IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHING DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS, on behalf of itself, its members, and their patients; AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of itself, its members, and their patients; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS, on behalf of itself, its members, and their patients; SHAUN JESTER, D.O., on Behalf of himself and his patients; REGINA FROST-CLARK, M.D., on behalf of herself and her patients; TYLER JOHNSON, D.O., on behalf of himself and his patients; and GEORGE DELGADO, M.D., on behalf of himself and his patients	§	
VS.	§	Case No. 2:22-CV-00223-z
U.S. FOOD AND DRUG ADMINISTRATION; 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; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary, U.S. Department of Health and Human Services	§	

BRIEF OF *AMICUS CURIAE*, SUSAN B. ANTHONY PRO-LIFE AMERICA, CATHOLIC HEALTH CARE LEADERSHIP ALLIANCE, THE NATIONAL CATHOLIC BIOETHICS CENTER, CATHOLIC BAR ASSOCIATION, CATHOLIC BENEFITS ASSOCIATION, AND CHRIST MEDICUS FOUNDATION IN SUPPORT OF PLANTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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Susan B. Anthony Pro-Life American, Catholic Health Care Leadership Alliance, The National Catholic Bioethics Center, Catholic Bar Association, Catholic Benefits Association, and Christ Medicus Foundation, file this Amicus Brief in support of Plaintiffs' Complaint (Doc. 1) and Plaintiff's Motion for Preliminary Injunction (Doc. 6), and in support shows the following:

INTERESTS OF AMICI CURIAE

Amicas Curae, **Susan B. Anthony Pro-Life America** is a "pro-life advocacy organization," *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 153 (2014) (internal quotation marks omitted), dedicated to ending abortion while protecting the lives of mothers and their babies. The organization is involved in public education and issue advocacy, working to advance pro-life laws and health-saving regulatory measures for women, girls, and the unborn through direct lobbying and grassroots campaigns.

Amicus Curiae **Catholic Health Care Leadership Alliance** (CHCLA) is an alliance of Catholic organizations whose mission is to support the rights of patients and professionals to receive and provide health care in accordance with the moral, ethical, and social teachings of Jesus Christ and His Church through ongoing evangelization, education, advocacy, and mutual support. CHCLA's allied members include professionals involved in all areas of health care, including physicians and nurses, as well as practice groups and hospitals. These CHCLA members are engaged in the active practice of health care on a daily basis, working in both secular and religious environments, and adhere to Catholic doctrine as their sincerely held religious beliefs. These members collectively provide medical care to hundreds of thousands of patients across the country.

Amicus Curiae **The National Catholic Bioethics Center** (NCBC) is a nonprofit research and educational institute committed to applying the principles of natural moral law, consistent with many traditions including the teachings of the Catholic Church, to ethical issues arising in health

care and the life sciences. NCBC is committed to fostering a culture of respect for human life and human dignity, particularly in the medical context.

Amicus Curiae **Catholic Bar Association** (CBar) 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. The CBar's mission and purpose include upholding the principles of the Catholic faith in the practice of law, and assisting the Church in the work of communicating Catholic legal principles to the legal profession and society at large.

Amicus Curiae **Catholic Benefits Association** ("CBA") is an Oklahoma non-profit limited cooperative association committed to assisting its Catholic employer members in providing health coverage to their employees consistent with Catholic values. The CBA provides such assistance through its website, training webinars, legal and practical advice for member employers, and litigation services protecting members' legal and conscience rights. The CBA's member employers include 78 Catholic dioceses, over 7000 parishes, over 1300 schools and colleges, as well as social services agencies, hospitals, senior housing, and closely held for profit employers. One of the conditions of membership is that the member affirm that its health care coverage complies with Catholic values.

Amicus Curiae **Christ Medicus Foundation** (CMF) was established in 1997 to defend religious freedom by educating religious and lay leaders on the intersection of health care, the exercise of faith and religious freedom, and the right to life. For decades, it has led coalitions, campaigns, and conferences to educate and inform Christ-centered health care decisions. As part of this mission, CMF helps defend the rights, health, and wellbeing of patients and families through the Health Care Civil Rights Taskforce and builds momentum around this movement through the Religious Freedom Campaign.

In support of Plaintiffs' Complaint and Motion for Preliminary Injunction, *Amici* urge this Court to recognize the profound legal and ethical consequences of the U.S. Food and Drug Administration's improvident and illegal approval of chemical abortion drugs, and in particular its failure to implement or enforce safeguards necessary to ensure adequate, informed consent for women who use such drugs.

