

IN THE
United States Court of Appeals
for the Fifth Circuit

LOUISIANA, ET AL.,

*Plaintiffs-Appellants/Cross-
Appellees,*

v.

FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants-Appellees,

v.

GENBIOPRO, INC.,

*Intervenor-Appellee/Cross-
Appellant,*

v.

DANCO LABORATORIES, L.L.C.,

*Intervenor-Appellee/Cross-
Appellant,*

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

**BRIEF OF FEMINEM FOUNDATION, AMERICAN COLLEGE OF
EMERGENCY PHYSICIANS, AMERICAN ACADEMY OF EMERGENCY
MEDICINE, AND EMERGENCY MEDICINE RESIDENTS' ASSOCIATION
AS AMICI CURIAE IN SUPPORT OF INTERVENOR-APPELLEES**

(Counsel listed on inside cover)

LEAH R. BRUNO
(*Counsel of Record*)
EMILY D. STEEB
MARY STRONG
Dentons US LLP
233 South Wacker Drive,
Suite 5900
Chicago, Illinois 60606
(312) 876-8000
leah.bruno@dentons.com

Attorneys for Amici Curiae

CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Amici Curiae

- FemInEM Foundation
- American College of Emergency Physicians
- American Academy of Emergency Medicine
- Emergency Medicine Residents' Association

Counsel for Amici Curiae

- Leah R. Bruno, Dentons US LLP

/s/ Leah R. Bruno
Leah R. Bruno
Attorney for Amici Curiae

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STATEMENT OF INTEREST OF AMICI CURIAE¹

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 in 2015, FemInEM 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 College of Emergency Physicians (“ACEP”) is the leading professional body for emergency physicians and sets the standard for emergency medical care. ACEP’s mission is to promote the highest quality of emergency care and advocate for emergency physicians and their patients, and the public. Founded in 1968, ACEP represents more than 38,000 emergency physicians, emergency medicine residents, and medical students.

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

¹ No other party’s counsel authored this brief in whole or in part 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.

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. AAEM's mission is to fight for high-quality patient care delivered by board-certified emergency physicians and champion a fair and equitable workplace for emergency physicians through advocacy and education. AAEM has over 8,000 members.

Amicus curiae Emergency Medicine Residents' Association ("EMRA") is the oldest and largest independent emergency medical resident organization in the world. Founded in 1974, EMRA has more than 19,000 emergency medicine resident, fellow, medical student, and alumni members. EMRA is the voice of emergency medicine physicians-in-training and the future of their specialty. EMRA is committed to advancing emergency medicine and protecting its patients through its core pillars: Education, Leadership, and Advocacy.

Amici offer this brief to assist the Court in better understanding the role of emergency departments in medical care in the United States and to illustrate the realities of what emergency department visits following medication abortion typically entail. *Amici's* firsthand experience with women who visit the emergency department, as well as published research, demonstrate that efforts to rely on emergency department visits after use of mifepristone to undermine the vast body of scientific research showing that the drug is safe and effective with extremely low

rates of serious adverse events, including when dispensed by mail and pharmacies, are unfounded. Plaintiffs-Appellants’ “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.

Plaintiffs-Appellants 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. Relying on that misrepresentation would not only deny patients safe methods of accessing care but also impose far reaching effects on emergency departments' ability to provide necessary healthcare.

Emergency departments are the only place where any person at any time of day regardless of their financial resources or ability to pay can obtain the healthcare they need. As the nation's safety net, emergency departments serve patients presenting with complaints that span the full spectrum of acuity. Federal law guarantees that a patient can receive treatment in the emergency department if a person who possesses an average knowledge of health and medicine (the "prudent layperson") could reasonably expect the absence of immediate medical attention to result in placing the patient's health in serious jeopardy, severe impairment to bodily functions or serious dysfunction, regardless of whether the condition ultimately does result in an adverse outcome to the patient. One of the results of this reality is that many individuals use emergency departments for symptoms that require a variety of treatments, including what may ultimately be routine reproductive healthcare.

Patient visits to the emergency department following mifepristone use are not indicative of serious adverse events caused by mifepristone, and therefore do not undermine the robust evidence of the drug's safety. 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. Mifepristone is prescribed in emergency departments for patients experiencing pregnancy loss (spontaneous abortion) in the same way that it is used for induced abortion. The mifepristone-misoprostol combination is a first-line treatment for miscarriage management. 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 retail pharmacy access, would inhibit emergency departments’ ability to provide standard-of-care treatment for miscarriage and other pregnancy complications, resulting in reduced access to important reproductive healthcare and worse patient outcomes.

