Nos. 23-235 and 23-236

In the

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
RESPONDENTS.

DANCO LABORATORIES, L.L.C.,
PETITIONER,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
RESPONDENTS.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF OF *AMICI CURIAE* SUSAN B. ANTHONY PRO-LIFE AMERICA AND UNITED STATES CONFERENCE OF CATHOLIC BISHOPS, ET AL., IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*

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

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

United States Conference of Catholic Bishops is a nonprofit corporation, the members of which are the active Catholic Bishops in the United States. The Conference advocates and promotes the pastoral teachings of the U.S. Catholic Bishops in such diverse areas of the nation's life as the free expression of ideas, fair employment and equal opportunity for the underprivileged, the importance of education, and the sanctity of human life.

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.

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[1] Pursuant to S. Ct. 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).

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.

Coalition for Jewish Values (CJV) is the largest Rabbinic public policy organization in America, representing over 2,000 traditional, Orthodox rabbis. The CJV Healthcare Council was formed by Torah-observant medical professionals under the auspices of the CJV Rabbinic Board to promote medical practices consonant with Jewish values and to preserve conscience rights for healthcare professionals.

Catholic Benefits Association is a nonprofit 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.

Texas Conference of Catholic Bishops is an unincorporated association consisting of the Bishops of the 15 Catholic dioceses in Texas and the Ordinariate of the Chair of St. Peter. Through this association, the various Bishops speak with one voice on issues facing the

Catholic Church in Texas. The Church in Texas has a long history of ministering to the needs of pregnant women and their unborn children through various health care and social service ministries. The Bishops regularly advocate for both conscience protection of health care providers and the protection of the life and health of mothers and their unborn children in Texas.

National Catholic Partnership on Disability (NCPD) was established to implement the 1978 *Pastoral Statement of U.S. Catholic Bishops on Persons with Disabilities*. NCPD serves hundreds of thousands of persons with disabilities, and those who minister to them, fostering inclusion in Church and society. They know intimately the challenges, and risks related to bias toward persons with disabilities. Such biases become even more evident when a pregnant mother has a disability or is from a family with a disability, especially if of genetic origin, and there are efforts to discourage the mother from continuing her pregnancy. True informed consent, with protections against coercion are essential. The bias is not only against the mother but also against her unborn child, especially if there is evidence of a congenital disability. Furthermore, the medical risks to any mother by the FDA-approved protocol for prescribing and dispensing mifepristone, described herein, are significantly heightened for a mother with a disability, for example accessing emergency care for hemorrhage or infection in a timely manner. NCPD continues to advocate for policies that protect all persons with disabilities, including mothers and their unborn children.

National Association of Catholic Nurses, USA is the national professional organization for Catholic nurses in the United States. A nonprofit group of

hundreds of nurses of different backgrounds, the NACN-USA focuses on promoting moral principles of patient advocacy, human dignity, and professional and spiritual development in the integration of faith and health within the Catholic context in nursing. Its members are critically concerned for the wellbeing of women and their unborn children threatened by the FDA-approved protocol for prescribing and dispensing mifepristone, described herein.

* * *

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

SUMMARY OF ARGUMENT

The requirement that a healthcare provider obtain a patient's freely given informed consent before medical treatment is firmly established in law and is a cornerstone of modern bioethics.[3] The patient's decision must be based on adequate disclosure of the diagnosis, the proposed treatment, its benefits, risks, and alternatives, and the patient must have capacity and freedom from coercion. These fundamental principles, which protect both patients and medical professionals, cannot be met when healthcare providers prescribe mifepristone under FDA's current protocol.[4]

Because of the risks posed by taking mifepristone to cause an abortion, its availability is limited by an FDA-imposed Risk Evaluation and Mitigation Strategy (REMS) with post-marketing "elements to assure safe use" (ETASU).[5] But to the detriment of women, FDA's

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[3] AMA Code of Medical Ethics, Ch. 2 "Consent, Communication & Decision Making," Op. 2.1.1 (2016), https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf ("Informed consent to medical treatment is fundamental in both ethics and law.").