SUMMARY OF THE ARGUMENT

The requirement that a healthcare provider obtain a competent patient's informed consent before treatment is firmly established in both law and medical ethics. Section I lays out the general principles of the doctrine of informed consent, which both protects patient well-being and autonomy and promotes and protects the physician-patient relationship. To consent (or refuse consent) to a treatment or procedure, a patient must have capacity to make a decision. If the patient does not have sufficient capacity, for example in the case of minors, consent from a parent or legal guardian is necessary to obtain. Next, in order to make an intelligent decision, the patient's decision must be based on an adequate disclosure of the diagnosis, the proposed treatment, its benefits, its risks, and its alternatives. Finally, the patient, having capacity and being duly informed, must consent to the treatment or procedures without coercion or duress.

The fundamental principles of informed consent, which protect both patients and medical professionals, cannot be met when healthcare providers prescribe mifepristone,[1] for many reasons

[1] Unless otherwise stated, references to mifepristone in this brief 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. *See,* https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390. All cited FDA documents can be found at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

including those explained in this brief. Mifepristone is dangerous[2] for women when used for abortion (*i.e.*, for the purpose of ending the life of a developing unborn human being),[3] as is the FDA-approved chemical abortion regimen that combines the use of mifepristone with the drug misoprostol.[4] 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] However, as *amici* explain in this brief, these post-marketing requirements were substantially weakened, to the detriment of women and girls, in 2016[6] and 2023.[7] While the

[2] Mifepristone, when used to end a pregnancy, carries risks of life-threatening hemorrhage, infection, continued pregnancy (necessitating additional drugs or surgery), retained tissue, need for emergency surgery, and death. *See* 2023 mifepristone label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

[3] All abortions are dangerous, carrying risks of physical and mental health complications and a negative impact on future pregnancies. *See* Skop I. Abortion safety: at home and abroad. *Issues Law Medicine* 2019;34:43-75; Reardon DC. The abortion and mental health controversy: A comprehensive literature review of common ground agreements, disagreements, actionable recommendations, and research opportunities. *SAGE Open Med*. 2018 Oct 29;6:2050312118807624. doi: 10.1177/2050312118807624. eCollection 2018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207970/; Rooney B, Calhoun BC. Induced abortion and risk of later premature births. *J of Am Physicians and Surgeons* 2003;8(2):46-49.

[4] The terms "FDA-approved chemical abortion regimen," "FDA-approved regimen," "medication abortion," "medical abortion," "chemical abortion," and "drug-induced abortion" [or termination of pregnancy] share the same meaning (unless otherwise stated) and refer to the use of abortion-inducing drugs, rather than surgery, to induce abortion.

[5] Before the United States Food and Drug Administration (FDA) approves a drug, an applicant (*i.e.*, the drug's sponsor and/or manufacturer) must make certain demonstrations regarding the drug's safety and efficacy "for use under the conditions prescribed, recommended, or suggested in the proposed labeling." FDCA § 505, 21 U.S.C. § 355. When FDA determines that protocols are "necessary to ensure that the benefits of the drug outweigh the risks," FDA may require a 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.*

[6] In 2016, with minimal scientific data, FDA increased the maximum gestational age for mifepristone use for abortion from 49 days (7 weeks) gestation to 70 days (10 weeks) gestation. Additional 2016 changes that continue to jeopardize women's health include allowing home administration of mifepristone and misoprostol, permitting non-physicians to become certified prescribers, and a decrease from three to one mandatory office visits by the patient. Perhaps most damaging, FDA removed the requirement that prescribers report to Danco Laboratories or GenBioPro, the sponsors (*i.e.*, manufacturers) of mifepristone, all serious adverse events associated with mifepristone; today they are only required to report deaths. *See* U.S. Gov't Accountability Office, GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts 4-7 (2018); Mifepristone Shared System REMS, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2021_05_14_REMS_Full.pdf.

[7] In 2023, FDA removed the requirement that mifepristone be dispensed in-person and only in certain health care settings. Mifepristone may now be dispensed by or under the supervision of a certified prescriber or by a certified pharmacy after receiving a prescription issued by a certified prescriber. Certified pharmacies are also permitted to ship mifepristone. *See*, Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, available at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

REMS with ETASU still contains explicit informed consent requirements, including the requirement that certified prescribers "ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained,"[8] *amici* believe that this is wholly inadequate to constitute a basis for genuine informed consent.

Section II explains that informed consent cannot be properly obtained because the clinical studies used to obtain FDA approval afforded protections to patients that are not required by the drug's label or Risk Evaluation and Mitigation Strategy. 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. Section III explains that informed consent cannot be obtained because 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. Section IV explains that 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. Section V explains that informed consent cannot be obtained because, without in-person care, prescribing healthcare providers cannot adequately determine whether the patient is giving free consent without coercion or duress.

I. General Principles of Informed Consent.

The requirement that a healthcare provider must obtain a patient's consent before treatment but after informing the patient about the nature of the proposed treatment and its benefits, risks, and alternatives is firmly established in law and medical ethics.[9] Indeed, the principle is so

[8] Patient Agreement Form (updated Jan. 2023).