For these and the reasons set forth more fully below, *amici curiae* urge this Court to grant the relief requested by Intervenor-Appellees/Cross-Appellants.

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 the "safety net of the safety net."⁵

Emergency departments receive and treat patients who reasonably believe that a failure to treat their symptoms could result in the impairment of bodily functions, organs, or place the patient's health in serious jeopardy, in compliance with Federal Law. 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 a

² Talia Ruxin 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 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.

variety of complaints that span the full spectrum of acuity, from life-threatening emergencies to concerns that, upon clinical evaluation, require reassurance or routine supportive care. 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. Kimberly Chernoby explains that care delivered in emergency departments spans the level of acuity from traumatic—life-threatening heart attacks and strokes, gunshot wounds and mass casualties—to routine care—cold symptoms, expected side effects of medications, joint pain, headaches, pregnancy confirmation, sunburn, bug bites, and rashes.⁷ The patient has the right under federal law to seek treatment for any one of these symptoms, even if the ultimate outcome is that their life is not at risk. A systematic review found that an average of 37% of emergency department visits were retrospectively classified as non-urgent.⁸ In a study at five urban

⁶ Kimberly Chernoby & Brian Acunto, *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.

⁸ Lori Uscher-Pines et al., *Deciding to Visit the Emergency Department for Non-Urgent Conditions: A Systematic Review of the Literature*. Am J Manag Care, at 1 (2013), <https://pubmed.ncbi.nlm.nih.gov/23379744/>. In this review, the definition of “non-urgent” included visits for conditions for which a delay of several hours would not increase the likelihood of an adverse outcome. *Id.*

nonfederal teaching hospital emergency departments in the northeastern United States, researchers found that 50% of the 1,696 participants had non-urgent conditions.⁹ Indeed, patients *often* go to the emergency department because they have no primary care provider, know of no other option to confirm whether they require immediate medical intervention, or are referred by their primary care provider.¹⁰ Dr. Chernoby has observed that patients frequently utilize the emergency department to seek assurance that they are not having a concerning healthcare issue.

B. Patients Use Emergency Departments for Routine Healthcare Because of Barriers to Accessing Other Healthcare Resources.

Many patients go to the emergency department for routine healthcare because emergency departments do not require payment upfront and do not turn patients away. The Emergency Medical Treatment & Labor Act (EMTALA) requires that emergency departments provide a medical screening exam to any presenting patient to determine whether an emergency medical condition exists.¹¹ If an emergency medical condition is present, then a physician must provide stabilizing care or risk-

⁹ Laura A. Petersen et al., *Nonurgent Emergency Department Visits: The Effect of Having a Regular Doctor*, 36 Med. Care 1249, 1250 (1998).

¹⁰ See Kristen A. Matteson et al., *Accessing Care: Use of a Specialized Women's Emergency Care Facility for Nonemergent Problems*, 17 J. Women's Health 269, 273, 275-76 (Nov. 2, 2008) (21% of patients presented at the emergency department due to access barriers and 42% of patients were referred to the emergency department by a physician).

¹¹ 42 U.S.C.A. § 1395dd(a).

minimizing treatment and transfer to another medical facility.¹² 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.¹³ 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. The ability of patients to seek care when experiencing what they believe is an emergency medical condition is the bedrock of the healthcare safety net. The emergency department serves as many patients' main access point for an array of care, including reproductive healthcare.¹⁴ For example, women experiencing bleeding while pregnant may make repeated visits to the emergency department, although most will be discharged without

¹² 42 U.S.C.A. § 1395dd(b), (c).

¹³ Institute of Medicine, *supra* note 3, at 42.

¹⁴ Glenn Goodwin et al., *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>.

admission.¹⁵ Patients have also reported coming to the emergency department to seek reassurance.¹⁶

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.¹⁷ And about 17 million people live in medically underserved areas identified as having a shortage of primary care health services.¹⁸ Rural communities in particular are affected by a reduction in obstetrical services.¹⁹ For many people in medically underserved areas, an emergency department may be the only physical location where they can seek the medical care they need.

Studies have also shown that a significant number of patients use the emergency department because of financial barriers, such as lack of funds, inability to pay upfront, or lack of insurance coverage.²⁰ In 2024, the total number of people

¹⁵ *Id.* at 92.

¹⁶ Dave Boushy & Isser Dubinsky, *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).

