-existing conditions. The Society for Maternal-Fetal Medicine emphasizes that pregnancy itself carries a significant risk of morbidity and mortality,[76] a risk much higher than carried by abortion. Pre-existing conditions such as cardiovascular disease, diabetes, hypertension, and cancer can substantially exacerbate those risks.[77] Emergency department visits by women who take mifepristone and then present at the emergency department for serious pre-existing conditions (or exacerbation from them as a result of their pregnancy) should not be attributed to mifepristone in an attempt to misclassify it as dangerous.

iv. *Telehealth Has Not Increased Adverse Events in Patients Presenting at Emergency Departments.*

The use of telehealth to prescribe mifepristone has not produced any measurable increase in hemorrhage or other serious adverse events in patients presenting at emergency departments.[78] One study found that among 3,779

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[76] Soc'y for Maternal-Fetal Med., *Clinical considerations for management of severe complications when abortion care is restricted*, at 3 (August 11, 2022), https://publications.smfm.org/publications/450-clinical-considerations-for-management-of-severe-complications-when/.

[77] *Id.* at 4.

[78] M. Ender et al., *Telemedicine for medical abortion: a systemic review*, 126 BJOG 1094, 1098–99 (2019) (finding rates of complete abortion, continuing pregnancy, hospitalization, and hemorrhage after abortion via telemedicine were at similar levels to those reported after in-person abortion care in the published literature); Daniel Grossman, MD, et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296, 299–300 (2011)

medication abortions performed with no in-person pre-abortion testing (*i.e.*, ultrasounds), 95% were completed without any procedural intervention and only 0.5% experienced a serious adverse event.[79] The effectiveness and safety of the medication abortions were similar whether medications were dispensed in person or by mail.[80]

Another study followed thousands of patients across the United States from three virtual clinics to estimate the effectiveness and safety of medication abortion care provided through telehealth.[81] The study found the overall effectiveness rate for telehealth medication abortions was 98%, similar to previous large studies of in-person medication abortion care in the United States finding effectiveness rates of 95–98%.[82] The serious adverse event rate of telehealth medication abortions was only 0.25%.[83] This rate was likewise similar to previous studies of in-person medication abortion care finding adverse event rates of 0.2–0.5%.[84] As noted in Section II.B. *supra*, overall, only 1.3% of the telehealth medication abortions were followed by a known emergency department visit, 38.3% of which resulted in no treatment.[85] Other studies analyzing the impact of telemedicine mifepristone on the incidence of serious

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(no significant difference in the prevalence of adverse events reported between telemedicine and in-person medical abortion patients).

[79] Upadhyay et al., *supra* note 65, at 1192.

[80] *Id.*

[81] *Id.*

[82] *Id.* at 1194.

[83] *Id.*

[84] *Id.*

[85] *Id.* at 1193.

adverse events have found it comparable to in-person abortion care in the published literature.[86]

Dr. Dara Kass's personal experience providing care to women in a safety net hospital affiliated with a telehealth abortion hotline for the last year corroborates the findings in these studies.[87] She reports that she has observed, and is aware of, no unexpected complications reported as result of telehealth-prescribed medication abortions. Instead, she found that the ability to prescribe mifepristone to patients through telehealth allowed for far greater efficiency while providing increased access to underserved populations that rely on public health facilities for their reproductive healthcare needs.

III. MIFEPRISTONE IS CRITICAL TO PATIENT CARE IN THE EMERGENCY DEPARTMENT.

Louisiana's attempt to restrict access to mifepristone because of its objection to one clinical indication—abortion—does not account for the reality that mifepristone is used to treat many clinical indications. Such restrictions create barriers to care that extend across specialties and patient populations.

A. Physicians Prescribe and Administer Mifepristone for Indications Unrelated to Abortion.

Restricting access to mifepristone would impact a much larger patient

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[86] M. Ender et al., *supra* note 78, at 1098–99; Upadhyay et al., *supra* note 65, at 1194.

[87] Dr. Kass is an emergency medicine physician at NYC H+/Lincoln Hospital in the Bronx, New York, founder and CEO of FemInEM, and a former HHS official (2021–2024) where she led federal public health communications. In addition to practicing emergency medicine, she serves as a Professor of Practice at Brown University, co-directing the Advancing Impact in Maternal and Reproductive Health Lab.

population than those seeking abortions. Mifepristone is a staple of modern medicine with broad, well-established clinical applications in reproductive healthcare and beyond, including for management of early miscarriage and as an adjunct therapy for uterine fibroids.[88]

The impact of restricting mifepristone on miscarriage care is especially significant. An estimated 10–15% of pregnancies end in miscarriage.[89] Patients experiencing early pregnancy loss often present to the emergency department.[90] The American College of Obstetricians and Gynecologists ("ACOG") recommends the mifepristone–misoprostol combination for medical management of miscarriage.[91]

Use of mifepristone and misoprostol together to manage a miscarriage reduces the need for subsequent procedures to remove the pregnancy. Because emergency

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[88] Dara Kass, MD, & Kimberly Chernoby MD, JD, MA, *Classifying Mifepristone, Misoprostol, and Methotrexate as Controlled Substances: Patient Care Consequences and Clinical Implications*, at 3 (Apr. 13, 2026), https://sph.brown.edu/sites/default/files/2026-04/Classfying%20Mife%20FINAL%20April%2013.%20(1).pdf.

[89] *Miscarriage*, Johns Hopkins Med., https://www.hopkinsmedicine.org/health/conditions-and-diseases/miscarriage (estimating 10% of pregnancies end in miscarriage); Jay Ghosh et al., *Methods for managing miscarriage: a network meta-analysis*, Cochrane Library, at 17 (2021), https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012602.pub2/full. (estimating 15% of pregnancies end in miscarriage).

[90] Christopher S. Evans MD, MPH, *Early Pregnancy Loss in the Emergency Department: Lessons Learned as a Spouse, New Father, and Emergency Medicine Resident*, 77 Annals of Emergency Med. 233, 233 (2021), https://doi.org/10.1016/j.annemergmed.2020.08.035; Kayleigh Gregory et al., *Emergency department care for early pregnancy loss: A scoping review of patient experiences and compassionate clinical practices in the United States*, 85 Int'l Emergency Nursing 1, 1 (2026), https://doi.org/10.1016/j.ienj.2026.101763.

[91] Kass & Chernoby, *supra* note 88, at 7; *ACOG Practice Bulletin No. 200: Early Pregnancy Loss*, 132 Obstetrics & Gynecology e197, e200 (2018).

departments often do not stock mifepristone, emergency physicians frequently rely on the ability to prescribe mifepristone through a retail pharmacy. The stay of the 2023 REMS cuts off this critical access point for emergency department patients in need of care for early pregnancy loss.

CONCLUSION

For these, and the foregoing reasons, *amici curiae* respectfully urge this Court to stay or vacate the Fifth Circuit Court of Appeals' May 1, 2026, Opinion pending all appeals to the Fifth Circuit and any further proceedings in this Court.

Respectfully submitted,

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