No. 26-30203

In the United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *Commissioner, U.S. Food and Drug Administration*; RICHARD PADZUR, *in his official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*,
Defendants-Appellees,

GENBIOPRO, INCORPORATED,
Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,
Intervenor-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Western District of Louisiana, Lafayette Division
No. 6:25-CV-1491

BRIEF OF AMICI CURIAE SUSAN B. ANTHONY PRO-LIFE AMERICA, ET AL., IN SUPPORT OF APPELLANTS/CROSS-APPELLEES

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Certificate of Interested Persons

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STATE OF LOUISIANA, ET AL.,
Plaintiffs-Appellants/Cross-Appellees,

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

Plaintiffs-Appellants/Cross-Appellees	**Former or present counsel**
• State of Louisiana, by & through its Attorney General, Liz Murrill • Rosalie Markezich	Louisiana Department of Justice • Jorge Benjamin Aguinaga • Caitlin Ann Huettemann Alliance Defending Freedom • Erik C. Baptist • Julie M. Blake • Erin M. Hawley • Gabriella McIntyre Johnson Siebeneicher & Ingram • Michael T. Johnson
Defendants-Appellees	**Former or present counsel**
• Food and Drug Administration • U.S. Department of Health and Human Services • Marty Makary, Commissioner of Food and Drugs • Richard Padzur, in his official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration • Robert F. Kennedy, Jr., Secretary, U.S. Department of Health and Human Services	U.S. Department of Justice • Daniel Winik • Andrew Marshall Bernie • Noah T. Katzen

Intervenor-Appellees/Cross-Appellants	**Former or present counsel**
• GenBioPro, Incorporated	Arnold & Porter Kaye Scholer, LLP • John Patrick Elwood • John N. Adcock • Robert J. Katerberg • Daphne O'Connor Democracy Forward Foundation • Carrie Yvette Flaxman • Lisa Newman
• Danco Laboratories, L.L.C.	Hogan Lovells LLP • Jessica L. Ellsworth • Katherine McKay • William Brock Most • Dana A. Raphael • Jo-Ann Tamila Sagar • Danielle Desaulniers Stempel
Amici Curiae	**Former or present counsel**
• Susan B. Anthony Pro-Life America • Charlotte Lozier Institute • Louisiana Right to Life • Texas Right to Life • The March for Life Education and Defense Fund • National Catholic Bioethics Center • Catholic Medical Association • National Association of Catholic Nurses, USA • Christ Medicus Foundation	Hacker Stephens LLP • Heather Gebelin Hacker

• Catholic Health Care Leadership Alliance • National Catholic Partnership on Disability • Texas Alliance for Life • Texans for Life Coalition	

/s/ Heather Gebelin Hacker
HEATHER GEBELIN HACKER
Counsel for Amici Curiae

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Interest of Amici Curiae

Amici curiae[1] are a preeminent group of organizations devoted to addressing important social and medical issues—particularly healthcare decisions involving moral and bioethical concerns—and represent knowledge and experience across various disciplines:

Susan B. Anthony Pro-Life America is a "pro-life advocacy organization"[2] dedicated to ending abortion, while protecting the lives of mothers and their babies, including through advancement of pro-life laws and health-saving regulatory measures for women, girls, and the unborn through direct lobbying and grassroots campaigns.

Charlotte Lozier Institute (CLI) is a nonprofit educational foundation that advises the pro-life movement with scientific, statistical, and medical research, working with a network of over 70 Associate Scholars, who are credentialed experts in medicine, statistical analysis, sociology, science, bioethics, public health, law, and social services for women and families.

Louisiana Right to Life is a non-partisan, nonsectarian organization established in 1970. It works through education, public policy, activism, and service to protect

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[1] Pursuant to Rule 29(a)(2), no motion for leave to file is necessary as all parties have consented to the filing of this brief. Pursuant to Rule 29(a)(4)(E), undersigned counsel affirms that no counsel for any party authored this brief in whole or in part and that no person or entity other than amici or their counsel made a monetary contribution intended to fund the preparation and submission of this brief.