¹⁷ *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).

¹⁸ *Id.*

¹⁹ 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>.

²⁰ Institute of Medicine, *supra* note 3, at 45.

ages 0–64 without health coverage increased by more than 1.3 million to 26.7 million.²¹

Many patients use the emergency department due to primary care provider referrals or an inability to get an appointment with their primary care provider.²² Physicians refer patients to emergency departments for various reasons, including when patients need attention after regular clinical hours, when diagnostic testing unavailable in the outpatient setting is needed, or because outpatient providers are concerned about liability if they do not refer the patient to the emergency department for evaluation.²³ Moreover, FDA drug labels often advise patients to seek care at the emergency department if certain side effects present.²⁴

For example, Dr. Chernoby has observed that patients frequently utilize the emergency department to be evaluated for effects of common medications such as a 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, legitimate patient concerns often lead the patient to present to

²¹ 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>.

²² Matteson et al., *supra* note 10, at 275.

²³ Institute of Medicine, *supra* note 3, at 46.

²⁴ See, e.g., FDA Label Viagra Tablet, at 1 (2014), https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/20895s039s042lbl.pdf.

an emergency department. It is therefore not surprising that patients who experience bleeding after taking mifepristone for abortion or miscarriage care find themselves going to emergency departments to have their bleeding evaluated, even when that bleeding is an integral part of the treatment, is expected, and is discussed with patients in advance. This kind of use of the emergency department is not unique to abortion (or miscarriage) care. It reflects the typical pattern of patients using emergency departments as the healthcare safety net.

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 pregnancy-related care in the United States.²⁵ 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.²⁶ Emergency department visits related to early pregnancy complications, such as miscarriage, represent approximately 3% of all visits among females of reproductive age, amounting to about one million annual visits nationally.²⁷

²⁵ 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).

²⁶ Chernoby, *supra* note 6, at 1.

²⁷ Emily E. Ager 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

The emergency department is 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.²⁸ 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.²⁹

Many pregnancy-related visits are non-urgent, meaning the patients present with health concerns that in retrospect could have been addressed in an outpatient setting.³⁰ Seeking care for a health concern later determined to be “non-urgent” is not an inappropriate use of the emergency department.³¹ Further, it is protected under the federal prudent layperson standard. Among pregnant women who visited the emergency department, 35% had at least one non-urgent visit,³² which was strongly

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].

²⁸ Kimberly A. Kilfoyle 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].

²⁹ Matteson, *supra* note 10, at 271–72.

³⁰ Kilfoyle, *supra* note 28, at 2.

³¹ See Matteson, *supra* note 10, at 273.

³² Kilfoyle, *supra* note 28, at 4.

associated with lack of private insurance. Uninsured women had more than five times the odds of non-urgent emergency department use as privately insured patients.³³ This data demonstrates a pattern: pregnant women seek reassurance at emergency departments for low-acuity health concerns, largely due to limited access to timely outpatient care.

The majority of emergency department visits following an abortion similarly did not result in treatment for a serious complication. In data from the California Medicaid program following 54,911 patients undergoing abortion (medication and procedural), roughly 6.4% of these abortions were followed by an emergency department visit within 6 weeks.³⁴ However, 49.8% of those visits were for health concerns completely *unrelated* to the abortion, and another 9.4% were for conditions unrelated to the abortion but that were diagnosed or treated at the time of the abortion care (e.g., for a preexisting condition).³⁵ Only 40.5% of the 6.4% of patients who sought emergency department care sought abortion-related care, and of those cases, 66.6% involved patients who ***required no medical intervention*** from emergency department clinicians.³⁶ The rate of visits that actually resulted in a diagnosis or

³³ *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).

³⁴ Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 *Obstetrics & Gynecology* 175, 180 (2015).

³⁵ *Id.* at 181.

³⁶ *Id.*

treatment for an abortion-related issue was a mere 0.87%, and the rate of major complications following medication abortion was 0.31%.³⁷

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

Reliance on emergency departments for reproductive healthcare is especially 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.³⁸ In twelve states, fewer than one third of hospitals offer such services.³⁹ 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.⁴⁰ These counties are home to more than 2.3 million women of reproductive age.⁴¹

The crisis only continues to deepen. In the last thirteen years, 217 rural hospitals have closed their labor and delivery units.⁴² Since the end of 2020, 133

³⁷ *Id.*

³⁸ *Stopping the Loss of Rural Maternity Care*, Center for Healthcare Quality & Payment Reform (Mar. 2026), https://ruralhospitals.chqpr.org/Maternity_Care.html.