[9] *See generally* Alexander M. Capron, "Informed Consent in Catastrophic Disease and Treatment," 123 U. Pa. L. Rev. 340 (1974); 1 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Making Health Care Decisions (1982) (hereafter 1982 President's Commission Report).

fundamental that it has constitutional dimensions.[10] Originally established in common law, the right to consent or refuse medical treatment is rooted in bodily integrity.[11] This is a long-standing principle in tort law; if proper consent is not obtained, the treatment is a battery (an unwanted touching).[12] To avoid committing a battery, a physician, before treating a patient, must obtain informed, voluntary consent.[13] Generally, a physician must disclose to the patient accurate information about the nature, risks, benefits, and alternatives to the procedure or treatment in question.[14] The patient must have capacity to make a decision,[15] and make that decision freely and without coercion.[16]

Crucial to fully informed consent is an adequate disclosure of the patient's medical condition, and the risks and benefits of the proposed medical treatment. In the landmark case, *Canterbury v. Spence*,[17] the United States Court of Appeals for the District of Columbia Circuit held that "[t]he topics importantly demanding a communication of information are the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated." The court further explained that "[t]he factors contributing significance to the dangerousness of a medical technique are, of course, the incidence of injury and the degree of the harm threatened. A very small chance of death or serious disablement may well be significant; a potential disability which dramatically outweighs the potential benefit of the therapy or the detriments of the existing malady may summons discussion

[10] *See, e.g., Cruzan v. Dir., Mo. Dep't of Health,* 497 U.S. 261, 278–79 (1990) (holding that a competent person has a liberty interest under the Due Process Clause to refuse unwanted medical treatment).
[11] *See* W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Law of Torts § 9, pp. 39-42 (5th ed. 1984).
[12] *Id.*
[13] *See id*. at 189-192.
[14] *Id.* Exceptions exist for such required disclosure, e.g., in the case of an emergency. *Id.* at 192.
[15] *See* 1982 President's Commission Report pp. 169-75.
[16] *Id.* at p. 63 ("a consent forced by threats or induced by fraud or misrepresentation is legally viewed as no consent at all").
[17] 464 F. 2d 772 (D.C. 1972).

with the patient."[18] In other words, the court agreed that "'[a] risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.'"[19] Likewise, the American Medical Association Principles of Medical Ethics provide:

> Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making….[20]

Additionally, the requirement that the patient have capacity to provide informed consent has special application in the context of minors. As a general rule, before the age of majority 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, although parents may not have an absolute veto of their minor daughter's decision,[21] the majority of states require parental notice or consent before a minor may obtain an abortion.[22] And of course the parent's consent must be fully informed as well.

Finally, the doctrine of informed consent also benefits the medical profession. At a minimum, of course, it reduces the likelihood of potential legal liability. But the doctrine of

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[18] *Id*. at 787-88.
[19] *Id*. at 787, citing Comment, Informed Consent in Medical Malpractice, 55 Calif.L.Rev. 1396, 1407 n. 68 (1967).
[20] 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.
[21] *Bellotti v. Baird*, 433 U.S. 622 (1979).
[22] *See generally Parental Involvement in Minors' Abortions*, Guttmacher Institute (Jan. 1, 2023), available at https://www.guttmacher.org
/state-policy/explore/parental-involvement-minors-abortions (summarizing state laws; only 36 states require parental involvement).

informed consent also promotes "trust and confidence" and encourages better interactions" between the patient and her physician.[23]

II. Because The Clinical Trials Used To Obtain FDA Approval For Mifepristone For Abortion Afforded Protections To Patients That Are Not Required By The Drug's Label Or Risk Evaluation And Mitigation Strategy, 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."[24] This requirement is necessary for prescribers and their patients to know how the drug will impact patient safety outside of the controlled environment in clinical studies. However, the "conditions" in the U.S. Trial afforded protections that are not and have never been required by mifepristone's label or REMS.

In the U.S clinical trial, transvaginal ultrasonography, with menstrual history and pelvic examination, was used to confirm the gestational age of each pregnancy and exclude women with ectopic pregnancies. Further, the prescribers were physicians experienced in performing surgical abortions, training in the administration of abortion drugs, and possessing admitting privileges at medical facilities that could provide emergency care and hospitalization. Also, all patients were

[23] Morgan, at 365. *See also* Brian Murray, "Informed Consent: What Must a Physician Disclose to a Patient?," AMA Journal of Ethics, Virtual Mentor, 563-66 (2012), available at https://journalofethics.ama-assn.org/article/informed-consent-what-must-physician-disclose-patient/2012-07.
[24] 21 U.S.C. § 355(d).

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.[25]

None of these conditions, all of which are critical to protecting the health and safety of women using mifepristone (see the discussion in Section IV of the need for ultrasound prior to chemical abortion and provider availability in post-abortion emergencies), 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.