[2] *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 153 (2014) (internal quotation marks omitted).

the right to life, help moms, promote adoption, and light the way to a pro-life Louisiana. As a trusted public policy organization engaging in legislative advocacy and education, Louisiana Right to Life has a substantial interest in preventing the erosion of state laws that protect the dignity of human life and the real needs of Louisiana women, including Plaintiff Rosalie Markezich, who experience coercion, exploitation and known health dangers of drug-induced abortion.

Texas Right to Life, founded in 1973, is the largest Texas Christian non-profit organization dedicated to legally, peacefully, and prayerfully protecting the God-given right to life of innocent human beings from fertilization to natural death. Texas Right to Life is opposed to abortion and spearheads the legislative efforts in the Texas State Capitol to protect innocent human life.

The March for Life Education and Defense Fund is a non-profit organization that sponsors the annual March for Life in Washington D.C., which has occurred annually since January 22, 1974, the first anniversary of *Roe v. Wade*, and state Marches for Life around the country. The National March for Life attracts people from around the country annually to protest the tragedy of abortion and cultivate in the United States a culture where every human life is valued and protected. The March for Life's mission is to promote the dignity of human life by working to end abortion; to make abortion unthinkable. This is accomplished through uniting, educating, equipping, and mobilizing persons who are pro-life in the public square.

The National Catholic Bioethics Center is a nonprofit research and educational institute committed to applying the principles of natural and moral law,

consistent with many traditions including the teachings of the Catholic Church, to ethical issues arising in healthcare and the life sciences.[3]

Catholic Medical Association (CMA) is a national, physician-led community that includes as members about 2500 physicians and healthcare providers nationwide in all fields of practice. CMA represents faithful Catholics in the healthcare field so that its members can grow in faith, maintain ethical integrity, and provide excellent healthcare in accordance with the teachings of the Catholic Church. CMA members oppose direct abortion in any of its forms, including chemical abortion, especially prescribed and dispensed through telemedicine. CMA physicians, especially those in emergency rooms, but also those practicing in family medicine and a number of other specialties, are faced with the tragic results of current regulation of mifepristone. Such physicians, not the prescribing physicians, often are the ones treating the life-threatening circumstances this situation has created. And the evidence of women left inadequately informed and aborting alone in their bathrooms, and seeking medical care, is growing. CMA physicians across a number of specializations encounter these preventable scenarios fostered by the current status of inadequate regulation. CMA physicians in such situations will do all they can to provide excellent care to these mothers, and their unborn children, when called to provide care.

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[3] While The National Catholic Bioethics Center holds that any deliberate and direct killing, by whatever means it is carried out, of a human being in the initial phase of his or her existence, extending from conception to birth, is gravely immoral, the federal government has an obligation to assure that any medical procedure it allows and regulates must protect the informed consent and safety of the subject of that medical procedure.

National Association of Catholic Nurses, USA (NACN-USA) is a non-profit organization of nurses from different backgrounds and specialties. NACN-USA shares the ministry of Catholic Nursing which advocates for human rights of vulnerable populations, the most significant being the right to life of an unborn child. Our members endorse the dignity and sanctity of all human life from conception to natural death, and oppose all direct abortions, including chemical abortion, especially prescribed and dispensed through telemedicine. Catholic nurses, especially those practicing in emergency rooms, but also those practicing in community health, are faced with the tragic results of current regulation of mifepristone. Such nurses are not the prescribers, but often are the ones treating the life-threatening circumstances this situation has created. And the evidence of women left inadequately informed and aborting alone in their bathrooms, and seeking medical care, is growing. Nurses encounter these preventable scenarios fostered by the current status of inadequate regulation. At the same time NACN-USA members in such situations will do all they can to provide excellent care to these mothers, and their unborn children, when called to provide care.

Christ Medicus Foundation (CMF) is a Catholic nonprofit dedicated to returning Jesus Christ's healing love to health care by defending and building the culture of life. CMF believes that each person is made in the image and likeness of God with inherent human dignity and infinite worth. Christ Medicus Foundation prayerfully works to be an instrument for Jesus Christ, the Divine Physician, and his healing love to be actively present in the American health care system. CMF is dedicated to protecting every person's life and dignity from conception to natural death and

upholding the conscience and religious freedom rights of every patient and medical professional. Christ Medicus Foundation accomplishes its mission by (1) promoting human dignity and right to life, religious freedom, and medical conscience rights in law and public policy, (2) offering Catholic pro-life health and wellness options for the healing and flourishing of individuals and families, and (3) supporting Christ-centered, life-affirming medical care for pregnant mothers, unborn children, families, the poor, and the most vulnerable.