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

[5] Before approval, an applicant (the drug's sponsor and/or manufacturer) must demonstrate the drug's safety and efficacy "for use under the conditions prescribed, recommended, or suggested in the proposed labeling." 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

approval was based on studies containing safeguards not used when actually prescribing the drugs post-approval. This prevents prescribers from being able to accurately convey the true risks of the drug to patients. FDA then eroded those post-marketing requirements in 2016, 2021 and 2023. FDA's newer post-marketing restrictions do not require reporting of non-fatal adverse events to the drug's sponsors, which is critical to ensuring drugs' safety. FDA also no longer requires in-person appointments to prescribe mifepristone.[6] But in-person visits are critical. Without it, physicians are unable to adequately diagnose ectopic pregnancy, verify Rh status, or detect other contraindications. Physicians thus cannot adequately inform a woman of her personal risks related to mifepristone. And without in-person visits, prescribers also cannot adequately determine whether patients are giving consent without coercion. Women can only benefit from more information and more protection, especially when considering whether to take a drug that FDA acknowledges is dangerous and that has permanent consequences. Affirming the district court's ruling would help prevent further harm to women from the lack of informed consent.

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be approved with specific safeguards, the REMS includes ETASU. 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 HHS. *Id.*

[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 a Cornerstone of Modern Bioethics and Is Especially Critical in the Context of Abortion.

A. Informed consent is fundamental to bodily autonomy and is firmly rooted in American law.

The principle of respect for autonomy and self-determination "predominates in modern bioethics: 'Because of the intimate and intrusive nature of biomedical decisions, a central focus of bioethics has been to respect and protect an individual's autonomy in making those decisions.'" O. Carter Snead, *The (Surprising) Truth About Schiavo: A Defeat for the Cause of Autonomy*, 22 Const. Comment. 383, 387 (2005) (quoting John A. Robertson, *Precommitment Issues in Bioethics*, 81 Tex. L. Rev. 1849, 1849 (2003)). "The principle of informed consent—the cornerstone of modern biomedical ethics—is in large measure an extension of this general concept of personal autonomy." *Id.* at 388. According to this principle, "no medical intervention may be undertaken without the *intelligent* and *voluntary* consent of the patient." *Id.* (footnote omitted) (emphasis added).

The requirement that a healthcare provider obtain a patient's informed consent before treatment is also firmly established in law. The right to consent to or refuse medical treatment was originally established in common law, and "this notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 269 (1990). Before the early 1900s, treatment was often left to the

discretion of physicians with little patient involvement. Eventually, courts recognized 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). "The informed consent doctrine has become firmly entrenched in American tort law." *Cruzan*, 497 U.S. at 269. And this Court has recognized that the principle is so fundamental that it has constitutional dimensions. *See id.* at 278–79.

According to both accepted ethical principles and the law, informed consent requires three elements: information, comprehension, and voluntariness.[7] To satisfy the first element, a physician must give a patient accurate information about the nature of the procedure, risks, benefits, and alternatives to the proposed procedure or treatment, and allow the patient to ask questions.[8] That includes the risks to the particular patient given her own circumstances and conditions.[9] It also includes informing a patient of the availability of diagnostic

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[7] Part C.1, Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979), *available at* https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf.

[8] *Id.*; *see also Canterbury v. Spence*, 464 F.2d 772, 787–88 (D.C. 1972); AMA Code of Medical Ethics, *supra* n. 3.

[9] Bryan Murray, *Informed Consent: What Must a Physician Disclose to a Patient?*, 14 Am. Med. Asso. J. of Ethics 563, 564-65 (2012), *available at* https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-05/hlaw1-1207.pdf.

tests that may rule out a possible condition that would influence the patient's treatment decision.[10]

The patient must also have capacity to make, and must in fact make, the decision freely and without coercion. *Cruzan*, 497 U.S. at 280 ("An incompetent person is not able to make an *informed* and *voluntary* choice to exercise a hypothetical right to refuse treatment or any other right." (emphasis added)). Generally, minors lack legal capacity to provide consent to medical treatment or procedures and consent must instead be obtained from the minor's parent or legal guardian.[11] In the context of abortion, most states require parental notice or consent before a minor may obtain an abortion.[12]

Aside from the obvious benefits to the patient, the doctrine of informed consent also benefits the medical profession. At minimum, it reduces the likelihood of potential legal liability.[13] Informed consent also helps physicians provide quality patient care, promotes trust and

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[10] *See id.*; *see also, e.g., Jandre v. Physicians Ins. Co. of Wis.*, 792 N.W.2d 558, 568 (Wis. Ct. App. 2010) (noting that informed consent under Wisconsin law requires physicians to inform patients of "a test to rule out a condition [the patient] was possibly suffering from, and which [the physician] did not rule out.").

