IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN 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, Plaintiffs, v. 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, Defendants.	§	Case No. 2:22-cv -00223-Z

BRIEF AMICUS CURIAE ON BEHALF OF HUMAN COALTION IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTEREST OF AMICUS CURIAE[1]

Human Coalition is a nonprofit organization committed to rescuing children, serving families, and making abortion unthinkable and unnecessary by offering pregnant mothers life-affirming counsel and tangible, needed services. The group builds holistic, comprehensive-care networks across the United States to reach pregnant women and provide needed support and care to empower them to choose life for their children. Human Coalition operates its own specialized women's care clinics and virtual clinics in major cities across the country.

Human Coalition has a strong interest in protecting women and their unborn children from the dangers of medication abortion. The staff and volunteers at Human Coalition's clinics have seen firsthand the physical and mental harms that medication abortion causes the mothers who enter their facilities. Human Coalition opposes the FDA's dangerous and politically-motivated deregulation of medication abortion. Because of the significant harm that medication abortion has caused and will continue to cause, Human Coalition further believes that the FDA should have never approved the medication abortion drug regimen for sale in the United States. Human Coalition thus files this brief in support of Plaintiffs' motion for preliminary injunction.

[1] No counsel for any party authored this brief in whole or in part, and no person or entity, other than amicus and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

INTRODUCTION

Politics should never trump the lives of women and girls. But when the FDA approved the medication abortion regimen—and later removed basic safeguards to protect mothers from the harms of a dangerous drug—it chose politics over the health of women and girls.

Medication abortion[2] is a procedure that involves taking two prescription drugs to end a pregnancy: mifepristone[3] and misoprostol. Together, both drugs are known as the "abortion pill." When mifepristone was first approved, it gained approval only under the restrictive "Risk Evaluation and Mitigation Strategy" (REMS) regulatory scheme, "a drug safety program that the [FDA] can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks."[4] REMS require a drug label to include, among other components, medication safety guides, patient package inserts, and sometimes—such as with mifepristone—Elements to Assure Safe Use (ETASU).[5] One of the most important features of the mifepristone ETASU was that it required that the drug be dispensed only in clinics, medical offices, and hospitals by an approved medical provider.[6] Thus,

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[2] Medication abortion is also referred to as a "chemical" or "medical" abortion.
[3] The brand name of mifepristone is "Mifeprex." It has also been referred to as "RU-486." Unless otherwise noted, this brief focuses on mifepristone.
[4] FDA, *Risk Evaluation and Mitigation Strategies*, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (last accessed Jan. 31, 2023).
[5] FDA, *What's in a REMS?*, https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems (last accessed Jan. 31, 2023).
[6] FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-

a woman seeking an abortion had to be seen in-person at a medical facility to receive the pregnancy-ending medications.

But even with the REMS restrictions in place, women and girls experienced severe injury to their physical and mental health as a direct result of medication abortion. Worse yet, women are often not adequately apprised of the risks of medication abortion or even what they will experience during their abortions. Women who are not given complete information about the medication abortion procedure cannot grant informed consent to it.

The FDA's recent removal of the in-person dispensing requirement for mifepristone will lead to increased harm to women and girls. For years, abortion activists have pressured the FDA to remove the in-person dispensing requirement to allow for easy access to this dangerous drug. And in 2021, the FDA caved to that political pressure, eliminating the in-person safety protocols. Now, "medication abortion may be administered without a physical exam or ultrasound to confirm the location and age of the pregnancy, Rhesus antigen (Rh) status testing, or any interaction with a physician."[7] These important safeguards detect contraindications and prevent complications, many of which can be life-threatening. Now the entire abortion process can take place without any physician interaction or oversight.

mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last accessed Jan. 31, 2023).

[7] American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), *Dangers of Relaxed Restrictions on Mifepristone* at 1, https://aaplog.org/wp-content/uploads/2022/07/CO-9-Mifepristone-restrictions-update-Jul-22.pdf (last accessed Feb. 9, 2023).

Removal of the in-person dispensing requirement will also increase reproductive coercion and crimes against pregnant women.