Catholic Health Care Leadership Alliance (CHCLA) is an alliance of Catholic organizations dedicated to advancing the healing ministry of Jesus Christ through Christ-centered Catholic health care and to promoting an American health care system that protects the life, dignity, and health of the human person from conception to natural death. CHCLA supports the rights of patients and professionals to receive and provide life-affirming health care in accordance with the moral, ethical, and social teachings of Jesus Christ and His Church. Through ongoing evangelization, education, public policy and advocacy, and mutual support, CHCLA accomplishes its mission. CHCLA has a particular concern for the care of those persons who are vulnerable in society, beginning with unborn children who are truly most vulnerable, as well as pregnant mothers, persons with disabilities, and those persons who are materially poor and underserved.

National Catholic Partnership on Disability (NCPD) works with dioceses, parishes, ministers, and laity to promote the full and meaningful participation of persons with disabilities in the life of the Church. It promotes this ever-evolving mission to renovate and sustain ministry to-and-with all people with disabilities and their

families, advocating for policies that respect the life, full dignity, and inclusion of all persons, especially those with varying abilities. It is a statistical fact that unborn children diagnosed with disabilities are very frequently the victims of eugenic abortion.[4] Sometimes just the familial history of a congenital disability can cause future pregnancies to be aborted. NCPD opposes all direct abortions, including chemical abortions which further perpetrate this eugenic mentality. The current FDA regulations advance this eugenic mentality by denying already vulnerable families full informed consent in considering this life ending option.

Texas Alliance for Life is a statewide nonsectarian, non-partisan organization committed to protecting the fundamental right to life of all innocent human beings and promoting respect for their value and dignity from conception until natural death, using peaceful and legal means. Through education, legislative advocacy, protecting our laws when challenged in court, and promotion of compassionate alternatives to abortion, Texas Alliance for Life works to protect unborn children and their mothers from the harms of abortion.

Texans for Life Coalition is a leading statewide pro-life nonprofit organization dedicated to building a culture of life through pro-life education, public policy, and voter engagement. Texans for Life has consistently advocated for public policies that protect women from chemical abortion drugs, including the requirement that physicians only dispense the drugs in person.

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[4] Mary O'Callaghan, *Teaching human Dignity Prenatal Diagnosis & Disability Selective Abortion: An Expert Guide*, McGrath Institute for Church Life (University of Notre Dame, 2019).

The current FDA protocol for mifepristone use has profoundly negative legal and ethical consequences because it lacks safeguards necessary to ensure informed consent. Amici are well-suited to discuss how the FDA's failure harms women who may take mifepristone to cause an abortion.

Summary of the Argument

The requirement that a healthcare provider obtain a patient's informed consent before treatment is firmly established in both law and medical ethics. The patient's decision must be based on an adequate disclosure of the diagnosis, the proposed treatment, its benefits, its risks, and its alternatives, and the patient must have capacity and freedom from coercion. These fundamental principles of informed consent, which protect both patients and medical professionals, cannot be met when healthcare providers prescribe mifepristone under FDA's current protocol.[5] By contrast, if the Court reverses the district court and grants the preliminary relief requested by the Plaintiffs, the protocol simply reverts back to the protocol FDA approved for 20 years, which, while not as protective as it should be, was at least more protective of informed consent.

Because of the risks posed by taking mifepristone to cause an abortion, mifepristone's availability is limited by an FDA-imposed Risk Evaluation and Mitigation

[5] Unless otherwise stated, references to mifepristone apply to both Mifeprex and its generics, which have shared a REMS since April 11, 2019. Mifeprex and generic mifepristone are sponsored and manufactured by Intervenors Danco Laboratories and GenBioPro, respectively. Also, unless otherwise stated, any reference to the mifepristone REMS applies to the REMS shared by Mifeprex and the generics.