[11] AMA Code of Medical Ethics, *supra* n. 3, at Op. 2.2.1 (noting "parents' authority as decision makers" in treatment decisions for minor children).

[12] *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).

[13] *See, e.g.,* Murray, *supra* n. 9.

confidence, and encourages better interactions between patient and physician.[14]

B. Federal courts have long recognized that informed consent is particularly important for abortion.

The fundamental importance of informed consent is underscored in the abortion context. This Court acknowledges that "[a]bortion 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 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, this Court has also repeatedly recognized the unique 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

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[14] *Id.*; *see also* AMA Code of Medical Ethics, *supra* n. 3, at Op. 2.1.3 ("Truthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy.").

(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) (citation omitted).

II. Under FDA's Current Mifepristone Regime, Prescribers Cannot Adequately Inform Patients of Potential Risk.

A. Clinical trials relied on for mifepristone's initial approval provided more protection for women than has ever been required by mifepristone's label or REMS.

For a healthcare provider to adequately inform patients about risks of a treatment or procedure, those risks must be reasonably known. Applicants seeking approval for a drug 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*." 21 U.S.C. § 355(d) (emphasis added). But the "conditions" in the U.S. trial for mifepristone afforded protections to women that are not 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.[15] The prescribers were physicians with experience in performing

[15] *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.

surgical abortions, training in the administration of the mifepristone-misoprostol procedure, and admitting privileges at medical facilities that could provide emergency treatment.[16] And 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.[17] None of these conditions have ever been included in the REMS since mifepristone's approval in 2000. Clinical trials used to justify mifepristone's approval that include extra safeguards cannot provide a basis to assess accurately the drug's risks *without* those safeguards. *Cf. All. for Hippocratic Med. v. Food & Drug Admin.*, No. 23-10362, 2023 WL 2913725, at *17 (5th Cir. Apr. 12, 2023) (*AHM II*). And a woman cannot give truly informed consent if her physician cannot inform her as to the true risks of medication abortion.

B. The studies relied upon in FDA's decision to remove safety measures from mifepristone's approved conditions of use did not establish the safety of mifepristone use under the reduced requirements.

Likewise, FDA is tasked with reviewing scientific evidence to support any proposed changes to a REMS. 21 C.F.R. § 314.70. However, the studies FDA relied upon in 2016, 2021, and 2023 when removing safety requirements from the mifepristone REMS did not evaluate the safety of mifepristone when used in the newly approved conditions of use, rendering the findings in those studies useless for informed consent. As the stay panel observed,

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[16] *Id.*

[17] *See id.*

in 2016, "FDA eliminated REMS safeguards based on studies that *included those very safeguards.*" *AHM II*, 2023 WL 2913725, at *17. The Fifth Circuit panel, in affirming in part the district court's stay, similarly addressed defects in the 2021 Non-Enforcement Decision regarding the REMS in-person dispensing requirements:

> In the face of concededly limited data, and lacking more probative information from prescribers, FDA fell back on studies that were merely 'not inconsistent' with its intended conclusion. It did not refer to any literature that affirmatively supported the notion that mifepristone would remain safe and effective even without the in-person dispensing requirement.

All. for Hippocratic Med. v. U.S. Food & Drug Admin., 78 F.4th 210, 251 (5th Cir. 2023) (*AHM III*). Without such studies, an abortion provider cannot fully inform his patient about the risks posed by obtaining mifepristone without in-person dispensing.

