No. 23-10362

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Alliance for Hippocratic Medicine; American Association of Pro-Life Obstetricians & Gynecologists; American College of Pediatricians; Christian Medical & Dental Associations; Shaun Jester, D.O.; Regina Frost-Clark, M.D.; Tyler Johnson, D.O.; George Delgado, M.D.,
Plaintiffs – Appellees

v.

Food & Drug Administration; Robert M. Califf, Commissioner of Food and Drugs; Janet Woodcock, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; Patrizia Cavazzoni, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; United States Department of Health and Human Services; Xavier Becerra, Secretary, U.S. Department of Health and Human Services,
Defendants – Appellants

v.

Danco Laboratories, L.L.C.,
Intervenor – Appellant

On Appeal from the United States District Court, N. Dist. of Tex. (Amarillo Div.), No. 2:22-cv-223, Judge Matthew J. Kacsmaryk

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BRIEF FOR *AMICI CURIAE* SUSAN B. ANTHONY PRO-LIFE AMERICA, ET AL. IN OPPOSITION TO MOTIONS TO STAY

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CERTIFICATE OF INTERESTED PERSONS

Alliance for Hippocratic Medicine, et al. v.
U.S. Food and Drug Administration, et al., No. 23-10362

The undersigned counsel of record for the *Amici Curiae* 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-Appellees

Alliance for Hippocratic Medicine

American Association of Pro-Life Obstetricians & Gynecologists

American College of Pediatricians

Christian Medical & Dental Associations

Shaun Jester, D.O.

Regina Frost-Clark, M.D.

Tyler Johnson, D.O.

George Delgado, M.D.

Defendants-Appellants

U.S. Food and Drug Administration

U.S. Department of Health and Human Services

Robert M. Califf, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration

Janet Woodcock, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration

Patrizia Cavazzoni, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Xavier Becerra, in his official capacity as Secretary, U.S Department of Health and Human Services

Intervenor Defendant-Appellant

Danco Laboratories, LLC
(owned by Danco Investors Group, LP)

Amici Curiae

Susan B. Anthony Pro-Life America
Catholic Health Care Leadership Alliance
The National Catholic Bioethics Center
Catholic Bar Association
Catholic Benefits Association
Christ Medicus Foundation

Other Known Proposed *Amici Curiae* of Record

State of New York
State of Arizona
State of California
State of Colorado
State of Connecticut
State of Delaware
State of Hawaii
State of Illinois
State of Maine

State of Maryland
State of Massachusetts
State of Michigan
State of Minnesota
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Dated: April 11, 2023

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INTEREST OF *AMICI CURIAE*[1]

Amici Curiae 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:

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.

[1] This brief is filed under Federal Rules of Appellate Procedure 27(a)(3)(A) and 29(a)(2) with the consent of all parties having been obtained. Undersigned counsel for *Amici* certifies that this brief was not authored in whole or part by counsel for any of the parties; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no one other than *Amici*, their members, or their counsel have contributed money that was intended to fund preparing or submitting this brief.

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.

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.

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.

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.

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

The subject motions to stay filed by Defendants and Intervenor, 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 the FDA's improvident and illegal approval of those drugs militates against a stay of the district court's order pending appeal. *Amici* have a substantial interest is seeking that this Court's resolution of the motions will not further erode the protections of informed consent that need to be provided to women who are potential consumers of these drugs.

SUMMARY OF ARGUMENT

Defendants' and Intervenor's motions to stay should be denied to prevent harm to members of the public who otherwise would be deprived of the information about mifepristone necessary to give informed consent to consumption of this chemical abortion drug. 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.[3]

Mifepristone is dangerous for women when used for abortion (*i.e.,* for the purpose of ending the life of a developing unborn human being),[4] as is the FDA-approved chemical abortion regimen that combines the use of mifepristone with the drug misoprostol. Because of the drug's risks, 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 the FDA substantially weakened those post-

[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 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] Mifepristone, when used to end a pregnancy, carries various life-threatening risks. Additionally, all abortions are dangerous, carrying risks of physical and mental health complications and a negative impact on future pregnancies.

[5] Before the United States Food and Drug Administration (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

marketing requirements, to the detriment of women and girls, in 2016 and 2023.

In approving mifepristone for use, the FDA's acts and omissions made it impossible for informed consent to be obtained. First, the clinical studies used to obtain FDA approval afforded protections to patients that are not required by the drug's label or REMS. Therefore, conclusions about the drug's "safety" drawn from these trials cannot predict the safety of the drug when used by patients outside of a clinical trial. Second, FDA's post-marketing restrictions do not require reporting of non-fatal adverse events, and both FDA and mifepristone's sponsors have failed to demonstrate that mifepristone's adverse events can be reliably reported by other means. Third, prescribing healthcare providers cannot obtain informed consent without providing in-person care because they are unable to adequately diagnose ectopic pregnancy, verify Rh status, or detect other contraindications to mifepristone. Lastly, without in-person

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benefits of the drug outweigh the risks," FDA may require a Risk Evaluation and Mitigation Strategy (REMS). If the drug can only be approved with specific safeguards, the REMS includes *elements to assure safe use* (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.*

care, prescribing healthcare providers cannot adequately determine whether patients are giving free consent without coercion.