Strategy (REMS) with post-marketing "elements to assure safe use" (ETASU).[6] But FDA substantially weakened those post-marketing requirements—to the detriment of women and girls—in 2023 by stating that in-person care is no longer required to prescribe mifepristone.[7] In-person care is critical to informed consent because physicians are unable to adequately diagnose ectopic pregnancy, verify Rh status, or detect other contraindications to mifepristone without seeing the woman seeking a medication abortion in person. In other words, physicians cannot adequately inform a woman of her particular risks related to mifepristone without treating her in person. And without in-person care, prescribing healthcare providers also cannot adequately determine whether patients are giving voluntary consent without coercion. Abortion providers are now exploiting the FDA's lax rule by encouraging the stockpiling of abortion pills and prescribing abortion pills to women who aren't even pregnant to keep on hand, even though taking abortion pills outside the conditions contemplated

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[6] Before the FDA approves a drug, an applicant (the drug's sponsor and/or manufacturer) must make certain demonstrations regarding the drug's safety and efficacy "for use under the conditions prescribed, recommended, or suggested in the proposed labeling." FDCA § 505, 21 U.S.C. § 355. When FDA determines that protocols are "necessary to ensure that the benefits of the drug outweigh the risks," FDA may require a REMS. If the drug can only be approved with specific safeguards, the REMS includes ETASU. FDCA § 505-1, 21 U.S.C. § 355-1. REMS with ETASU may be weakened, strengthened, or removed following the submission of a proposal from the drug manufacturer or on the initiative of the Secretary of Health and Human Services. *Id.*

[7] *See* FDA, *Questions and Answers on Mifepristone for Termination of Pregnancy Through 10 Weeks Gestation*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

by the FDA's approval indisputably involves great risk.[8] This practice further endangers informed consent and places more women at risk of coercion. And a recent peer-reviewed study by scholars from amici Charlotte Lozier Institute demonstrated that many women that have undergone a chemical abortion felt they needed more information than was provided about complications, such as bleeding, pain, mental and emotional health, incomplete abortion, and failed abortion.[9]

Women can only benefit from more information and more protection, especially when considering whether to take a drug that FDA acknowledges is dangerous and that can have irreversible consequences. Reversing the district court's decision and granting preliminary relief would help prevent further harm to women from the lack of informed consent.

ARGUMENT

I. Informed consent is fundamental to bodily autonomy and is especially critical in the context of abortion.

The requirement that a healthcare provider obtain a patient's informed consent before treatment is firmly established in law and medical ethics. Indeed, the principle

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[8] *See* Selena Simmons-Duffin, *Abortion pills "just in case"? Planned Parenthood will offer them in two states*, NPR (May 21, 2026), https://www.npr.org/2026/05/21/nx-s1-5827444/abortion-pills-mifepristone-misoprostol-planned-parenthood-advance-provision.

[9] *See* Maka Tsulukidze, et al., *Seeking HELP beyond the pill: Women's perceptions of informed consent for medication abortion: Mixed methods research*, PLoS One 21(6): e0349065 (June 10, 2026), *available at* https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0349065.

is so fundamental that it has constitutional dimensions.[10] Originally established in common law, the right to consent to or refuse medical treatment is rooted in bodily integrity.[11] Before the early 1900s, treatment was often left to the discretion of physicians with little involvement of the patient. Eventually, courts began to recognize that a patient should be able to assess a procedure's risks and consequences and that failing to obtain a patient's consent for a medical procedure should result in legal liability. *E.g.*, *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (Cardozo, J.); *Pratt v. Davis,* 79 N.E. 562 (Ill. 1906); *Mohr v. Williams*, 104 N.W. 12 (Minn. 1905). This is a long-standing principle in tort law: if proper consent is not obtained, the treatment is a battery (unwanted touching).[12] Informed consent requires that a physician disclose to the patient accurate information about the nature, risks, benefits, and alternatives to the proposed procedure or treatment.[13] The patient also must have capacity and must make the decision freely and without coercion.

This is even more pronounced in the abortion context. As the Supreme Court has acknowledged, "Abortion is inherently different from other medical procedures,

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[10] *See, e.g., Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 278–79 (1990).

[11] *See* W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *Prosser and Keeton on Law of Torts* § 9, pp. 39-42 (5th ed. 1984).

