**Nos. 22A901 and 22A902**

# In the Supreme Court of the United States

DANCO LABORATORIES, L.L.C.,
*Applicant*,

*v.*

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
*Respondents.*

FOOD & DRUG ADMINISTRATION, *et al.*,
*Applicant*,

*v.*

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
*Respondents.*

**BRIEF OF AMICI CURIAE SUSAN B. ANTHONY PRO-LIFE AMERICA, CATHOLIC HEALTH CARE LEADERSHIP ALLIANCE, THE NATIONAL CATHOLIC BIOETHICS CENTER, CATHOLIC BAR ASSOCIATION, CATHOLIC BENEFITS ASSOCIATION, AND CHRIST MEDICUS FOUNDATION IN SUPPORT OF RESPONDENTS' OPPOSITION TO THE APPLICATIONS TO STAY THE ORDER ENTERED BY THE DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS**

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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 representing knowledge and experience across a variety of 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.

**Catholic Health Care Leadership Alliance** is an alliance of Catholic organizations supporting the rights of patients and professionals to receive and provide healthcare in accordance with the moral, ethical, and social teachings of Jesus Christ and His Church.

**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.

**Catholic Bar Association** is a community of legal professionals that educates, organizes, and inspires its members to faithfully uphold and bear witness to the Catholic faith in the study and practice of law.

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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).

**Catholic Benefits Association** is a non-profit limited cooperative association committed to assisting its Catholic employer members in providing health coverage to their employees consistent with Catholic values, including protection of members' legal and conscience rights.

**Christ Medicus Foundation** is an organization that defends religious freedom by educating religious and lay leaders on the intersection of healthcare, the exercise of faith and religious freedom, and the right to life.

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. Amici are 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 district court'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. That deprivation is worsened[3] by FDA's 2016, 2019, 2021, and 2023 ("post-approval changes") changes to the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, which were stayed by the district court'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

[3] Amici believe that the original approval REMS also fails to adequately allow for informed consent, but focuses on the post-approval changes as those are what are at issue in the applications for stay.

the other parties interested in the proceeding"). 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.[4] By contrast, if the Court denies the applications and permits the district court's ruling to go into effect, the protocol simply reverts back to the protocol FDA approved for 16 years, which, while not as protective as it should be, was 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).[5] But FDA substantially weakened those post-marketing requirements—to the detriment of women and girls—in 2016 and 2021. FDA's newer post-marketing restrictions do not require reporting

[4] 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 Applicant 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.

[5] 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.*

of non-fatal adverse events, and both FDA and mifepristone's sponsors failed to demonstrate that mifepristone's adverse events can be reliably reported by other means. FDA also stated in 2021 that in-person care is no longer required to prescribe mifepristone, and those changes were made permanent in 2023.[6] But 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 personal 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 FDA credibly argue that women and girls will suffer irreparable harm if the post-approval changes are not reinstated, as those changes made the law *less protective*. Women can only benefit from more information and more protection, and allowing the district court's ruling on the post-approval changes to go into effect would accomplish that.

[6] *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.

## 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.[7] Originally established in common law, the right to consent to or refuse medical treatment is rooted in bodily integrity.[8] 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).[9] 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.[10] 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,

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

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

[9] *Id.*

[10] *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.

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

[11] *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).

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.

## II. Conclusions about the "safety" of mifepristone drawn from clinical trials relied on by FDA cannot form the basis for informed consent because the studies afforded patient protections FDA does not require.

Applicants seeking approval for a drug from FDA must conduct "investigations, reports of which are required to be submitted to the Secretary [which] include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof."[12] This requirement is necessary for prescribers and their patients to know how the drug will impact patient safety outside of the controlled environment that characterizes clinical studies. But the "conditions" in the U.S. trial for mifepristone afforded protections to women that are not—and have never been—required by the drug's label or REMS.

In the U.S clinical trial, transvaginal ultrasonography, menstrual history, and pelvic examination were used to confirm the gestational age of each pregnancy and exclude women with ectopic pregnancies.[13] FDA currently requires no in-person examination.[14] Further, the prescribers were physicians with experience in performing surgical abortions, training in the administration of the mifepristone-misoprostol procedure, and admitting privileges

[12] 21 U.S.C. § 355(d).

[13] *See* Citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists, the Christian Medical Association, and the Concerned Women for America on Aug. 2, 2002, Docket No. FDA-2002-P-0364-0001 at 75-76.

[14] *Id.*

at medical facilities that could provide emergency care and hospitalization.[15] Also, all patients were required to be within one hour of emergency facilities or the facilities of the principal investigator, and women were monitored for four hours for adverse events after taking misoprostol.[16] None of these conditions—all of which are critical to protecting the health and safety of women using mifepristone—have been part of the mifepristone post-marketing requirements. FDA's approval therefore cannot apprise prescribers or patients of the risks posed by the FDA-approved regimen because the clinical trials did not reflect the manner in which the drugs are actually prescribed.