C. FDA's post-2016 REMS changes fail to allow for adequate post-marketing surveillance of mifepristone's safety.

If a drug is approved for use, physicians can also rely on post-marketing safety data to assess the risks when informing their patients. And from the FDA's perspective, post-marketing surveillance of adverse effects is "essential" for ensuring a drug's safety.[18] Because all possible side effects of a drug cannot be anticipated

[18] FDA, *Postmarketing Surveillance Programs*, https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs (last visited Apr. 27, 2023).

based on preapproval studies involving small numbers of patients, FDA maintains a system of post-marketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug-approval process.[19] Federal regulations require sponsors to report *all* adverse drug experiences to the FDA Adverse Event Reporting System (FAERS). 21 C.F.R. § 314.80(c). "Adverse drug experiences" are defined broadly and include even adverse events that occur while using the drug "whether or not considered drug related." *Id.*[20]

As a condition of mifepristone's approval in 2000, FDA required certified prescribers to report *any* serious adverse event associated with mifepristone to the sponsor.[21] But in 2016, FDA modified the mifepristone REMS with ETASU and eliminated the reporting requirement

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[19] *Id.*

[20] According to 21 C.F.R. § 314.80(a), an "adverse drug experience" is "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action."

[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.

for non-fatal adverse events.[22] As a result, the sponsors may not receive reports of non-fatal adverse events, even if they are serious. The removal of the requirement to report non-fatal adverse events causes vastly undercounted adverse event reports (AERs), skewing the safety profile of mifepristone. As the stay panel pointed out, "[i]t's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision." *AHM II*, 2023 WL 2913725, at *17.

There are other limitations on the safety data that make FDA's choice even more concerning. For example, emergency-room doctors or other non-prescribing providers handle most hemorrhages from drug-induced abortion. An analysis of AERs for mifepristone submitted to FDA from 2000 to 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."[23] Sponsors likely do

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[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] 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.

not know about (or report to FAERS) most hemorrhages because non-prescribing doctors are not required to report them. This problem is exacerbated by the limited-to-nonexistent follow-up performed by abortion providers after chemical abortion; follow-up is now merely advised, no longer required, by the REMS. Patients and non-prescribing providers may choose to report adverse events to FDA through the MedWatch website.[24] But this reporting is entirely voluntary and thus incomplete.[25]

Further decreasing the likelihood that AERs are reliably reported, some prescribers encourage their patients to hide consumption of abortion-inducing drugs if treated by other healthcare providers for complications. Before FDA changed the mifepristone prescribing information and Patient Agreement Form in 2023, the 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

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[24] 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.

[25] For instance, in a study involving a similar system in Germany, 75-85% of providers had never voluntarily reported an adverse event and 20% did not even know about the voluntary reporting system. Shirley Murphy and Rosemary Roberts, *Black box 101: How the Food and Drug Administration evaluates, communicates, and manages drug benefit/risk*, 117 J. Allergy & Clinical Immunol. 34, 38 (2006); https://www.jacionline.org/action/showPdf?pii=S0091-6749%2805%2902325-0.

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."[26] Yet, some prescribers, such as Aid Access, instruct their patients to lie to emergency medical personnel about having taken mifepristone.[27]

Tragically, FDA's 2023 changes further enable this deception. Prescribers are no longer directed to instruct patients to take the medication guide with them when seeking emergency treatment, and patients are no longer directed to do so in the Patient Agreement Form. This change undermines emergency healthcare providers' ability to care for patients because they will be missing critical information. It also decreases the likelihood that adverse events will be reported.

Ample evidence shows that adverse events are significantly underreported. In October 2021, plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) warned:

> 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

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[26] 2016 Patient Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2021_05_14_Patient_Agreement_Form.pdf.

[27] *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.

> documented. Two analyses examined the [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.[28]

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

> [FAERS] 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.[29]

Another study compared 2009 and 2010 AERs reported through FAERS, those provided by FDA via Freedom of Information Act request, and those identified by other researchers as having occurred at Planned Parenthood.[30] While Planned Parenthood performs 37% of U.S. abortions, the study identified 1,530 mifepristone cases with

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[28] 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.

[29] Aultman, *supra* n. 23.