³⁹ *Id.*

⁴⁰ *Nowhere to Go: Maternity Care Deserts Across the U.S.*, March of Dimes (2024), <https://www.marchofdimes.org/maternity-care-deserts-report>.

⁴¹ *Id.*

⁴² Chernoby, *supra* note 6, at 1.

rural hospitals have ended deliveries or planned to do so before the end of 2026.⁴³ Thirty labor and delivery units at rural hospitals shuttered in 2025, surpassing the twenty-one closures recorded the prior year.⁴⁴ “This means that an increasing number of emergency physicians are responsible for managing pregnancy complications . . . without the support of an in-house [obstetrician].”⁴⁵

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.⁴⁶

II. EMERGENCY DEPARTMENT VISITS BY PATIENTS FOLLOWING USE OF MIFEPRISTONE ARE 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 for reassurance or evaluation of a low-acuity condition, or a lack of accessible alternatives.⁴⁷ Characterizing emergency department visits

⁴³ *Stopping the Loss*, *supra* note 33.

⁴⁴ *Id.*

⁴⁵ Chernoby, *supra* note 6, at 1.

⁴⁶ Liana R. Woskie 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].

⁴⁷ See *supra* Section I.B. Upadhyay, *supra* note 34, at 183; Ushma D. Upadhyay et al., *Distance Traveled for an Abortion and Source of Care After Abortion*, 130 *Obstetrics & Gynecology* 616,

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 symptoms such as nausea, diarrhea, or the bleeding and cramping that is an expected and necessary part of the abortion; to ask questions; or to confirm they are no longer pregnant.⁴⁸ A national study found that more than 50% of abortion-related emergency department visits involve observational care only.⁴⁹ 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.⁵⁰

Emergency department visits following medication abortion sometimes occur when there are no accessible alternatives, such as when a patient lives far from the

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*”].

⁴⁸ 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>.

⁴⁹ *Abortion-Related ED Visits*, *supra* note 47, at 1.

⁵⁰ Ushma D. Upadhyay & Chris E. Adkins, *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>.

abortion provider.⁵¹ Emergency department visits are also common among individuals with Medicaid coverage, many of whom lack a primary care provider.⁵² Medicaid enrollees have more fragmented care and higher rates of emergency department use across all conditions, not just those related to medication abortion.⁵³ These findings implicate systemic 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.⁵⁴ While Plaintiffs-Appellants 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,”⁵⁵ given the common use of emergency departments for routine healthcare, and read in context with the FDA’s safety findings and the peer-reviewed literature, this data does nothing to

⁵¹ *Distance Traveled*, *supra* note 47, at 624.

⁵² 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).

⁵³ Upadhyay, *supra* note 50, at 2.

⁵⁴ 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>.

⁵⁵ 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).

negate the evidence that mifepristone use, regardless of where the drug is dispensed to patients, is extremely safe.

To start, Louisiana’s misleading reliance on the label’s emergency room statistic ignores that the very same label reports that serious adverse reactions occurred in fewer than 0.5% of women.⁵⁶ Thus, the label itself distinguishes between where patients went (emergency departments) and whether anything serious happened (rarely). The “1 in 25” statistic addresses only the former and not the latter.

The FDA has consistently found complications and serious adverse events associated with mifepristone to be exceptionally rare.⁵⁷ In 2016, the FDA concluded that medication abortion’s “efficacy and safety have become well-established,”⁵⁸ and that “serious complications have proven to be extremely rare,”⁵⁹ with serious adverse events described as “exceedingly rare.”⁶⁰

The FDA’s 2024 Post-Marketing Adverse Events Summary (through December 31, 2024) reaches the same conclusion.⁶¹ It noted no established causal

⁵⁶ FDA Label Mifepristone Tablet, at 7 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

⁵⁷ 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”].

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 47.

⁶¹ FDA, Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024, at 1

relationship between *any* serious adverse events and mifepristone.⁶² A Cochrane Library systematic review likewise found serious adverse events to be rare.⁶³

The medical literature reports mifepristone's continued safety. Major complications occur in fewer than 0.4% of patients.⁶⁴ Emergency department clinicians have found that severe complications like hemorrhage are exceedingly rare, inherent to pregnancy itself, and not proven to be caused by mifepristone.⁶⁵

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 49.⁶⁶ A majority of those—over 51%—involved observation care only.⁶⁷ 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 medications administered were pain and anti-nausea

(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).