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 "review of information from the Mifepristone REMS Program one-year (1st) REMS assessment data and postmarketing safety information, and supported by [FDA] review of the published literature."[26] However, the available "safety information" provided by the sponsors or through FAERS failed to demonstrate that *any* postmarketing restrictions ensure the safety of mifepristone and certainly

[25] *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.
[26] 2021 CP Response at 25.

did not support further curtailing the REMS (see the discussion in Section III of the inadequacy of adverse events reporting). Regarding the studies[27] 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.[28] We did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States.[29]

Yet, "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 postmarketing safety data, mifepristone will remain safe … if the in-person dispensing requirement is removed from the Mifepristone REMS Program."[30]

Simply stated, in making the determination that it is safe to remove the in-person dispensing requirements from the mifepristone REMS, FDA relied upon data from the "woefully

[27] Deficiencies in studies supporting mail order pharmacies: (1) Grossman: only an interim analysis; women have an in-person clinical assessment before receiving the drugs through the mail, which is not the model that is predominately being promoted and used; (2) Upadhyay: FDA acknowledges that "determining outcomes at 3 days is insufficient to determine outcome rates or safety findings because a 3-day follow-up period is too short;" "the study used a model with numerous deviations from standard provision of medical abortion in the United States…;" "limited follow-up information, and small sample size;" (3) Hyland: FDA states that there is insufficient detail about adverse events; "reported frequency of hospitalizations (3 percent) is higher than the less than 1 percent in the FDA-approved mifepristone labeling…." *See* 2021 CP Response at 30-31. Observations from studies supporting clinic dispensing by mail that advise *against* removing in-person dispensing requirements: "Study reports of Raymond, Chong, and Kerestes all suggest there may be an increase in ED/urgent care visits with telemedicine visits and dispensing by mail from the clinic….Anger's comparative analysis suggests a pre-abortion examination may decrease the occurrence of procedural intervention and decrease the number of unplanned visits for postabortion care." 2021 CP Response at 33.

[28] Again, FDA cannot know that "most serious adverse events with medical abortion are infrequent," because adverse events are grossly underreported.

[29] 2021 CP Response at 29.

[30] *Id.*

inadequate"[31] 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. 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 sufficient 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 Have Failed To Demonstrate That Mifepristone's Adverse Events Can Be Reliably Reported, Prescribers Of Mifepristone Cannot Obtain Adequate Informed Consent From Their Patients.

In order for a healthcare provider to adequately inform patients as to 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.[32] 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.[33] 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).[34]

The sponsors are still required under FDA regulations to transmit any adverse event reports (AERs) that they receive from prescribers, other healthcare professionals, or patients to FDA

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[31] *See* 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 at 26.

[32] Questions and Answers on FDA's Adverse Event Reporting System (FAERS), *How Does FDA Use the Information in FAERS?*, available at https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers.

[33] 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-08-571, Food and Drug Administration: Approval and Oversight of the Drug Mifeprex Appendices II and III (2008).

[34] *See* U.S. Gov't Accountability Office, GAO-18-292; Mifepristone Shared System REMS.

through the FDA Adverse Event Reporting System (FAERS).[35] However, because FDA only requires prescribers to report deaths to the sponsors, Danco and GenBioPro are unlikely to receive many such reports of other adverse events and therefore have little to report to FDA.[36]

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.[37] They may report adverse events directly to FDA through the MedWatch website.[38] However, the reporting is entirely voluntary,[39] and therefore data from that program cannot adequately or accurately apprise anyone of the risks of such drugs.

The reality is that the removal of the requirement to report non-fatal adverse events results in vastly undercounted AERs and other complications caused by the FDA regimen,[40] thus skewing the safety profile of the drugs and resulting in incomplete and inaccurate information on which to rely for informed consent purposes. Prescribers and patients who are ignorant of the actual risks of the chemical abortion regimen cannot participate in genuine informed consent decision-making.

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35 *See* 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 20-21; Questions and Answers on FDA's Adverse Event Reporting System (FAERS), *Who sends reports to FAERS?*, https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers.

[36] FDA disingenuously states that Danco and GenBioPro "report adverse events, including serious adverse events, to FDA in accordance with applicable regulations." 2021 CP Response at 27, *citing* 21 CFR 314.98, 21 CFR 314.80, and 21 CFR 314.81. However, the sponsors cannot report adverse events to FDA that are not first reported to them.

[37] In any case, as explained below, many such providers may not even be aware that a patient is experiencing complications from a medication abortion because the patients are instructed to hide the fact that they took an abortion-inducing drug.

[38] *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*.

[39] *See* 2021 CP Response at 20-21.

[40] *See* American Association of Pro-Life Obstetricians and Gynecologists, Committee Op. No. 9: Dangers of Relaxed Restrictions on Mifepristone (Oct. 2021).