The FDA's approval of mifepristone and its subsequent removal of the in-person dispensing requirement for mifepristone has caused—and will continue to cause—irreparable harm to women and girls. Amicus curiae Human Coalition requests that this Court grant Plaintiffs' motion for preliminary injunction.

I. Medication abortion has caused—and will continue to cause—significant physical harm to women and girls.

a. Medication abortion causes grave complications, including severe infections, life-threatening bleeding, and death.

Medication abortion physically harms women and girls, even causing death. According to the FDA, mifepristone caused 28 deaths[8] since its approval.[9] There are two primary ways a medication abortion can be fatal. First, an attempted abortion may result in an incomplete abortion if fetal tissue is left inside the mother. This may cause her to bleed to death or develop sepsis, a life-threating infection.[10] Second, a medication abortion may cause a ruptured ectopic (tubal) pregnancy because misoprostol and mifepristone cannot terminate an ectopic pregnancy.[11] "An ectopic

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[8] In contrast, a drug manufacturer recalled blood-pressure medication heparin when only 4 heparin-related deaths were reported. Janice Hopkins Tanne, *Four death and 350 adverse events lead to US recall of heparin*, THE BMJ Vol. 336, No. 7641, 412–13 (Feb. 23, 2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2249657/.

[9] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 6/30/2022*, https://www.fda.gov/media/164331/download (last accessed Jan 31, 2023).

[10] Kathi Aultman, et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, ISSUES IN LAW & MED. Vol. 36, No.1, 3–26 (2021).

[11] *Id.*

pregnancy occurs when a fertilized egg grows outside of the uterus," in most cases within the fallopian tube.[12] "As the pregnancy grows, it can cause the tube to burst (rupture), which "can cause major internal bleeding" that "can be a life-threatening emergency that needs immediate surgery."[13] The FDA reported at least 97 cases in which women with ectopic pregnancies took mifepristone.[14]

Along with incomplete abortion and missed ectopic pregnancy, medication abortion results in other serious complications, most commonly bleeding, infection, and ongoing pregnancy.[15] As of June 2022, 1,048 hospitalizations, 604 blood transfusions, and 414 infections (including 71 severe infections)—with a total of 4,213 adverse events—were reported.[16] But the FDA data is likely incomplete. Despite the serious risks associated with mifepristone, the FDA only requires deaths to be reported. Physicians are not required to report other serious adverse events associated with the drug—reporting any other adverse event is *voluntary*.[17] For this

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[12] American College of Obstetricians and Gynecologists (ACOG), *FAQs: Ectopic Pregnancy*, https://www.acog.org/womens-health/faqs/ectopic-pregnancy (last accessed Jan. 31, 2023).
[13] *Id.*
[14] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 6/30/2022*, https://www.fda.gov/media/164331/download.
[15] FDA, *Highlights of Prescribing Information: Mifeprex (mifepristone) Tablets, 200 mg*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (last accessed Jan. 31, 2023); *see also* AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 7 at 2–4 (internal citations omitted).
[16] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 6/30/2022*, https://www.fda.gov/media/164331/download.
[17] FDA, *Mifeprex clinical review* at 48–49, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (last accessed Jan. 31, 2023); Tessa Longbons, *Analysis: FDA Decision Ignores Data on Complications, Puts Women at Risk*, CHARLOTTE LOZIER INSTITUTE (Dec. 16,

reason, the rate of severe complications and deaths from medication abortion is likely higher than the FDA data suggests.

The lack of mandatory reporting for adverse events other than death means that even serious complications are not reported. First, the abortion provider may not be the same one treating a woman's medication abortion complications. One study suggests clinicians other than the abortion provider often manage her emergency complications.[18] For this reason, treating providers may not know about the relationship between the adverse event and mifepristone. In the same vein, the abortion provider may be unaware that their patient suffered an adverse event. Second, medical professionals may be unable to trace every deadly infection back to the use of these drugs, as there are potential intervening causes (such as medical malpractice, issues with misoprostol rather than mifepristone, and more). And finally, a physician may fail to report serious complications simply because they are not required to do so.

One recent study affirms mifepristone causes more complications than the incomplete FDA data suggests. It found the rate of abortion-related emergency room visits following medication abortion increased over 500% from 2002 through 2015.[19]

2021), https://lozierinstitute.org/analysis-fda-decision-ignores-data-on-complications-puts-women-at-risk/ (last accessed Jan. 31, 2023).