[12] *Id.*

[13] *See Canterbury v. Spence*, 464 F.2d 772, 787–88 (D.C. 1972); AMA Code of Medical Ethics, Ch. 2 "Consent, Communication & Decision Making," (2016), https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf.

because no other procedure involves the purposeful termination of a potential life." *Harris v. McRae*, 448 U.S. 297, 325 (1980); *accord Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 231 (2022) ("[A]bortion is fundamentally different, as both *Roe* and *Casey* acknowledged, because it destroys what those decisions called 'fetal life' and what the law now before us describes as an 'unborn human being.'"); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 852 (1992), *overruled by Dobbs,* 597 U.S. at 231 ("Abortion is a unique act. It is an act fraught with consequences for others: for the woman who must live with the implications of her decision . . . and, depending on one's beliefs, for the life or potential life that is aborted."). Thus, the Supreme Court has also repeatedly recognized the gravity of the abortion decision and the importance of ensuring it is fully informed: "The decision to abort, indeed, is an important, and often a stressful one, and it is desirable and imperative that it be made with full knowledge of its nature and consequences." *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 67 (1976). "Whether to have an abortion requires a difficult and painful moral decision. . . . The State has an interest in ensuring so grave a choice is well informed." *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007) (internal citation omitted).

The requirement that the patient have capacity to provide informed consent also has special application in the context of minors. As a general rule, a minor does not possess legal capacity to provide consent to medical treatment or procedures, and consent must be obtained from the patient's parent or legal guardian. In the context of abortion, the majority of states require parental notice or consent before a minor

may obtain an abortion.[14] Of course, the parent's consent must be fully informed, as well.

The doctrine of informed consent also benefits the medical profession. At a minimum, it reduces the likelihood of potential legal liability. It also promotes trust and confidence and encourages better interactions between the patient and her physician.

II. Without providing in-person care, a certified prescriber cannot obtain informed consent because the prescriber cannot adequately inform a patient of her unique personal risks.

To obtain genuine informed consent, a healthcare provider must inform the patient of the medical condition requiring the proposed treatment or procedure and must also explain any risks, such as those related to contraindications or conditions that increase the likelihood of the patient's risk. But FDA's 2023 changes to the REMS do not require certified prescribers of mifepristone to adequately screen their patients for potential risks. A certified prescriber who merely consults with a patient though video, phone, or email—which is now explicitly permitted by FDA—cannot accurately assess the duration of a patient's pregnancy, diagnose ectopic pregnancy, or even establish a provider-patient relationship that enables the patient to trust the prescriber or the prescriber's designee for emergency care.

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[14] *See, e.g.,* Guttmacher Inst., *Parental Involvement in Minors' Abortions*, https://www.guttmacher.org/state-policy/explore/parental-involvement-minors-abortions (last visited Apr. 17, 2023) (summarizing state laws; 36 states require parental involvement).

The 2023 changes are undermined by the REMS itself. The existing REMS acknowledges the importance of a healthcare provider's *ability* to identify increased risks, like the presence of an ectopic pregnancy, because it requires sponsors to ensure that "healthcare providers who prescribe their mifepristone are specially certified in accordance with the requirements described [in the REMS] and de-certify healthcare providers who do not maintain compliance with certification requirements."[15] In turn, the REMS requires healthcare providers who wish to be certified to sign a Prescriber Agreement Form stating:

> [Y]ou agree that you meet the qualifications [] and will follow the guidelines for use. You are responsible for overseeing implementation and compliance with the Mifepristone REMS program. You also understand that if the guidelines [] are not followed, the distributor may stop shipping mifepristone to the locations that you identify and certified pharmacies may stop accepting your mifepristone prescriptions.[16]

The qualifications of prescribers and guidelines for use are also listed on the form:

> Mifepristone must be provided by or under the supervision of a certified prescriber who meets the following qualifications:
>
> - Ability to assess the duration of pregnancy accurately.

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[15] Mifepristone Tablets, 200 mg Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg, 2 (most recent modification 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf.

[16] Prescriber Agreement Form (updated Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_GenBioPro_Inc..pdf.

- Ability to diagnose ectopic pregnancies.

- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

- Has read and understood the Prescribing Information of mifepristone….

In addition to meeting these qualifications, you also agree to follow these guidelines for use:

- Ensure that the Patient Agreement Form is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.

- Ensure that the healthcare provider and patient sign the Patient Agreement Form.

- Ensure that the patient is provided with a copy of the Patient Agreement Form and the Medication Guide.

- Ensure that the signed Patient Agreement Form is placed in the patient's medical record.