[30] 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.

AERs at Planned Parenthood alone, while FAERS only identified 664 *from all providers* and FDA released only 330 AERs through FOIA.[31] These discrepancies show that the AER reporting system is unreliable.

AERs 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. Yet the FDA has done just that by reducing reporting requirements and overlooking limitations with the data that is reported. As the stay panel pointed out, "[t]his ostrich's-head-in-the-sand approach is deeply troubling—especially on a record that, according to [FDA's] own documents, necessitates a REMS program, a 'Patient Agreement Form,' and a 'Black Box' warning." *AHM II*, 2023 WL 2913725, at *17.[32] These agency actions are "well 'outside the zone of reasonableness.'" *Id.* (citation omitted). Because FDA's REMS does not require comprehensive reporting of adverse events, 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, robbing women of their right to make well-informed decisions.

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[31] *Id.*

[32] A "Black Box" warning means that there is "reasonable evidence of an association of a serious hazard with the drug" and "the adverse reaction may lead to death or serious injury." Murphy & Roberts, *supra* n. 25, at 36-39; *accord* 21 C.F.R. § 201.57(e).

III. Without Providing In-Person Visits, Mifepristone Prescribers Cannot Adequately Inform a Patient of Her Personal Risks.

To obtain genuine informed consent, a physician must inform the patient of the medical condition requiring the proposed treatment, and must explain any risks, including contraindications that increase 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 prescriber who merely consults with a patient through video, phone, or email—which is now explicitly permitted by FDA—cannot accurately assess the duration of a patient's pregnancy or diagnose ectopic pregnancy.

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."[33] In turn, the REMS requires healthcare providers who wish to be certified to sign a Prescriber Agreement

[33] 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.

Form stating that "you agree that you meet the qualifications [] and will follow the guidelines for use."[34]

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. . . .
>
> 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.

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[34] 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.

- 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. . . . [35]

But the prescriber qualification requirements and guidelines regarding a provider's *abilities* in the REMS are meaningless if a prescriber does not actually *use* 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 perform the diagnostic tests to determine whether the patient has an ectopic pregnancy? A prescriber cannot obtain true informed consent without adequately screening the patient for contraindications. *See, e.g., Jandre*, 792 N.W.2d at 568.

FDA claims that it is inappropriate to mandate how providers assess women for gestational age or ectopic pregnancy, and that certified prescribers do not have to be physically present with the patient.[36] 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 the opinion of another provider, that the patient's pregnancy is 10 weeks or less and that it is an intrauterine

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[35] *Id.*

[36] 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 25.

pregnancy.[37] 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 agree that "[u]ltrasound measurement of the embryo or fetus in the first trimester . . . is the most accurate method to establish or confirm gestational age."[38] Women often underestimate gestational age.[39] And mifepristone's failures (requiring surgery) and complications indisputably increase as gestational age advances, which is why mifepristone is only approved for use in early pregnancy.[40]

The possibility that women receiving remote "care" may take mifepristone with an ectopic or extrauterine pregnancy is extremely troubling. An ectopic pregnancy can rupture the fallopian tube as the pregnancy progresses, causing major internal bleeding, severe pain, and possibly death if emergency surgical intervention is unavailable.[41] Half of women who experience ectopic

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

[38] 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.

[39] *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).

[40] *See* AAPLOG Committee Op. No. 9, *supra* n. 28 (citing Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018, https://www.fda.gov/media/112118/download).

[41] "What is ectopic pregnancy?," ACOG, *FAQ: Ectopic Pregnancy*, https://www.acog.org/womens-health/faqs/ectopic-pregnancy.

pregnancy do not have any risk factors.[42] As noted above, ectopic pregnancies can only be reliably diagnosed through an ultrasound evaluation and confirmation of the location of the pregnancy. If a woman with an extrauterine pregnancy is given mifepristone, she may believe her symptoms are simply the effects of drug-induced abortion because they are similar, and may delay obtaining immediate medical care at great risk to her safety.[43] As of June 30, 2021, at least 97 women with ectopic pregnancies in the United States had been given mifepristone.[44] At least two of these women bled to death from an undiagnosed ectopic pregnancy.[45] They likely did not recognize that their abdominal pain and bleeding were indications of a life-threatening ectopic pregnancy, not expected effects of a chemical abortion. 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.[46]

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[42] *Id.* at "What are the risk factors for ectopic pregnancy?"