[18] Kathi Aultman, et al., *supra* note 10 (Concluding that only 39.75% of follow-up D&C procedures after a failed medication abortion are done by abortion providers).

[19] James Studnicki, et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015*, HEALTH SERVICES RESEARCH AND MANAGERIAL EPIDEMIOLOGY (Nov. 9, 2021), https://journals.sagepub.com/doi/full/10.1177/23333928211053965 (last accessed Feb. 8, 2023).

The study also discovered that 60.9% of these emergency room visits were miscoded as spontaneous miscarriages instead of accurately reported as medication abortion complications.[20] When compared to data for surgical abortion, women who underwent chemical abortion were at a 53% greater risk of visiting the emergency room for an abortion-related reason.[21]

Data from other countries support these conclusions. In a study from the United Kingdom looking at 4,132 medication abortions between 1994 and 2001, approximately 1% of women were hospitalized.[22] Another study from Finland showed that medication abortion leads to *more* complications than surgical abortion.[23] That study found adverse events in women who underwent medication abortion were nearly *four times higher* (20% vs. 5.6%) than women who a surgical abortion.[24] Women in the study experienced a significantly higher rate of hemorrhage with medication abortion (15.6%, compared to 2.1% for surgical abortion), higher rates of incomplete abortion (6.7% vs. 1.6%), as well as unplanned surgical evacuation (5.9% vs. 1.8%).[25] And recent research from Canada further suggests that medication

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[20] Studnicki, et al., *supra* note 19.
[21] *Id.*
[22] AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone, supra* note 7 at 5, (citing Premila W. Ashok, et al., *Factors affecting the outcome of early medical abortion: a review of 4132 consecutive cases*, BRITISH J. OBSTETRICS & GYNECOLOGY VOL. 109, No. 11, 1281–89 (2002)).
[23] Maarit Niinimäki, et al., *Immediate complications after medical compared with surgical termination of pregnancy*, OBSTETRICS & GYNECOLOGY Vol. 114, No. 4, 795–804 (2009), https://pubmed.ncbi.nlm.nih.gov/19888037/ (last accessed Feb. 1, 2023).
[24] *Id.*
[25] *Id.*

abortion in the first trimester leads to more adverse events than surgical abortion during the same timeframe.[26]

Since the FDA approved mifepristone, medication abortions exponentially increased over the years along with significant physical harms to women and girls. These complications will only be compounded by the FDA's removal of in-person dispensing safeguards.

b. Eliminating the in-person dispensing requirement for mifepristone will lead to even more physical harm to women and girls.

Now that the FDA eliminated the precaution that women see a physician in-person to obtain a medication abortion, it can be administered without a physical exam, diagnostic ultrasound, blood tests, or any interaction with the abortion provider. The entire abortion process can take place within a woman's home, without any physician oversight. This will lead to increases in undetected ectopic pregnancies, failure to detect rH factor incompatibility, and misdiagnosis of gestational age, all of which can lead to severe—and even fatal—complications.

Failure to diagnose an ectopic pregnancy can result in life-threatening complications for a woman undergoing medication abortion. As noted in Section II.a, failure to detect an ectopic pregnancy before medication abortion can result in the rupture of a woman's fallopian tube, leading to hemorrhage and sometimes death. The rupture of a tubal pregnancy due to mifepristone can be avoided by simply

[26] Ning Liu, Ph.D and Joel G. Ray, MD, MSc, *Short-Term Adverse Outcomes After Mifepristone–Misoprostol Versus Procedural Induced Abortion*, ANNALS OF INTERNAL MEDICINE (Jan. 3, 2023), https://www.acpjournals.org/doi/10.7326/M22-2568 (last accessed Feb. 1, 2023).

providing an ultrasound before the procedure. But the FDA's elimination of the in-person dispensing requirement means that a woman may not even be offered an ultrasound before a medication abortion.