For example, emergency room doctors or other non-prescribing healthcare providers handle most hemorrhages from drug-induced abortion.[41] An analysis of AERs for mifepristone submitted to FDA from September 2000 to February 2019 using the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAEv3) showed that fewer than 40% of surgeries to remove retained tissue after drug-induced abortion are done by abortion providers themselves.[42] Yet, the information in the AERs is "almost exclusively obtained from abortion providers, rather than the physician treating the complication."[43] This demonstrates that the sponsors likely do not know about (and therefore report to FAERS) most hemorrhages because non-prescribing doctors (such as emergency room physicians) are not required to report them.[44] This problem is exacerbated by the limited to nonexistent follow-up performed by abortion providers after chemical abortion, aggravated by the fact that such follow-up is advised but not explicitly 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 visit is posited to be a conservative 2%, then approximately 74,000 complications would be documented. Two analyses examined the adverse event reports (AERs) between 2000 to 2019 and documented 607 and 3,197 events. This total of 3,804 AERs suggests that the FDA received only 5% of an estimated 74,000 serious adverse events.[45]

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[41] 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.

[42] Id.

[43] Id.

[44] *See* Aultman, *supra.*

[45] AAPLOG Committee Op. No. 9, *citing* Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018. In:2018; *Upadhyay UD, Desai S, Zlidar V, et al*. Incidence of emergency department visits and complications after abortion. *Obstet Gynecol.* 2015;125(1):175-183; Gary MM, Harrison DJ. Analysis of severe

Further, in their study of nearly 20 years of AERs submitted to FDA, Aultman et al. 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.[46]

In another study, Cirucci et al. compared 2009 and 2010 AERs reported through FAERS, those provided by FDA via a Freedom of Information Act (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 AEs, while FAERS only identified 664 *from all providers* and FDA only released 330 AERs through FOIA.[47] These discrepancies again demonstrate that the AER reporting system is broken and cannot be relied upon to guarantee that all potential adverse events caused by or associated with mifepristone use are known.

Further decreasing the likelihood that AEs are reliably reported, some mifepristone prescribers blatantly encourage their patients to hide their 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."[48] Also, the *Patient Agreement*

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adverse events related to the use of mifepristone as an abortifacient. *Ann Pharmacother*. 2006;40(2):191-197; Aultman, *supra*.

[46] Aultman, *supra*.

[47] Cirucci, CA, Aultman, K, Harrison, DJ. 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. *Health Services Research and Managerial Epidemiology*. 2021; Vol. 8: 1-5.

[48] 2016 Mifeprex label.

Form required by the REMS 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."[49] Yet, some mifepristone prescribers blatantly violated FDA protocol, instructing their patients to lie to emergency medical personnel. The organization Aid Access instructs patients that if they need to go to an emergency room:

> You do not have to tell the medical staff that you tried to induce an abortion; you can tell them that you had a spontaneous miscarriage. Doctors have the obligation to help in all cases and know how to handle a miscarriage. The symptoms of a miscarriage and an abortion with pills are exactly the same and the doctor will not be able to see or test for any evidence of an abortion, as long as the pills have completely dissolved.[50]

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 medication guide with them. This change undermines emergency healthcare providers' ability to appropriately 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

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[49] 2016 Patient Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2021_05_14_Patient_Agreement_Form.pdf.

[50] 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. Notably, FDA issued a Warning Letter to Aidaccess.org in 2019 for "causing the introduction of a misbranded and unapproved new drug into interstate commerce." *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019. Aid Access continues mailing abortion pills within the U.S. regardless of laws. https://aidaccess.org/en/i-need-an-abortion.Other abortion advocates are similarly advising women to deceive emergency care providers. *See* Women on Waves video link here at 1:54, https://www.womenonweb.org/en/page/11873/how-to-do-an-abortion-with-pills; *See* Plan C, "Can I get in trouble for using abortion pills?" https://www.plancpills.org/guide-how-to-get-abortion-pills#faq:; *See* National Women's Health Network, "Health Facts: Medication Abortion and Miscarriage," Aug 15, 2019. https://nwhn.org/abortion-pills-vs-miscarriage-demystifying-experience/; *See* Renee Bracey Sherman (Sept. 1, 2021) sharing advice by We Testify (Oct. 27, 2020), https://twitter.com/RBraceySherman/status/1433039653217652736.

mechanism that should not be sacrificed in the interest of increasing the availability of an elective drug.[51] 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 complete information to prescribers that is necessary to obtain truly authentic informed consent. In turn, prescribers cannot fully inform their patients of the risks caused by or associated with mifepristone use, rendering it impossible for patients to "make well-considered decisions about care."[52]

IV. Without Providing In-Person Care, Certified Prescribers Cannot Obtain Informed Consent Because They Are Unable To Adequately Diagnose Ectopic Pregnancy, Verify Rh Status, Or Detect Other Contraindications To Mifepristone, And Thus Cannot Fully Inform A Woman Of Her Unique Personal Risks.