[43] *Compare id.* at "What are the symptoms of ectopic pregnancy?" (symptoms include vaginal bleeding, abdominal pain, dizziness, weakness, and fainting) *with* Planned Parenthood, *How does the abortion pill work?*, https://www.plannedparenthood.org/learn/abortion/the-abortion-pill/how-does-the-abortion-pill-work (last accessed May 9, 2022) (symptoms related to a medication abortion include heavy vaginal bleeding, abdominal pain, dizziness, vomiting, and weakness).

[44] 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.

[45] *Id.*

[46] Atrash H.K., et al., *Ectopic pregnancy concurrent with induced abortion: Incidence and mortality*, 162 Am. J. of Obstet. & Gynecol. 726, 727 (1990), *abstract available at* https://pubmed.ncbi.nlm.nih.gov/2316578/.

There are other contraindications that must also be investigated before administering mifepristone: presence of an intrauterine device (IUD), 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.[47]

Along with the danger of contraindications, a patient's Rh status is another concern not adequately addressed by FDA's current REMS, despite its importance in protecting a patient's future fertility. The Rh factor is a protein found on the surface of red blood cells.[48] If a mother's cells have this protein, she is Rh-positive.[49] 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 produce anti-Rh antibodies. These antibodies can cross the placenta in future pregnancies and lead to serious health problems, or even death, for the unborn child or newborn.[50] A woman's body can still produce these antibodies even if the first pregnancy is not carried to term because of abortion.[51] Thus, Rh-negative patients who have been pregnant before

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[47] *See* Highlights of Prescribing Information 4-5, https://www.accessdata.fda.gov/drugsatfdadocs/label/2016/020687s020lbl.pdf (mifepristone prescribing information approved by FDA for Danco).

[48] 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.

[49] *Id.*

[50] *Id.*

[51] *Id.*

must be administered Rhogam to avoid miscarriage or severe injury to their future unborn children.[52] But Rh-negative women who are not tested before a chemical abortion may not know that they need treatment.

FDA's elimination of follow-up visits also increases risks of post-abortion complications. The 2000 regimen's requirement that women return fourteen days after ingesting mifepristone and misoprostol is necessary to ensure that the unborn child and all pregnancy tissue have been expelled from the woman's body.[53] Retained tissue can lead to continued bleeding and serious intrauterine infections.[54] A return visit permits the healthcare provider to ensure that the patient is not experiencing complications and to administer Rhogam to Rh-negative women.[55] FDA's current framework does not require this visit, which means women may not recognize complications until they become more severe, resulting in greater harm.

The inadequacy of telemedicine is buttressed by the fact that twenty-nine states permit only physicians to prescribe mifepristone, with eighteen states requiring the provider to be physically present with the patient—

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[52] *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.

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

[54] 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.

[55] *Id.*

and for good reason.[56] A call to a hotline or remote prescriber will not help a hemorrhaging woman reach an emergency room quickly. It is nonsensical for FDA to acknowledge that the dangers posed to women from mifepristone require ETASU[57] yet also refuse to require prescribers to perform the most accurate assessments of women who wish to use the drug. Without these patient-specific determinations, certified prescribers cannot obtain truly informed consent. *See Canterbury*, 464 F.2d at 787. A woman cannot properly consent to a chemical abortion without knowing the specific risks that mifepristone poses to *her* life, health, and fertility.

IV. Without Providing In-Person Visits, Mifepristone Prescribers Cannot Adequately Screen for Coercion.

Voluntariness is essential to informed consent. Coerced consent is no consent at all, and there is an increased risk of coercion and abuse in the context of abortion drugs if the prescriber does not thoroughly screen the patient. Abortion-inducing drugs are inherently different from other prescription drugs in that they are prescribed with the purpose of ending a developing life, which increases both the probability and the magnitude of the risk that someone may force a pregnant patient to take the drugs against her will. This danger is increased by FDA's removal of the in-person dispensing requirement—an important safeguard to ensure that physicians can directly see and evaluate the voluntariness of the patient's consent. FDA's post-marketing restrictions thus

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

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

fail to protect women from coercive partners and predators.