FDA recently repeated this error and relied upon clinical studies that afford more protections than required by the mifepristone label or REMS to further eviscerate the already insufficient safeguards for women in its post-approval changes. In 2021, FDA removed the REMS "in-person dispensing requirement," a change that became permanent in 2023.[17] FDA based its decision on a claimed review of information from the REMS assessment data and post-marketing safety information, allegedly supported by review of published literature.[18] But the available "safety information" provided by the sponsors or through the FDA Adverse Event Reporting System (FAERS) failed to demonstrate that *any* post-marketing restrictions ensure the safety of mifepristone and certainly did not support further curtailing the REMS. As to the studies that FDA relied upon, FDA acknowledged that:

> [T]he ability to generalize the results of these studies to the United States population is hampered by differences between the studies with regard to pre-abortion

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[15] *Id.*

[16] *See id.*

[17] *See* Questions and Answers on Mifepristone, *supra* n. 6.

[18] FDA's citizen petition response dated Dec. 16, 2021, to the citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians on Mar. 29, 2019 [FDA's Petition Response 2021], Docket No. FDA-2019-P-1534 at 25.

> care (e.g., telemedicine versus in-person). In addition, the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy. There are also factors which complicate the analysis of the dispensing element alone. Some of these factors are: (1) only a few studies have evaluated alternatives for in-person dispensing of mifepristone in isolation (for example, most studies on mail dispensing of mifepristone also include telemedicine consultation); and (2) because most serious adverse events with medical abortion are infrequent, further revaluation of changes in dispensing would require studies with larger numbers of participants. We did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States.[19]

Despite the limitations of the studies, FDA nonetheless concluded that "overall the outcomes of these studies are not inconsistent" with FDA's conclusion that "based on the 1st year REMS assessment report and post-marketing safety data, mifepristone will remain safe and efficacy will be maintained if the in-person dispensing requirement is removed from the Mifepristone REMS Program."[20]

Simply stated, in determining that it is safe to remove the in-person dispensing requirements from the mifepristone REMS, FDA relied upon data from the demonstrably inadequate FAERS, buttressed by studies FDA acknowledges cannot be generalized to the U.S. population. Such a basis cannot support any decision that purports to rest on science, reason, and concern for patients' well-being, and it certainly does not provide a basis for informed consent.

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[19] *Id.* at 29.
[20] *Id.*

## III. FDA's post-approval restrictions do not require comprehensive reporting of non-fatal adverse events, so mifepristone prescribers cannot obtain informed consent because they cannot adequately inform patients of potential risk due to inadequate safety data.

For a healthcare provider to adequately inform patients about risks of a treatment or procedure, those risks must be known. FDA's post-marketing surveillance of an approved drug is crucial to ensure the drug's continued safety and to recognize new safety concerns. As a condition of mifepristone's original approval in 2000, FDA required certified prescribers to report *any* serious adverse event associated with mifepristone to the sponsor (*i.e.*, manufacturer), Danco.[21] But in 2016, FDA modified the mifepristone REMS with ETASU, eliminating the reporting requirement for non-fatal adverse events. Certified prescribers are only required to report *deaths* to the sponsor (today there are two sponsors—Danco and GenBioPro).[22] As a result, the sponsors are unlikely to receive many reports of other, non-lethal adverse events, even if they are quite serious or result in permanent injury.

Patients and all healthcare providers, including emergency room doctors or other providers who handle complications from abortion-inducing drugs they did not prescribe, are also not required to report adverse events to the sponsors. They may report adverse events directly to FDA through the MedWatch website.[23] But this reporting is entirely voluntary,

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[21] Memorandum from FDA to NDA 20-687 MIFEPREX (mifepristone) Population Council (Sept. 28, 2000), http://wayback.archive-it.org/7993/20161024033545/http:/www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111366.pdf; U.S. Gov't Accountability Office, GAO-08-751, Food and Drug Administration: Approval and Oversight of the Drug Mifeprex Appendices II and III (2008), https://www.gao.gov/products/gao-08-751.

[22] *See* U.S. Gov't Accountability Office, GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts (2018), https://www.gao.gov/products/gao-18-292; Mifepristone Shared System REMS (updated 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[23] MedWatch is the FDA's medical product safety reporting program for health professionals, patients and consumers. Information submitted through MedWatch is reflected in the FAERS database. *See* https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

so data from that program is necessarily incomplete. Thus, it cannot adequately or accurately apprise anyone of the risks of abortion drugs.