Failure to test the mother's rH factor before medication abortion can lead to grievous complications. "The Rh factor is a protein that can be found on the surface of red bloods cells," and its presence indicates that someone is Rh positive—its absence, Rh negative.[27] During pregnancy, complications can result if the mother is Rh negative and her unborn child is Rh positive. This is because "[w]hen the blood of an Rh-positive fetus gets into the bloodstream of an Rh-negative woman, her body will recognize that the Rh-positive blood is not hers," and "[h]er body will try to destroy it by making anti-Rh antibodies."[28] "These antibodies can cross the placenta and attack the fetus's blood cells," which "can lead to serious health problems, even death, for a fetus or a newborn."[29] A simple blood test performed during pregnancy can determine whether a woman is Rh-negative, and the medication can be administered to prevent antibodies from forming.[30] ACOG recommends that this medication be given to Rh-negative women before a medication abortion.[31] ACOG

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[27] 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 (last accessed Jan. 17, 2023).
[28] *Id.*
[29] *Id.*
[30] AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 7 at 7, (citing ACOG, *Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, OBSTETRICS & GYNECOLOGY Vol. 130, No. 2, e57–e70 (2017)).
[31] *Id.* (citing ACOG, *Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, OBSTETRICS & GYNECOLOGY Vol. 130, No. 2, e57–e70 (2017)).

further notes that Rh testing and treatment (if needed) is the standard of care.[32] But eliminating the in-person dispensing requirement means this test may never happen.

If a woman does not receive an ultrasound before a medication abortion, the gestational age of the child might not be known, which can lead to serious complications. Higher gestational age means a higher failure rate of medication abortion and increased interventions and risks for the woman. The failure rate for medication abortion at 10 weeks is nearly 7%.[33] And in the second trimester, the failure rate reaches 40%.[34] While it is possible to guess the gestational age based on a woman's menstrual cycle, as many as 40% of women are redated with the use of ultrasound in the first trimester.[35] Without the requirement of an in-person visit before medication abortion, an ultrasound might not be administered to determine whether gestational age is too late for medication abortion.

Elimination of the in-person dispensing requirement dangerously isolates women from preventative testing and medical oversight. The results may be deadly.

(citing ACOG, *Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, OBSTETRICS & GYNECOLOGY Vol. 130, No. 2, e57–e70 (2017)).

[32] AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 7 at 7, (citing ACOG, *Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, OBSTETRICS & GYNECOLOGY Vol. 130, No. 2, e57–e70 (2017)).

[33] *Id*. (citing Melissa J. Chen and Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, OBSTETRICS & GYNECOLOGY Vol. 126, No. 1, 12–21 (2015)).

[34] *Id*. (citing Maarit J. Mentula, et al., *Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study*, HUMAN REPRODUCTION Vol. 26, No. 4, 927–32 (2011)).

[35] *Id*. (citing Kelly A. Bennett, et al., *First trimester ultrasound screening is effective in reducing postterm labor induction rates: a randomized controlled trial*, AM. J. OBSTETRICS & GYNECOLOGY Vol. 190, No. 2, 1077–81 (2004)).

c. Human Coalition's clients are consistently misinformed about risks associated with medication abortion and therefore are unable to provide informed consent to mifepristone.

The FDA's diminished protocols leave women in the dark about their abortions. Despite the risk of serious harm, abortion providers often give insufficient, limited, or misleading information to women seeking medication abortion.[36] In one study, 14% of women reported being inadequately prepared about what to expect during their medication abortion and many felt openly deceived.[37] In their own words, women wished they had more information about side effects, the intensity of cramping and bleeding, what to do after passing the baby, and potential negative emotions like fear, uncertainty, sadness, regret and pain.[38]

Unfortunately, these experiences are pervasive among women obtaining a medication abortion. Human Coalition served approximately 45,000 pregnant women last year. Women who visit Human Coalition's care clinics and call their help line consistently report they were not provided adequate information about their medication abortion. Many are not even informed about the medication abortion process—they may not know that they will see the remains of their child and can experience significant pain and bleeding. Abortion providers also consistently fail to inform clients when to seek help if a complication arises.