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."[58] 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."[59] 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)."[60] In 2007, the prevalence of intimate partner violence was nearly three times greater for women seeking abortions than for women who continued their pregnancies.[61]

With no in-person contact, prescribers lose the ability to ensure that abusers are not just out of the frame of a video conference pressuring their victims into requesting abortion-inducing drugs or ordering the drugs

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[58] 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.

[59] *Id.*

[60] *Id.*

[61] *Id.*

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.[62]

This concern is not hypothetical; abusers have been prosecuted for drugging pregnant women with abortion-inducing drugs without their consent.[63] Tragically, the vast majority of these cases are unlikely to be detected, reported, and prosecuted.

A 2023 peer-reviewed survey demonstrated the prevalence of coercion in women's abortion decisions that will undoubtably grow with the removal of the in-person dispensing requirement for mifepristone. A survey of more than 1,000 American women between the ages of 41 and 45 included over 200 who acknowledged having had abortions.[64] Of the women who had abortions, close to 70

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[62] AAPLOG Committee Op. No. 9, *supra* n. 28.

[63] Hannah Howard, *Medical and Social Risks Associated with Unmitigated Distribution of Mifepristone: A Primer,* On Point, Issue 51, Charlotte Lozier Institute (Oct. 1, 2020), https://lozierinstitute.org/medical-and-social-risks-associated-with-unmitigated-distribution-of-mifepristone-a-primer/.

[64] David C. Reardon and Tessa Longbons, *Effects of Pressure to Abort on Women's Emotional Responses and Mental Health*, Cureus 15(1) (Jan. 31, 2023), *available at* https://www.cureus.com/articles/124269-effects-of-pressure-to-abort-on-womens-emotional-responses-and-mental-health#!/.

percent "described them as coerced, pressured, or inconsistent with their own values and preferences."[65] Further, "a majority experienced pressure from other people in their lives – belying the dangerous assumption that abortion is strictly a matter of 'a woman's choice.'"[66]

This coerced "consent" had real consequences in these women's lives: "perceived pressure to abortion was significantly associated with more negative emotions; more disruption of daily life, work, or relationships; more frequent thoughts, dreams, or flashbacks to the abortion; more frequent feelings of loss, grief or sadness about the abortion; more moral and maternal conflict over the abortion decision; a decline in overall mental health that they attribute to their abortions; more desire or need for help to cope with negative feelings about the abortion."[67]

The BBC also commissioned a survey of one thousand women aged 18-44 to determine how common sexual coercion is, and found that *half* said they had experienced at least one type of reproductive coercion.[68] Fifteen percent of women surveyed said that they had experienced pressure to terminate a pregnancy against their will.[69]

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[65] Tessa Longbons and David C. Reardon, Ph.D., *Study: Many Women Who Had Abortions Felt Pressured by Others*, Charlotte Lozier Institute (May 25, 2023), https://lozierinstitute.org/study-many-women-who-had-abortions-felt-pressured-by-others/.

[66] *Id.*

[67] Reardon and Longbons, *supra* n. 64.

[68] 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 (Aug. 3, 2022), https://savanta.com/knowledge-centre/poll/reproductive-coercion-poll-bbc-radio-4-8-march-2022/.

[69] *Reproductive Coercion Poll*, *supra* n. 68.

Three percent were given a substance to cause an abortion without their knowledge or consent.[70] Five percent experienced physical violence with the intention to end their pregnancies.[71]

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—though an imperfect one—against coerced abortion. By ceasing to require in-person contact between prescribers and patients, FDA's post-marketing restrictions cannot ensure that women and girls are protected from coercive partners and predators—further eroding the ability of women to make independent, voluntary decisions to use mifepristone.

CONCLUSION

The Court should affirm the Fifth Circuit's order and remand for further proceedings.

Respectfully submitted.

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[70] *Id.*
[71] *Id.*