The removal of the requirement to report non-fatal adverse events causes vastly undercounted adverse event reports (AERs) and other complications caused by the FDA's regimen, skewing the safety profile of the drugs and causing incomplete and inaccurate information. Prescribers and patients, ignorant of the actual risks of the chemical abortion regimen, cannot participate in genuinely informed decision making. For example, emergency-room doctors or other non-prescribing healthcare providers handle most hemorrhages from drug-induced abortion. An analysis of AERs for mifepristone submitted to FDA from September 2000 to February 2019 showed that fewer than 40% of surgeries to remove retained tissue after drug-induced abortion are done by abortion providers themselves. Yet, the information in the AERs is "almost exclusively obtained from abortion providers, rather than the physician treating the complication."[24] This demonstrates that the sponsors likely do not know about (or report to FAERS) most hemorrhages because non-prescribing doctors (like emergency room physicians) are not required to report them. This problem is exacerbated by the limited-to-nonexistent follow-up performed by abortion providers after chemical abortion; such follow-up is advised but *not required* by the REMS.

[24] Aultman K, et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 Issues Law & Med. 3 (2021), https://issuesinlawandmedicine.com/wp-content/uploads/2021/01/Deaths-and-Severe-Adverse-Events-after-the-use-of-Mifepristone-as-an-Abortifacient-from-September-2000-to-February-2019-copy5.pdf.

There is ample support for the conclusion that AERs are significantly underreported. In its October 2021 position paper on the "Dangers of Relaxed Restrictions on Mifepristone," the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) warned:

> There is reason to believe that adverse events are underreported. The FDA estimates that 3.7 million medication abortions occurred between 2000 and 2018. If the rate of serious adverse events such as emergency room visits is posited to be a conservative 2%, then approximately 74,000 complications would be documented. Two analyses examined the adverse event reports (AERs) between 2000 to 2019 and documented 607 and 3,197 events. This total of 3,804 AERs suggests that the FDA received only 5% of an estimated 74,000 serious adverse events.[25]

Further, in a study of nearly 20 years of AERs submitted to FDA, the researchers concluded:

> The FDA Adverse Event Reporting System is woefully inadequate to determine the post-marketing safety of mifepristone due to its inability to adequately assess the frequency or severity of adverse events. The reliance solely on interested parties to report, the large percentage of uncodable events, the redaction of critical clinical information unrelated to personally identifiable information, and the inadequacy of the reports highlight the need to overhaul the current AER system.[26]

Another study compared 2009 and 2010 AERs reported through FAERS, those provided by FDA via a Freedom of Information Act request, and those identified by other researchers as having occurred at Planned Parenthood.[27] While Planned Parenthood performs 37% of U.S. abortions, the study identified *1,530 mifepristone cases with AERs at Planned Parenthood alone*, while FAERS only identified 664 *from all providers* and FDA

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[25] AAPLOG, *Committee Op. No. 9: Dangers of Relaxed Restrictions on Mifepristone* (Oct. 2021), https://aaplog.org/wp-content/uploads/2021/11/CO-9-Mifepristone-Restrictions-1.pdf.

[26] Aultman, *supra* n. 24.

[27] Cirucci, CA, et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Servs. Res. and Managerial Epidemiology 1, 5 (2021), https://journals.sagepub.com/doi/full/10.1177/23333928211068919.

only released 330 AERs through FOIA. These discrepancies demonstrate that the AER reporting system is unreliable and cannot demonstrate that all adverse events caused by or associated with mifepristone use are known.

Further decreasing the likelihood that AERs are reliably reported, some mifepristone prescribers blatantly encourage their patients to hide consumption of abortion-inducing drugs if they are treated by other healthcare professionals for complications. Before FDA made changes to the mifepristone prescribing information and *Patient Agreement Form* in January 2023, the mifepristone label instructed prescribers to "[a]dvise the patient to take the Medication Guide with her if she visits an emergency room or a healthcare provider who did not prescribe Mifeprex, so that the provider knows that she is undergoing a medical abortion." The REMS-required form also had stated: "I have the MEDICATION GUIDE for mifepristone. I will take it with me if I visit an emergency room or a healthcare provider who did not give me mifepristone so that they will understand that I am having a medical abortion with mifepristone."[28] Yet, some mifepristone prescribers, such as Aid Access, blatantly violated FDA protocol, instructing their patients to lie to emergency medical personnel about having taken mifepristone.[29]

Tragically, FDA's 2023 changes further enable this deception: prescribers are no longer directed to instruct their patients to take the medication guide with them when seeking emergency treatment, and patients are no longer directed in the *Patient Agreement Form* to take the guide with them. This change both undermines emergency healthcare providers'

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[28] 2016 Patient Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2021_05_14_Patient_Agreement_Form.pdf.

[29] *See, e.g.,* Aid Access, *How do you know if you have complications, and what should you do?*, https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-complications-and-what-should-you-do.

ability to care for their patients because they will be missing critical information, and decreases the likelihood that adverse events will be reported.