In order to obtain genuine informed consent, a healthcare provider must inform the patient of the medical condition necessitating 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, which means that they cannot satisfy this requirement. A certified prescriber who merely consults with a patient though video, phone, or email, which is now explicitly permitted by FDA,[53] cannot accurately assess the duration of a patient's pregnancy, diagnose ectopic pregnancy, or even establish a provider-patient relationship that empowers patients to trust the prescriber or the prescriber's designee for care in an emergency.

[51] *See* AAPLOG Committee Op. No. 9.
[52] AMA Code of medical ethics opinions on consent, communication & decision making, *supra.*
[53] *See* Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, available at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

The existing REMS acknowledges the importance of a healthcare provider's *ability* to identify increased risks, such as the presence of an ectopic pregnancy, because it provides that the sponsors must 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."[54] 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."[55] The qualifications and guidelines are listed on the form:

> *Mifepristone must be provided by or under the supervision of a certified prescriber who meets the following qualifications:*
> - Ability to assess the duration of pregnancy accurately.
> - Ability to diagnose ectopic pregnancies.
> - Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
> - Has read and understood the Prescribing Information of mifepristone….
>
> *In addition to meeting these qualifications, you also agree to follow these guidelines for use:*
> - Ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
> - Ensure that the healthcare provider and patient sign the *Patient Agreement Form.*
> - Ensure that the patient is provided with a copy of the *Patient Agreement Form* and the Medication Guide.
> - Ensure that the signed *Patient Agreement Form* is placed in the patient's medical record.

[54] Mifepristone Shared System REMS (updated Jan. 2023).
[55] Prescriber Agreement Form (updated Jan. 2023).

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

Ensure that healthcare providers under your supervision follow the guidelines listed above….

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 the care of a patient. What good is a healthcare provider's ability to diagnose an ectopic pregnancy, for example, if the healthcare provider does not examine the patient and perform the diagnostic testing to determine if she has an ectopic pregnancy? It is a toothless requirement which does nothing to promote the safety of women consuming these drugs. Further, a certified prescriber cannot possibly obtain adequate informed consent for prescribing drugs that induce abortion from a patient 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 the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians, FDA erroneously asserted that "it was inappropriate for [FDA] to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy. These decisions should be left to the professional judgment of each provider, as no method (including TVS [transvaginal ultrasound]) provides complete accuracy. The approved labeling for Mifeprex recommended ultrasound evaluation as needed, leaving this decision to the judgment of the provider."[56] Further, FDA argued that "[c]ertified prescribers do not have to be physically present with the patient as long as they have confirmed the patient's gestational age and intrauterine pregnancy. … Moreover, the evaluation of patients for contraindications to medical abortion does

[56] 2021 CP Response at 11.

not necessarily require direct physical contact with the certified prescriber and can be done in different types of healthcare settings."[57]

These assertions ignore the best practices that are necessary to protect women's health and ensure that they are providing informed consent. The REMS requires that certified prescribers are 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 - that the pregnancy is 10 weeks or less.[58] In fact, women often significantly underestimate gestational age.[59]

The possibility that women receiving remote "care" may suffer from ectopic pregnancy, which mifepristone cannot end, is even more troubling. An ectopic pregnancy (occurring 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.[60] If a woman with an extrauterine pregnancy is given

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[57] *Id*. at 12.

[58]Because relying upon LMP to determine gestation "assumes a regular menstrual cycle of 28 days, with ovulation occurring on the 14th day after the beginning of the menstrual cycle, this practice does not account for inaccurate recall of the LMP, irregularities in cycle length, or variability in the timing of ovulation. It has been reported that approximately one half of women accurately recall their LMP. In one study, 40% of the women randomized to receive first-trimester ultrasonography had … a discrepancy of more than 5 days between ultrasound dating and LMP dating. *See id.* at 2, *citing* Wegienka G, Baird DD. A comparison of recalled date of last menstrual period with prospectively recorded dates. J Womens Health (Larchmt) 2005;14:248–52; Savitz DA, Terry JW Jr, Dole N, Thorp JM Jr, Siega-Riz AM, Herring AH. Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination. Am J Obstet Gynecol 2002;187:1660–6; Barr WB, Pecci CC. Last menstrual period versus ultrasound for pregnancy dating. Int J Gynaecol Obstet 2004;87:38–9.

[59] Ellertson C., et al. (2000). Accuracy of assessment of pregnancy duration by women seeking early abortions. *Lancet*, 355(9207), 877-881. doi: 10.1016/S0140-6736(99)10170-3. Almost 15% of Atlanta women were in error by more than two weeks when calculating gestation based on LMP. Mifepristone's failures (requiring subsequent surgery) and complications indisputably increase with increasing gestational age.