- Ensure that any deaths of patients who received mifepristone are reported to [sponsor], identifying the patient by a non-identifiable patient reference and including the NDC and lot number from the package of mifepristone that was dispensed to the patient.

- Ensure that healthcare providers under your supervision follow the guidelines listed above.[17]

[17] *Id.*

The prescriber qualification requirements and guidelines regarding a provider's *abilities* in the REMS are meaningless, however, if a prescriber does not actually *utilize* these skills in caring for a patient. What good is a healthcare provider's ability to diagnose an ectopic pregnancy, for example, if the provider does not examine the patient and perform the diagnostic testing to determine if she has an ectopic pregnancy? A certified prescriber cannot possibly obtain adequate informed consent for prescribing drugs without screening the patient in person for contraindications or additional risks from the drugs.

The 2023 REMS ignores the best practices necessary to protect women's health and ensure informed consent. The REMS itself requires that certified prescribers be qualified to "assess" the duration of pregnancy and "diagnose" ectopic pregnancy—not simply "confirm" a patient's opinion, or even the opinion of another provider, that the patient's pregnancy is 10 weeks or less and that it is an intrauterine pregnancy.[18] In a joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG), The American Institute of Ultrasound in Medicine, and the Society for Maternal-Fetal Medicine stated unequivocally that "[u]ltrasound measurement of the embryo or fetus in the first trimester . . . is the most accurate method to establish or confirm gestational age."[19] In fact, women often significantly

[18] *Id.*

[19] ACOG Committee Op. No. 700, *Methods for Estimating the Due Date,* 129 Obstet. & Gynecol. 1, 3 (2017), https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date.pdf.

underestimate gestational age.[20] And mifepristone's failures (requiring subsequent surgery) and complications indisputably increase with increasing gestational age.[21]

The possibility that women receiving remote "care" may suffer from ectopic pregnancy is troubling. An ectopic pregnancy (which occurs outside the uterus) can rupture the fallopian tube as the pregnancy progresses, causing bleeding, severe pain, or death. Ectopic pregnancies can only be reliably diagnosed through an ultrasound evaluation and confirmation of pregnancy. If a woman with an extrauterine pregnancy is given mifepristone, she may believe the symptoms for ectopic pregnancy are simply the side effects of drug-induced abortion, which are similar. As of June 30, 2021, at least 97 women with ectopic pregnancies in the United States had been given mifepristone.[22] Of these women, at least two bled to death from an undiagnosed ectopic pregnancy.[23] They likely did not recognize that their cramps,

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[20] *See, e.g.,* Ellertson C., et al., *Accuracy of assessment of pregnancy duration by women seeking early abortions*, 355 Lancet 877, 879 (2000), *abstract available at* https://pubmed.ncbi.nlm.nih.gov/10752703/ (finding that almost 15% of Atlanta women were in error by more than two weeks when calculating gestation based on LMP).

[21] *See* AAPLOG, Committee Op. No. 9: Dangers of Relaxed Restrictions on Mifepristone (Oct. 2021), https://aaplog.org/wp-content/uploads/2021/11/CO9-Mifepristone-Restrictions-1.pdf (citing Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018, https://www.fda.gov/media/112118/download).

[22] Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2021, RCM # 2007-525, NDA 020687, ANDA 091178, https://www.fda.gov/media/154941/download.

[23] *Id.*

abdominal pain, and perhaps vaginal bleeding were dangerous indications of a life-threatening ectopic pregnancy, not side effects expected in a mifepristone abortion. Half of women who experience ectopic pregnancy do not have any risk factors. Yet, a woman is 30% more likely to die from an ectopic pregnancy while undergoing an abortion than if she had an ectopic pregnancy but had not sought an abortion.[24] And as the number of women undergoing chemical abortions continues to rise, as it has in the last five years,[25] and given that telehealth abortions now account for one in every four abortions,[26] it is certain that many more women with ectopic pregnancies are unknowingly facing the serious dangers presented.