Adverse event reports are FDA's only *objective* means to obtain data on the full range of effects of the FDA-approved regimen on women. Responsible reporting is a fundamental safety mechanism that should not be sacrificed in the interest of increasing the availability of an elective drug. Because FDA's post-marketing restrictions do not require comprehensive reporting of adverse events, and because both FDA and mifepristone's sponsors have failed to demonstrate that adverse events can be reliably reported, it is impossible for FDA to provide accurate and complete information to prescribers. In turn, prescribers cannot fully inform their patients of the risks caused by or associated with mifepristone, rendering it impossible for patients to make well-informed decisions about their care.

## IV. 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 post-approval changes to the mifepristone label and 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 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."[30] 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.[31]

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….

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[30] 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.

[31] 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.

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.[32]

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 for contraindications to or additional risks from the drugs.

[32] *Id.*

In FDA's 2021 response to the 2019 citizen petition submitted by Respondents AAP-LOG and American College of Pediatricians, FDA erroneously asserted that it was inappropriate for FDA to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy, and that certified prescribers do not have to be physically present with the patient.[33] These assertions ignore the best practices necessary to protect women's health and ensure informed consent. The REMS 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.[34] 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."[35] In fact, women often significantly underestimate gestational age.[36] And mifepristone's failures (requiring subsequent surgery) and complications indisputably increase with increasing gestational age.[37]

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[33] FDA's Petition Response 2021, *supra* n. 18.

[34] Prescriber Agreement Form, *supra* n. 31.

[35] 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.

[36] *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).

[37] *See* AAPLOG Committee Op. No. 9, *supra* n. 25 (citing Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018, https://www.fda.gov/media/112118/download).

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.[38] Of these women, at least two bled to death from an undiagnosed ectopic pregnancy.[39] 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% 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.[40]

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.[41] A prescriber bears responsibility to diagnose and rule out such

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[38] 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.

[39] *Id.*

[40] 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/.

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

contraindications prior to prescribing mifepristone. But a prescriber who does not physically meet with and examine a patient is not capable of fulfilling the explicit REMS requirements or of ruling 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.[42] If a mother's cells have this protein, she is Rh-positive.[43] 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.[44] Importantly, a woman's body can still produce these antibodies even if the pregnancy is not carried to term because of abortion.[45] 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.[46] But Rh-negative women who are not tested before a mifepristone abortion may never know that they need treatment.

A de-emphasis on follow-up care also increases risks of post-abortion complications. The 2000 regimen's requirement that women return approximately 14 days after ingesting mif-

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[42] 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.

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *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.

epristone was considered necessary to ensure that the unborn child and all pregnancy tissue had passed out of the woman's body.[47] Retained pregnancy tissue can lead to continued bleeding and serious intrauterine infections.[48] A return visit permits the healthcare provider to ensure that the patient is not experiencing such complications from the abortion procedure, and that Rh-negative patients are administered Rhogam to protect future pregnancies.[49] Under FDA's current framework, without this visit, women may not recognize complications that could have been mitigated if caught earlier, resulting in greater harm to women.

The inadequacy of telemedicine 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.[50] 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[51] 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 informed consent from that patient.[52] A woman cannot consent to a chemical

[47] Mifeprex 2000 label, Day 14: Post-Treatment Examination, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

[48] Citizen petition submitted by the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians on Mar. 29, 2019, Docket No. FDA-2019-P-1534 at 10.

[49] *Id.*

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

[51] See Questions and Answers on Mifepristone, *supra* n. 6.

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

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

## V. Informed consent cannot be obtained under FDA's post-2021 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. Mifepristone's post-marketing restrictions fail to protect women from coercive partners and predators nor ensures that women are giving voluntary consent.

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."[53] Pregnancy pressure includes "forcing a female partner to terminate a pregnancy when she does not want to [] or injuring a female partner in a way that may cause a miscarriage."[54]

[53] 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.

[54] *Id.*

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)."[55] 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.[56]

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.[57]

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.[58] Fifteen percent of women surveyed said that they had experienced pressure to terminate a pregnancy against their will.[59] Further, three percent had

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[55] *Id.*

[56] *Id.*

[57] AAPLOG Committee Op. No. 9, *supra* n. 25.

[58] 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.

[59] *Id.*

someone give them a substance to cause an abortion without their knowledge or consent.[60] Five percent had experienced physical violence with the intention to end their pregnancies.[61]

Tragically, most instances of coerced abortion are never publicly known, and there is no justice for the victims. In-person dispensing requirements 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 post-marketing restrictions 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.

[60] *Id.*
[61] *Id.*

## CONCLUSION

The applications for stay pending appeal should be denied.

Respectfully submitted.

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