[60] *See* ACOG Practice Bulletin 191: *Tubal Ectopic Pregnancy* (Feb. 2018), available at https://journals.lww.com/greenjournal/Fulltext/2018/02000/ACOG_Practice_Bulletin_No__191__Tubal_Ectopic.38.aspx.

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.[61] Of these women, at least two bled to death from an undiagnosed ectopic pregnancy.[62] 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.[63] Half of women who experience ectopic pregnancy do not have any risk factors.[64] 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.[65]

There are other known conditions that must be investigated before administering mifepristone. A prescriber bears responsibility to diagnose and rule out contraindications (*i.e.*, circumstances that make a treatment or medication *unadvisable*) 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. In addition to confirmed or suspected ectopic pregnancy, these physical contraindications include undiagnosed adnexal mass; chronic adrenal failure; concurrent long-term corticosteroid therapy; history of allergy to mifepristone, misoprostol, or other

[61] 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.
[62] *Id.*
[63] Donna Harrison, M.D. & Michael J. Norton Testimony before the Iowa Board of Medicine, p. 3 (Aug. 21, 2013), *citing* Postmarket Drug Safety Information for Patients and Providers, Questions and Answers on Mifeprex, https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm492705.htm.
[64] ACOG Practice Bulletin No. 191, *supra.*
[65] Atrash H.K., et al. (1990). Ectopic pregnancy concurrent with induced abortion: Incidence and mortality. *American Journal of Obstetrics & Gynecology*, 162(3), 726-730. doi: 10.1016/0002-9378(90)90995-j.

prostaglandins; hemorrhagic disorders or concurrent anticoagulant therapy (risk of heavy bleeding); or inherited porphyrias.[66]

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.[67] The 2017 ACOG practice bulletin on *Prevention of Rh D Alloimmunization* states unequivocally that "Rh D immune globulin should be given to Rh D-negative women who have pregnancy termination, either medical or surgical."[68] 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. While FDA argues in the 2021 CP Response that women can obtain Rh D immune globulin injections from sources other than their mifepristone prescribers, the petition response fails to address the major problem: Rh D-negative women who are not tested before a mifepristone abortion may never know that they need the injection.

A contactless approach to follow-up care is troubling. FDA wrongly relied upon an ACOG statement when it responded that a "patient and [her] healthcare provider should determine the best option for follow-up as part of the consultation and consent process."[69] It is inappropriate to expect a patient to "determine" her best follow-up option before she has any idea how the FDA-approved regimen will impact her. A de-emphasis on follow-up care increases risks of post-abortion complications. The 2000 regimen's requirement that women return approximately 14

[66] *See* mifepristone prescribing information.
[67] *See* ACOG Practice Bulletin 181*: Prevention of Rh D Alloimmunization* (Aug. 2017).
[68] ACOG Practice Bulletin 181*: Prevention of Rh D Alloimmunization* (Aug. 2017). *See also* SOGC Clinical Practice Guidelines: *Prevention of Rh Alloimmunization* (No. 133, Sept. 2003).
[69] 2021 CP Response at 13, *citing* ACOG Practice Bulletin Number 225, n. 22.

days after ingesting mifepristone was considered necessary to ensure that all pregnancy tissue had been passed.[70] In their 2019 Citizen Petition, the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and the American College of Pediatricians (ACPeds) explained that "[t]his determination is crucial, because retained pregnancy tissue can lead to continued bleeding and serious intrauterine infections. The return visit permits healthcare providers to ensure that a patient is not experiencing these or other complications from the abortion procedure, and that Rh-negative patients are administered Rhogam to protect future pregnancies."[71] Without this visit, women may not recognize complications that could have been mitigated.

At least 29 states permit only physicians to prescribe mifepristone,[72] with 18 states requiring the provider to be physically present with the patient.[73] For example, the law in Alabama states that the physical presence and care of a physician are necessary because "the failure and complications from medical abortion increase with advancing gestational age, because the physical symptoms of medical abortion can be identical to the symptoms of ectopic pregnancy, and because abortion-inducing drugs do not treat ectopic pregnancies but rather are contraindicated in ectopic pregnancies."[74] AAPLOG and ACPeds wrote that "[l]awmakers in these states recognize that abortion providers cannot diagnose contraindications and cannot adequately care for their patients through a videoconference. Fundamentally, telemedicine 'may be legitimate when it comes to discrete, document-based tasks such as reading X-rays,' but it 'is not the standard of care when it comes to abortion or the management of miscarriage.'"[75] Further,

[70] Mifeprex 2000 label, Day 14: Post-Treatment Examination.
[71] 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.
[72] Medication Abortion, Guttmacher Institute (Jan. 1, 2023), available at https://www.guttmacher.org/state-policy/explore/medication-abortion.
[73] *Id.*
[74] Ala. Code § 26-23E-7.
[75] 2019 Petition at 6, *citing* Harrison & Norton Testimony, p. 19.