⁶² *Id.*

⁶³ Jing Zhang, et al., *Medical methods for first trimester abortion*, Cochrane Library, at 35 (May 24, 2022), <https://doi.org/10.1002/14651858.CD002855.pub5>.

⁶⁴ Upadhyay, *supra* note 34, at 181 (study of nearly 55,000 abortions found a major complications rate of 0.31% for medication abortion).

⁶⁵ Haleigh P. Ferro 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 56, at 2, 5–6.

⁶⁶ *Abortion-Related ED Visits*, *supra* note 47, at 7.

⁶⁷ *Id.* at 8.

medications.⁶⁸ 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 who visited the emergency department after an abortion received an abortion-related diagnosis or treatment.⁶⁹ In a large study of telehealth medication abortions, only 1.3% were followed by a known emergency department visit, 38.3% of which resulted in no treatment.⁷⁰ 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 high numbers of patients evaluated and discharged without requiring medical intervention, let alone treatment for a serious complication, defeats Louisiana's attempts to misrepresent these visits as evidence of serious complications.

⁶⁸ *Id.* at 6.

⁶⁹ Upadhyay, *supra* note 34, at 181.

⁷⁰ 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>.

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.⁷¹

i. *Bleeding Is Expected, Yet Often Misclassified*

Like any means by which the pregnant uterus is emptied—including childbirth, miscarriage, or procedural abortion—a completed medication abortion always involves vaginal bleeding.⁷² A patient who arrives at the emergency room with bleeding after taking mifepristone is very likely to be experiencing the expected physiological response to treatment and not a complication.⁷³ Several researchers have warned that the term hemorrhage is often misused and captures many cases of

⁷¹ Ferro, *supra* note 65, at 161.

⁷² Alice F. Cartwright, et al., *Measurement of medication abortion-related bleeding: A systematic scoping review*, 160 *Contraception* 1, at 1 (2026), [https://www.contraceptionjournal.org/article/S0010-7824\(26\)00069-7/fulltext](https://www.contraceptionjournal.org/article/S0010-7824(26)00069-7/fulltext) [DOI: 10.1016/j.contraception.2026.111432]; FDA Label Mifepristone Tablet, *supra* note 56, at 16 (indicating bleeding is an expected part of ending a pregnancy).

⁷³ *Id.*; Ferro, *supra* note 65, at 161.

normal bleeding integral to a medication abortion, mischaracterizing it as a complication.⁷⁴

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

An incomplete medication abortion—where a patient presents with retained products of conception—is most commonly addressed with an additional dose of misoprostol.⁷⁵ As an alternative, patients can undergo a uterine aspiration, which is the 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.⁷⁶ This is a known and expected outcome for a small minority of patients.⁷⁷ 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.

⁷⁴ Jennifer L. Kerns et al., *Society of Family Planning Clinical Recommendation: Management of hemorrhage at the time of abortion*, 129 *Contraception* 1, at 4 (2024), <https://doi.org/10.1016/j.contraception.2023.110292>.

⁷⁵ *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>.

⁷⁶ Upadhyay, *supra* note 50, at 2.

⁷⁷ *Id.*

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

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.⁷⁸ Failing to make this distinction improperly attributes 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, 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,⁷⁹ a much higher risk than abortion. Pre-existing conditions such as cardiovascular disease, diabetes, hypertension, and cancer can substantially exacerbate those risks.⁸⁰ 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

⁷⁸ *Id.*

⁷⁹ 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/>.

⁸⁰ *Id.* at 4.

pregnancy) should not be attributed to mifepristone in an attempt to misclassify mifepristone 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.⁸¹ One study found that among 3,779 medication abortions performed with no in-person pre-abortion testing (*i.e.*, ultrasounds), 95% were completed without any procedural intervention and the differential between major adverse event rates between patients who received medication in person versus by mail was not statistically significant (and was rare for both).⁸² The effectiveness and safety of the medication abortions were similar whether medications were dispensed in person or by mail.⁸³

⁸¹ 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 et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296, 299–300 (2011) (no significant difference in the prevalence of adverse events reported between telemedicine and in-person medical abortion patients).

⁸² Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182(5) JAMA Internal Med. 482, 483 (2022), [DOI: 10.1001/jamainternmed.2022.0217].

⁸³ *Id.* at 487.