There are other known conditions that must be investigated before administering mifepristone, such as undiagnosed adnexal mass, chronic adrenal failure, concurrent long-term corticosteroid therapy, history of allergy to mifepristone, misoprostol, or other prostaglandins, hemorrhagic disorders or concurrent anticoagulant

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[24] Atrash H.K., et al., *Ectopic pregnancy concurrent with induced abortion: Incidence and mortality*, Am. J. of Obstet. & Gynecol. 726, 727 (1990), *abstract available at* https://pubmed.ncbi.nlm.nih.gov/2316578/.

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

[26] Karen Diep, et al., *Abortion Trends Before and After Dobbs*, KFF (Jan. 7, 2026), https://www.kff.org/womens-health-policy/abortion-trends-before-and-after-dobbs/.

therapy (risk of heavy bleeding), or inherited porphyrias.[27] A patient's Rh status is also of particular concern to protect a patient's future fertility and the health of her future unborn children. The Rh factor is a protein found on the surface of red blood cells.[28] If a mother's cells have this protein, she is Rh-positive.[29] But if a mother is Rh-negative and her unborn child is Rh-positive, when the baby's blood gets into the mother's bloodstream, her body will recognize that the Rh-positive blood is not hers and her body will produce anti-RH antibodies, which can cross the placenta and lead to serious health problems, or even death, for the unborn child or newborn.[30] Importantly, a woman's body can still produce these antibodies even if the pregnancy is not carried to term because of abortion.[31] And a woman may not know if she is Rh-negative. Thus, Rh-negative patients who have been pregnant before must be administered treatment to avoid miscarriage or severe injury to their future unborn

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[27] *See* Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (mifepristone prescribing information approved by FDA for Danco).

[28] ACOG, *The RH Factor: How it Can Affect Your Pregnancy*, https://www.acog.org/womens-health/faqs/the-rh-factor-how-it-can-affect-your-pregnancy#:~:text=The%20Rh%20factor%20is%20a,refers%20to%20your%20Rh%20status.

[29] *Id.*

[30] *Id.*

[31] *Id.*

children.[32] But Rh-negative women who are not tested before a mifepristone abortion may not know that they need treatment during a subsequent pregnancy.

The inadequacy of mail-order abortion pills is a view shared by many states, with 29 states permitting only physicians to prescribe mifepristone, and 18 states requiring the provider to be physically present with the patient.[33] And for good reason, since a call to a hotline or prescriber who lives on the other side of the country will not help a hemorrhaging woman reach an emergency room in time. It is nonsensical for FDA to acknowledge that the dangers posed to women from mifepristone require elements to assure safe use[34] yet refuse to require prescribers to perform the most accurate evaluations of women who wish to use the drug. Without these patient-specific determinations, certified prescribers cannot know the patient's situation and therefore cannot obtain truly informed consent from that patient.[35] A woman cannot consent to a chemical abortion without knowing the specific risks that mifepristone poses to *her* life, health, and fertility.

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[32] *Id.*; *see also* ACOG, *Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, 130 Obstet. & Gyncol. E57 (2017), https://journals.lww.com/greenjournal/Fulltext/2017/08000/Practice_Bulletin_No__181__Prevention_of_Rh_D.54.aspx.

[33] *See* Guttmacher Inst., *Medication Abortion*, https://www.guttmacher.org/state-policy/explore/medication-abortion (last updated Apr. 13, 2023). Of course, these state laws are skirted by the current mail-order abortion regime.

[34] *See Questions and Answers on Mifepristone*, *supra* n. 7.

[35] *See Canterbury*, 464 F.2d at 787.

III. Informed consent cannot be obtained under FDA's 2023 requirements because without in-person care, certified prescribers cannot adequately screen for coercion.

Voluntariness is essential to genuine informed consent. Coerced consent is no consent at all, and there is an increased risk of coercion in the context of abortion drugs and procedures if the prescribing physician does not thoroughly screen for abuse or coercion. Abortion-inducing drugs are thus inherently different from other prescribed drugs. This risk is greatly increased by FDA's removal of the in-person dispensing requirement from the mifepristone REMS, which is an important safeguard to ensure that a provider has a chance to see and evaluate the voluntariness of the woman's consent to the drug's administration. The 2023 REMS fails to protect women from coercive partners and predators, nor does it help to ensure that women are giving voluntary consent. That risk is vividly demonstrated by what was experienced by Plaintiff Rosalie Markezich, who was coerced into taking abortion pills ordered by her boyfriend. D. Ct. Doc. 1-92.