> Telemedicine abortion further distances women from the practitioners responsible for caring for them, and approval by FDA further absolves abortion providers of responsibility for the well-being of their patients. Promoting telemedicine abortion to women and adolescent girls in rural areas with limited access to healthcare is extremely dangerous—they have little recourse if they face known and predictable emergency complications such as severe hemorrhage.[76]

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, certified prescribers cannot "know [] the patient's position," and cannot therefore obtain adequate informed consent.[77] A woman or girl 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.

Voluntary consent is essential to genuine informed consent. Consent obtained through coercion is no consent at all. Abortion-inducing drugs are inherently different from other prescribed drugs because of the increased risk that women may be coerced to abort their children. This known risk of coercive abortion is greatly increased by the 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 woman's voluntary consent to the administration of the drug. Mifepristone's post-marketing restrictions fail to protect women from coercive partners and predators or ensure that women are giving consent.

[76] 2019 Petition at 19, *citing* Harrison & Norton Testimony, p. 9.
[77] *See Canterbury* at 787.

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."[78]

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…."[79] Surprisingly, the paper does not specifically cite an abortion appointment as an important visit for coercion screening, even while stating that "[i]n 2007, the prevalence of [intimate partner violence] was nearly three times greater for women seeking an abortion compared with women who were continuing their pregnancies."[80]

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.[81]

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[78] "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

[79] *Id.*

[80] *Id.*, *citing* Bourassa D, Berube J. The prevalence of intimate partner violence among women and teenagers seeking abortion compared with those continuing pregnancy. J Obstet Gynaecol Can 2007;29:415–23.

[81] AAPLOG Committee Op. No. 9, *citing* Hall M, Chappell LC, Parnell BL, Seed PT, Bewley S. Associations between intimate partner violence and termination of pregnancy: a systematic review and meta-analysis. *PLoS Med.* 2014;11(1):e1001581; Bourassa D, Bérubé J. The prevalence of intimate partner violence among women and

To find out how common sexual coercion is, "the BBC commissioned a survey of 1,000 UK women aged 18-44 - and found that 50% said they had experienced at least one type of reproductive coercion." Further, "15% of women in [the] survey told [the surveyors] they'd experienced pressure to terminate a pregnancy when they didn't want to."[82] Further, three percent have had someone give them "something (tablets/ substance) to cause an abortion without [their] knowledge or consent." Five percent have experienced "physical violence with intention to force a miscarriage / end a pregnancy."[83]

Tragically, most instances of coerced abortion[84] are never publicly known and there is no justice for the victims. In-person dispensing requirements provided a line of defense, albeit an imperfect one, against coerced abortion. By failing to require in-person contact between certified prescribers and their patients, FDA's post-marketing restrictions cannot ensure that vulnerable women and adolescents are protected against coercive partners and predators and can make "independent, voluntary" decisions to use mifepristone.

CONCLUSION

For these reasons, *Amici* respectfully urge this Court to grant the Plaintiffs' Motion for Preliminary Injunction.

DATE: February 10, 2023

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teenagers seeking abortion compared with those continuing pregnancy. *J Obstet Gynaecol Can.* 2007;29(5):415-423; Laura J. Lederer CAW. The health consequences of sex trafficking and their implications for identifying victims in healthcare facilities. *Annals of Health Law.* 2014;23(1):61-87.

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

[83] Reproductive Coercion Poll – BBC Radio 4 – 8 March 2022, Savanta ComRes, https://comresglobal.com/polls/reproductive-coercion-poll-bbc-radio-4-8-march-2022.

[84] *See, e.g.,* https://www.washingtonpost.com/news/true-crime/wp/2018/05/19/a-doctor-laced-his-ex-girlfriends-tea-with-abortion-pills-and-got-three-years-in-prison/; https://www.womenshealthmag.com/health/a19974681/man-spikes-girlfriends-drink-with-abortion-pill/; https://www.cnn.com/2013/09/10/justice/girlfriend-abortion-case/index.html; https://people.com/crime/man-spiked-pregnant-girlfriend-drink-abortion-drug/.

Respectfully submitted,

Weycer, Kaplan, Pulaski & Zuber, PC

By: */s/ Murphy S. Klasing*

Murphy S. Klasing
TX State Bar No. 00791034
2608 Hibernia Street
Dallas, Texas 75204
(713) 961-9045
(713) 961-5341 Fax
Email: mklasing@wkpz.com

ATTORNEYS FOR AMICUS CURIAE

CERTIFICATE OF SERVICE

On February 10, 2023, I filed the foregoing document with the clerk of court for the United States District Court, Northern District of Texas. I hereby certify that I have served the document on all counsel and/or pro se parties of record by a manner authorized by Federal Rule of Civil Procedure 5(b)(2) (ECF System).

/s/ Murphy S. Klasing
Murphy S. Klasing

Counsel for Proposed Amicus Curiae