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.⁸⁴ 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%.⁸⁵ The serious adverse event rate of telehealth medication abortions was only 0.25%.⁸⁶ This rate was likewise similar to previous studies of in-person medication abortion care finding serious adverse event rates of 0.2–0.5%.⁸⁷ 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.⁸⁸ Other studies analyzing the impact of telemedicine mifepristone on the incidence of serious adverse events have found it comparable to in-person abortion care in the published literature.⁸⁹

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

⁸⁴ Upadhyay, *supra* note 70, at 1192.

⁸⁵ *Id.* at 1194.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.* at 1193.

⁸⁹ *Id.* at 1194; Ender, *supra* note 81, at 1098–99.

findings in these studies.⁹⁰ She has observed, and is aware of, no unexpected complications reported as a result of telehealth-prescribed medication abortions. Instead, she found that the ability to prescribe mifepristone safely to patients through telehealth has allowed for far greater access, particularly for underserved populations that rely on public health facilities for their reproductive healthcare needs.

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

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 multiple clinical indications. Such restrictions create barriers to care that extend across specialties and patient populations.

Mifepristone has clinical applications in reproductive healthcare beyond abortion, including for management of early miscarriage and as an adjunct therapy for uterine fibroids.⁹¹ The impact of restricting mifepristone on miscarriage care is

⁹⁰ Dr. Kass is an emergency medicine physician at NYC H+/Lincoln Hospital in 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.

⁹¹ Dara Kass & Kimberly Chernoby, *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/Classifying%20Mife%20FINAL%20April%2013.%20\(1\).pdf](https://sph.brown.edu/sites/default/files/2026-04/Classifying%20Mife%20FINAL%20April%2013.%20(1).pdf).

especially significant. An estimated 10–15% of pregnancies end in miscarriage.⁹² Patients experiencing early pregnancy loss often present to the emergency department.⁹³ The American College of Obstetricians and Gynecologists recommends the mifepristone–misoprostol combination for medical management of miscarriage.⁹⁴

Use of mifepristone and misoprostol together to manage a miscarriage reduces the need for subsequent procedures to remove the pregnancy. Because emergency departments often do not stock mifepristone, emergency physicians frequently rely on the ability to prescribe mifepristone through a retail pharmacy. Reinstating the in-person dispensing REMS would cut off this critical access point for emergency department patients in need of care for early pregnancy loss.

As discussed in Section I.C., early pregnancy complications, including miscarriage, account for approximately one million emergency department visits

⁹² *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).

⁹³ Christopher S. Evans, *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>.

⁹⁴ Kass & Chernoby, *supra* note 91, at 7; *ACOG Practice Bulletin No. 200: Early Pregnancy Loss*, 132 *Obstetrics & Gynecology* e197, e200 (2018).

annually among women of reproductive age. For these patients, an emergency physician's prescription of mifepristone through a retail pharmacy is a critical means of accessing the standard and recommended treatment. Restricting that access does not eliminate the clinical need; it forces emergency physicians to manage early pregnancy loss with less effective alternatives or to refer patients for invasive procedures that may be unavailable in their community.⁹⁵

CONCLUSION

For these, and the foregoing reasons, *amici curiae* respectfully urge this Court to grant the relief requested by the Intervenor-Appellees/Cross-Appellants.

Dated: July 22, 2026

Respectfully submitted,

/s/ Leah R. Bruno
LEAH R. BRUNO
(Counsel of Record)
EMILY D. STEEB
MARY STRONG
Dentons US LLP
233 South Wacker Drive,
Suite 5900
Chicago, Illinois 60606
(312) 876-8000
leah.bruno@dentons.com

Attorneys for Amici Curiae

⁹⁵ Emily E. Ager et al., *Preliminary Post-Dobbs Trends in Emergency Department Use for Early Pregnancy Complications*, 27 W.J. Emergency Med. 85, 87 (2026); see also Benson, *supra* note 27.

CERTIFICATE OF COMPLIANCE

I hereby certify that this response complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of 32(a)(6), and Fifth Circuit Rule 32.1, because it has been prepared in 14-point Times New Roman proportionally spaced font, except that footnotes are in 12-point font. I further certify that this response complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 6,426 words, excluding the parts of the brief exempted by Rule 32(f), according to the count of Microsoft Word.

/s/ Leah R. Bruno
Leah R. Bruno
Attorney for Amici Curiae

CERTIFICATE OF SERVICE

I certify that on July 22, 2026, I electronically filed the foregoing response with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users, and that service will be accomplished by the CM/ECF system.

/s/ Leah R. Bruno
Leah R. Bruno
Attorney for Amici Curiae