The American College of Obstetricians and Gynecologists (ACOG) recognizes that "reproductive coercion," which "involves behavior intended to maintain power and control in a relationship related to reproductive health by someone who is, was, or wishes to be involved in an intimate or dating relationship with an adult or adolescent," includes "pregnancy pressure."[36] Pregnancy pressure includes "forcing a female partner to terminate a pregnancy when she does not want to [] or injuring a

[36] ACOG Committee Op. No. 554, *Reproductive and Sexual Coercion* (February 2013; Reaffirmed 2019), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/02/reproductive-and-sexual-coercion.

female partner in a way that may cause a miscarriage."[37] In a Committee opinion, ACOG advises that because violence is often linked to reproductive coercion, "providers should screen women and adolescent girls for . . . reproductive [] coercion at periodic intervals such as annual examinations, new patient visits, and during obstetric care (at the first prenatal visit, at least once per trimester, and at the postpartum checkup)."[38] The paper also states that in 2007, the prevalence of intimate partner violence was nearly three times greater for women seeking abortions than for women who continued their pregnancies.[39]

With no in-person patient contact, certified prescribers lose all ability to ensure that abusers are not sitting beside a phone pressuring their victims into requesting abortion-inducing drugs or ordering the drugs themselves to lace their victims' food or beverages. There is no way for prescribers to ensure that the person they think they are prescribing the pills for is the person who is going to take them.

AAPLOG writes:

> Intimate partner violence is associated with abortion and with repeat abortions, and this is particularly true of adolescents and women being trafficked for sex. . . . Interaction with the health care system is an opportunity for these women to be identified and helped, but availability of medication abortion to abusers removes this opportunity.[40]

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[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] AAPLOG Committee Op. No. 9, *supra* n. 21.

To find out how common sexual coercion is, the BBC commissioned a survey of one thousand women aged 18-44 and found that 50% said they had experienced at least one type of reproductive coercion.[41] Fifteen percent of women surveyed said that they had experienced pressure to terminate a pregnancy against their will.[42] Further, three percent had someone give them a substance to cause an abortion without their knowledge or consent.[43] Five percent had experienced physical violence with the intention to end their pregnancies.[44] Amicus Susan B. Anthony Pro-Life America has identified numerous cases of coerced abortion involving mifepristone.[45]

Tragically, while Rosalie Markezich was brave enough to share her heartbreaking story of coercion in this case, most instances of coerced abortion are never publicly known, and there is no justice for the victims. In-person dispensing requirements for mifepristone provided a line of defense—albeit an imperfect one—against coerced abortion. By failing to require in-person contact between prescribers and

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[41] Alys Harte and Rachel Stonehouse, *Reproductive coercion: 'I wasn't allowed to take my pill*,' BBC News (Mar. 13, 2022), https://www.bbc.com/news/newsbeat-60646285; *Reproductive Coercion Poll – BBC Radio 4 – 8 March 2022*, Savanta ComRes, https://comresglobal.com/polls/reproductive-coercion-poll-bbc-radio-4-8-march-2022.

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *See* Anna Callahan, *Abortion Drugs Fuel Abuse: The Women Poisoned Against Their Will*, Susan B. Anthony Pro-Life America (Feb. 26, 2026), https://sbaprolife.org/latest-news/abortion-drugs-fuel-abuse-the-women-poisoned-against-their-will.

their patients, FDA's 2023 REMS cannot ensure that vulnerable women and girls are protected from coercive partners and predators—further eroding the ability of women to make independent, voluntary decisions to use mifepristone.

CONCLUSION

The district court's order should be reversed.

Respectfully submitted.

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Certificate of Service

On June 22, 2026, this brief was served via CM/ECF on all registered counsel and transmitted to the Clerk of the Court. Counsel further certifies that: (1) any required privacy redactions have been made in compliance with Fifth Circuit Rule 25.2.13; and (2) the electronic submission is an exact copy of the paper document in compliance with Fifth Circuit Rule 25.2.1.

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Certificate of Compliance

This brief complies with: (1) the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 5383 words, excluding the parts exempted by Rule 32(f); and (2) the typeface and type style requirements of Rule 32(a)(5) and (6) because it has been prepared in a proportionally spaced typeface (14-point Equity) using Microsoft Word (the program used for the word count).

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