Nos. 25A1207 and 25A1208

In the Supreme Court of the United States

DANCO LABORATORIES, LLC,
Applicant,

v.

LOUISIANA, *et al.*,
Respondents.

GENBIOPRO, INC.,
Applicant,

v.

LOUISIANA, *et al.*,
Respondents.

BRIEF OF AMICUS CURIAE SUSAN B. ANTHONY PRO-LIFE AMERICA IN SUPPORT OF RESPONDENTS' OPPOSITION TO THE APPLICATIONS TO STAY THE ORDER ENTERED BY THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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INTEREST OF AMICUS CURIAE

Amicus curiae[1] **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.

The applications to stay, if granted, would have profoundly negative legal and ethical consequences for the implementation and enforcement of safeguards necessary to ensure informed consent for women who use chemical abortion drugs. Amicus is well-suited to discuss how the absence of informed consent resulting from FDA's improvident and illegal changes to the protocol for the use of these drugs weighs against a stay of the Fifth Circuit's order pending appeal, as it is both harmful to women who may take the drugs (and who are not parties to this case) and is contrary to the public's interest.

SUMMARY OF THE ARGUMENT

The applications for stay pending appeal should be denied to prevent harm to women from the lack of fully informed consent for the use of mifepristone under FDA's 2023 changes to the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, which was stayed by the Fifth Circuit's ruling. *See Nken v. Holder*, 556 U.S. 418, 434 (2009) (in deciding whether to grant a stay, courts must consider "whether issuance of the stay will substantially injure the other parties interested in the proceeding"). The requirement that

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[1] Pursuant to Rule 37.6, 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).

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.[3] By contrast, if the Court denies the applications and permits the Fifth Circuit's ruling to go into effect, 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 Strategy (REMS) with post-marketing "elements to assure safe use" (ETASU).[4] But FDA substantially weakened those post-marketing requirements—to the detriment of women and

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

[4] 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.*

girls—in 2023 by stating that in-person care is no longer required to prescribe mifepristone.[5] 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. Thus, granting the requested stay will not only "substantially injure the other parties interested in the proceeding," it is also contrary to the public's interest, another factor the Court must consider. *See Nken*, 556 U.S. at 434. Nor can Danco or GenBioPro credibly argue that women and girls will suffer irreparable harm if the 2023 REMS is not reinstated, as those changes made the law *less protective*. Women can only benefit from more information and more protection, and allowing the Fifth Circuit's ruling on the 2023 REMS to go into effect would accomplish that.

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 is so fundamental that it has constitutional dimensions.[6] Originally established in common law, the

[5] *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.

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

right to consent to or refuse medical treatment is rooted in bodily integrity.[7] 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).[8] 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.[9] 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 this Court has acknowledged, "Abortion is inherently different from other medical procedures, 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.*, 142 S. Ct. 2228, 2243 (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,* 142 S. Ct. at 2242 ("Abortion is a unique act. It is an act fraught

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

[8] *Id.*

[9] *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.

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 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 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.[10] Of course, the parent's consent must be fully informed, as well.

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

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[10] *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).

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.

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."[11] 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

[11] 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.

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.[12]

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.
- 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

[12] 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.

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.[13]

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.[14] 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."[15] In fact, women

[13] *Id.*

[14] *Id.*

[15] 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.

often significantly underestimate gestational age.[16] And mifepristone's failures (requiring subsequent surgery) and complications indisputably increase with increasing gestational age.[17]

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.[18] Of these women, at least two bled to death from an undiagnosed ectopic pregnancy.[19] They likely did not recognize that their cramps, 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%

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[16] *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).

[17] *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).

[18] 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.

[19] *Id.*

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.[20]

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 therapy (risk of heavy bleeding), or inherited porphyrias.[21] A prescriber bears responsibility to diagnose and rule out such contraindications prior to prescribing mifepristone. But a prescriber who does not physically meet with and examine a patient cannot fulfill the explicit REMS requirements or rule out additional contraindications to mifepristone use.

A patient's Rh status is 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.[22] If a mother's cells have this protein, she is Rh-positive.[23] 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

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[20] 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/.

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

[22] 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.

[23] *Id.*

health problems, or even death, for the unborn child or newborn.[24] Importantly, a woman's body can still produce these antibodies even if the pregnancy is not carried to term because of abortion.[25] 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 children.[26] But Rh-negative women who are not tested before a mifepristone abortion may never know that they need treatment.

The inadequacy of mail-order abortion pills is buttressed by the fact that 29 states permit only physicians to prescribe mifepristone, with 18 states requiring the provider to be physically present with the patient.[27] 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[28] 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.[29] A woman cannot consent to a

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[24] *Id.*

[25] *Id.*

[26] *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.

[27] *See* Guttmacher Inst., *Medication Abortion*, https://www.guttmacher.org/state-policy/explore/medication-abortion (last updated Apr. 13, 2023).

[28] See Questions and Answers on Mifepristone, *supra* n. 5.

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

chemical abortion without knowing the specific risks that mifepristone poses to *her* life, health, and fertility.

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 the evidence in this case of the coercion experienced by Plaintiff Rosalie Markezich. 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."[30] Pregnancy pressure includes "forcing a female partner to terminate a pregnancy

[30] 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.

when she does not want to [] or injuring a female partner in a way that may cause a miscarriage."[31]

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)."[32] 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.[33]

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. 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.[34]

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

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[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] AAPLOG Committee Op. No. 9, *supra* n. 17.

of reproductive coercion.[35] Fifteen percent of women surveyed said that they had experienced pressure to terminate a pregnancy against their will.[36] Further, three percent had someone give them a substance to cause an abortion without their knowledge or consent.[37] Five percent had experienced physical violence with the intention to end their pregnancies.[38] Amicus has identified numerous cases of coerced abortion involving mifepristone.[39]

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

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[35] 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.

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] *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.

CONCLUSION

The applications for stay pending appeal should be denied.

Respectfully submitted.

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May 2026