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[36] Katherine A. Rafferty & Tessa Longbons, *#AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*, HEALTH COMM. Vol. 36, No. 12, 1485–94 (2021), https://www.tandfonline.com/doi/full/10.1080/10410236.2020.1770507 (last accessed Feb. 8, 2023).
[37] *Id.*
[38] *Id.*

In the practice of medicine, informed consent is "fundamental in both ethics and law."[39] "Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care."[40] According to the American Medical Association, "[t]he process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention."[41] In seeking informed consent, a physician should:

> (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
>
> (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about: (i) the diagnosis (when known); (ii) the nature and purpose of recommended interventions; (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment...[42]

Under this definition, when patients are not provided accurate medical information about what they will experience, side effects, or even risks associated with mifepristone, they cannot provide informed consent to medication abortion.

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[39] American Medical Association Code of Medical Ethics, *Opinion 2.1.1: Informed Consent*, https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent (last accessed Feb. 1, 2023).
[40] *Id.*
[41] *Id.*
[42] *Id.*

Human Coalition's clinic staff often serve women who were not provided accurate information about medication abortion and its risks. They see firsthand how women become living victims of this failure. Abortion providers are reported to minimize concerns or side effects and focus on the positive—"easy process," "quick recovery," "like taking over the counter meds," and "no one will know". Or—as one study found—material misrepresentations: "it's just a pill" and "if you by chance are in pain."[43] Some Human Coalition clients who were prescribed medication abortion expressed they were told by the abortion provider that "it is as easy as taking Advil." Many clients report that they were not told about seeing fetal remains. Staff are told such things as: "I had no idea that the pill was going to be as painful as it was." "I bled way more than I was told. The whole procedure was more painful than I was led to believe." "I saw the baby come out in the toilet . . . It was very traumatic. And no one told me I would see a baby. I didn't know what to do . . . It felt wrong to flush the baby down the toilet." Women call Human Coalition nurses panicking in the middle of their abortions. The nurses support them over the phone, so they are not alone.

Abortion providers do not always return patients' calls, even after complications arise. Human Coalition has served many women whose medication abortions failed and found themselves still pregnant. Four clients were unknowingly ectopic when they arrived at Human Coalition with abortion pills in hand. Human Coalition sonographers provided potentially life-saving ultrasounds. This is not what informed consent looks like. And this is not what proper medical care looks like.

[43] Rafferty & Longbons, *supra* note 36.

Without informed consent, mothers may not know about the physiological symptoms that will occur during medication abortion. And they may not know about the side effects and risks of taking the medication. They may not even know what symptoms to look for to determine whether a serious complication is occurring—with life-threatening consequences. And now that the FDA has removed the in-person dispensing requirement for mifepristone, these patients may never see the abortion provider. Because the FDA has also failed to maintain accurate data on adverse events caused by mifepristone, *see* Section I.a, the elimination of the in-person dispensing requirement will lead to an increase in complications and serious medical harm to women. Human Coalition clients are already experiencing increased complications. Women deserve accurate and complete information, not material omissions or mistruths. Without it, it is impossible for them to give informed consent.

II. Abortion psychologically damages women and girls.

Abortion—whether it be by medication or surgery—causes significant mental health problems in women and girls, increasing the risk of depression, anxiety, substance abuse, and suicide. Mothers who choose abortion often experience grief, sadness, and feelings of loss.[44] The data and stories of post-abortive women shows that medication abortion inflicts unique psychological pain on mothers.

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[44] David C. Reardon, *The abortion and mental health controversy: A comprehensive literature review of common ground agreements, disagreements, actionable recommendations, and research opportunities*, SAGE OPEN MED. (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207970/ (last accessed Feb. 1, 2023) (citing Brenda Major, et al. *Report of the APA Task Force on mental health and abortion*, American Psychological Association, at 105 (2008), http://www.apa.org/pi/women/programs/abortion/mental-health.pdf).

a. Women who have an abortion of any kind experience a higher rate of mental health disorders compared to women who carry their pregnancies to term.