ARGUMENT

I. General principles of informed consent.

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 right to consent to or refuse medical treatment is rooted in bodily integrity.[7] This is a long-standing principle in tort law: if proper consent is not obtained, the treatment is a battery (an unwanted touching).[8] Informed consent requires that a physician disclose to the patient accurate information about the nature, risks, benefits, and alternatives

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

[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.*

to the proposed procedure or treatment.[9] The patient also must have capacity and must make the decision freely and without coercion.

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. 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.

[9] *See Canterbury v. Spence*, 464 F.2d 772, 787–88 (D.C. 1972); AMA Code of medical ethics opinions on consent, communication & decision making, available at https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf.

II. Because the clinical trials used to obtain FDA approval for mifepristone afforded patient protections not required by the drug's label or REMS, conclusions about the drug's "safety" drawn from these trials are legally and medically inadequate and cannot form the basis for informed consent.

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."[10] 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. However, 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. Further,

[10] 21 U.S.C. § 355(d).

the prescribers were physicians with experience in performing surgical abortions, training in the administration of the mifepristone-misoprostol procedure, and admitting privileges at medical facilities that could provide emergency care and hospitalization. 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.[11]

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. Therefore, FDA should never have relied upon the conclusions about mifepristone's safety drawn from the U.S. clinical trial as a basis to approve mifepristone under its 2000 label. FDA has not fully apprised prescribers or patients of the risks posed by the FDA-approved regimen because clinical trials did not reflect the manner in which the drugs are actually prescribed.

[11] *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.

Recently, FDA has again 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. On December 16, 2021, FDA removed the REMS "in-person dispensing requirement," a change that became permanent in 2023. 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. However, the available "safety information" provided by the sponsors or through 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

> …the 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 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.[12]

Despite the limitations of the studies, FDA erroneously 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."[13]

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 woefully inadequate FDA Adverse Event Reporting System, buttressed by studies the FDA acknowledges are so problematic that their results cannot be generalized to the United States population.

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[12] 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, Docket No. FDA-2019-P-1534 at 29.

[13] *Id.*

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.

III. Because FDA's post-marketing restrictions do not require comprehensive reporting of non-fatal adverse events and both FDA and mifepristone's sponsors failed to show reliable reporting of mifepristone's adverse events, mifepristone prescribers cannot obtain informed consent.

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 to the sponsor (*i.e.,* manufacturer), Danco, *any* serious adverse event associated with mifepristone. However, 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). As a result, the sponsors are unlikely to receive many reports of other, non-lethal adverse events.

Patients and all healthcare providers, including emergency room doctors or other providers who handle complications from abortion-inducing drugs that they did not prescribe, are not required to report adverse events to the sponsors. They may report adverse events directly to FDA through the MedWatch website. However, the reporting is entirely voluntary, and therefore data from that program cannot adequately or accurately apprise anyone of the risks of such 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 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 genuine 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."[14] 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.

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

[14] Aultman K, Cirucci CA, Harrison DJ, Beran BD, Lockwood MD, Seiler S. Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019, ISSUES LAW MED. 2021;36(1):3-26.

> 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.[15]

Further, in their study of nearly 20 years of AERs submitted to FDA, the Aultman study 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.[16]

In another study, Cirucci et al. compared 2009 and 2010 AERs reported through FAERS, those provided by FDA via a FOIA request, and those identified by Cleland et al. as having occurred at Planned Parenthood. While Planned Parenthood only performs 37% of U.S. abortions, the Cleland study identified 1,530 Planned Parenthood mifepristone cases with AERs, while FAERS only identified 664 *from all providers* and FDA only released 330 AERs through FOIA. These discrepancies demonstrate that the AER reporting system is broken and

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[15] AAPLOG Committee Op. No. 9.

[16] Aultman, *supra* n.14.

cannot be relied upon to 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."[17] Yet, some mifepristone prescribers, such as Aid Access,

[17] 2016 Patient Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2021_05_14_Patient_Agreement_Form.pdf.

blatantly violated FDA protocol, instructing their patients to lie to emergency medical personnel about having taken mifepristone.[18]

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 undermines emergency healthcare providers' ability to care for their patients 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 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

[18] 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.

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 care.

IV. Without providing in-person care, a certified prescriber cannot obtain informed consent because the prescriber cannot adequately diagnose ectopic pregnancy, verify Rh status, or detect other contraindications to mifepristone, failing to 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. However, FDA does 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."[19] In turn, the REMS requires healthcare providers who wish to be certified to sign a *Prescriber Agreement Form* stating: "you 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."[20]

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.

[19] Mifepristone Shared System REMS (updated Jan. 2023).

[20] Prescriber Agreement Form (updated Jan. 2023).

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.

In FDA's 2021 response to the 2019 citizen petition submitted by AAPLOG and the American College of Pediatricians (ACPeds), 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. 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. In a joint Committee Opinion, the American College of Obstetricians and Gynecologists, 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."[21] In fact, women often significantly underestimate gestational age.

The possibility that women receiving remote "care" may suffer from ectopic pregnancy is even more 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. Of these women, at least two bled to death from an

[21] American College of Obstetricians and Gynecologists' Committee on Obstetric Practice, *Methods for Estimating the Due Date,* Committee Opinion *No. 700 (May 2017)* p.1, available at https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date.pdf.

undiagnosed ectopic pregnancy. They likely did not recognize that their cramps, abdominal pain, and perhaps vaginal bleeding were dangerous indications of an 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 but had not sought an abortion.

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. A prescriber bears responsibility to diagnose and rule out such contraindications prior to prescribing mifepristone; however, 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.

Of particular concern to protect a patient's future fertility and the health of her future unborn children is the patient's Rh status. Rh D-negative patients must be administered Rh D immune globulin to prevent Rh isoimmunization in subsequent pregnancies, which can lead to pregnancy loss or severe injury to unborn children.[22] A patient may not know if she is Rh negative. Women who do not presently want future pregnancies may change their minds or wish to continue future planned or unplanned pregnancies. Rh D-negative women who are not tested before a mifepristone abortion may never know that they need the injection.

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 mifepristone was considered necessary to ensure that all pregnancy tissue had passed. Retained pregnancy tissue can lead to continued bleeding and serious intrauterine infections. A return visit permits the healthcare provider to ensure that the patient is not experiencing such complications from the

[22] *See* ACOG Practice Bulletin 181*: Prevention of Rh D Alloimmunization* (Aug. 2017).

abortion procedure, and that Rh-negative patients are administered Rhogam to protect future pregnancies.[23] Under the FDA's framework, without this visit, women may not recognize complications that could have been mitigated.

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. AAPLOG and ACPeds documented that abortion providers cannot diagnose contraindications or adequately care for their patients through a videoconference, and further, that telemedicine does not meet the standard of care for abortion or miscarriage management. 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*, and yet refuse to require prescribers to perform the most accurate evaluations of women who are seeking the drug. Without these patient-specific determinations,

[23] 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.

certified prescribers cannot know the patient's situation, and therefore cannot obtain informed consent. A woman cannot consent to a chemical abortion without knowing the specific risks that mifepristone poses to *her* life, health, and fertility.

V. Informed consent cannot be obtained 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. Therefore, abortion-inducing drugs are inherently different from other prescribed drugs. This known risk of coercive abortion 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 or ensure that women are giving 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." 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."[24]

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)."[25] 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.

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[24] "Reproductive and Sexual Coercion," ACOG Committee on Health Care for Underserved Women opinion (February 2013; Reaffirmed 2019), No. 554, American College of Obstetricians and Gynecologists, https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/02/reproductive-and-sexual-coercion.

[25] *Id.*

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.[26]

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. Fifteen percent of women surveyed said that they had experienced pressure to terminate a pregnancy against their will. Further, three percent had someone give them a substance to cause an abortion without their knowledge or consent. Five percent had experienced physical violence with the intention to end their pregnancies.

[26] AAPLOG Committee Op. No. 9.

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 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.

CONCLUSION

For the foregoing reasons, *Amici Curiae* respectfully ask this Court to deny the motions to stay.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 11th day of April, 2023, an electronic copy of the foregoing brief was filed with the Clerk of Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF system, that all parties to the case are registered CM/ECF users, and that service will be accomplished by the appellate CM/ECF system.

/s/ Joshua P. Clayton

Joshua P. Clayton

CERTIFICATE OF COMPLIANCE

1. This petition complies with the type-volume limitations of Federal Rules of Appellate Procedure 27(d)(2) and 29(a)(5) because it contains 5,184 words, as determined by the word-count function of Microsoft Word, excluding parts of the brief that are exempted from the word-count requirement by Federal Rule of Appellate Procedure 32(f) and Fifth Circuit Rule 32.2.

2. This brief complies with the typeface requirements of Federal Rules of Appellate Procedure 29(a)(4) and 32(a)(5) and the typestyle requirements of Federal Rules of Appellate Procedure 29(a)(4) and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point for text, and 12-point for footnotes, in Century Schoolbook font.

/s/ Joshua P. Clayton

Joshua P. Clayton

Dated: April 11, 2023