Abortion can seriously harm a woman's mental health. Research indicates that women face an 81% increase in risk of mental health disorders after receiving an abortion.[45] These women also face a 34% increased risk of anxiety, 37% increased risk of depression, and 155% increased risk of suicidal behavior.[46] "[M]ost social and medical science scholars [agree] that a minimum of 20% to 30% of women who abort suffer from serious, prolonged negative psychological consequences, yielding at least 260,000 new cases of mental health problems each year."[47] Many studies also indicate "abortion significantly increases [the] risk" that a woman will engage in substance abuse.[48]

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[45] AAPLOG, *Committee Opinion 6: Induced Abortion & the Increased Risk of Maternal Mortality* at 8, https://aaplog.org/wp-content/uploads/2020/01/FINAL-CO-6-Induced-Abortion-Increased-Risks-of-Maternal-Mortality.pdf (last accessed Feb. 1, 2023) (citing Priscilla K. Coleman, *Abortion and mental health: quantitative synthesis and analysis of research published 1995–2009*, BRITISH J. PSYCHIATRY Vol. 199, No. 3, 180–86 (Sept. 2011), https://pubmed.ncbi.nlm.nih.gov/21881096/).

[46] *Id*. (citing Priscilla K. Coleman, *Abortion and mental health: quantitative synthesis and analysis of research published 1995–2009*, BRITISH J. PSYCHIATRY Vol. 199, No. 3, 180–86 (Sept. 2011), https://pubmed.ncbi.nlm.nih.gov/21881096/).

[47] AAPLOG, *Practice Bulletin: Abortion and Mental Health* at 6, https://aaplog.org/wp-content/uploads/2019/12/FINAL-Abortion-Mental-Health-PB7.pdf (last accessed Feb. 1, 2023) (citing Brenda Major & Catherine Cozzarelli, *Psychological predictors of adjustment to abortion*, J. OF SOCIAL ISSUES Vol. 48, 121–142 (1992), https://spssi.onlinelibrary.wiley.com/doi/abs/10.1111/j.1540-4560.1992.tb00900.x; and G. Zolese & C.V. Blacker, *The psychological complications of therapeutic abortion*, BRITISH J. PSYCHIATRY Vol. 160, 742–49 (June 1992), https://pubmed.ncbi.nlm.nih.gov/1617354/).

[48] *Id*. at 6 (citing Priscilla K. Coleman, *Resolution of unwanted pregnancy during adolescence through abortion versus childbirth: Individual and family predictors and psychological consequences*, J. YOUTH ADOLESCENCE Vol. 35, 903–11 (2006), https://link.springer.com/article/10.1007%2Fs10964-006-9094-x; Daniel I. Rees and

Abortion places women at risk of suffering post-traumatic stress disorder. PTSD "is a psychiatric disorder" often seen in "people who have experienced or witnessed a traumatic event, series of events or set of circumstances."[49] Women and girls who suffer from this disorder experience "intense, disturbing thoughts and feelings related to their experience that last long after the traumatic event has ended."[50] And research has shown that "women who disagree[] with their partners concerning the decision to abort were more likely to report symptoms of intrusion and to meet the diagnostic criteria for PTSD."[51] Not surprisingly, then, women who think their pre-abortion counseling was inadequate are "more likely to report relationship problems, symptoms of intrusion, avoidance, and hyperarousal and to meet diagnostic criteria for" PTSD. [52]

Joseph J. Sabia, *The relationship between abortion and depression: New evidence from the Fragile Families and Child Wellbeing Study*, MED. SCI. MONITOR Vol. 13, No. 10, CR430–36 (Oct. 2007) https://pubmed.ncbi.nlm.nih.gov/17901849/; Willy Pedersen, *Childbirth, Abortion and subsequent substance use in young women: a population-based longitudinal study*, ADDICTION Vol. 102, No. 12, 1971–78 (2007), https://pubmed.ncbi.nlm.nih.gov/18031432/; and David C. Reardon, et al., *Substance use associated with prior history of abortion and unintended birth: A national cross sectional cohort study*, AM. J. OF DRUG AND ALCOHOL ABUSE Vol. 30, No. 2, 369–83 (May 2004), https://pubmed.ncbi.nlm.nih.gov/15230081/).

[49] American Psychiatric Association, *What Is Posttraumatic Stress Disorder?,* https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd (last accessed Feb. 1, 2023).

[50] *Id.*

[51] AAPLOG, *Practice Bulletin: Abortion and Mental Health*, *supra* note 47 at 6, (citing C. T. Coyle, et al., *Inadequate pre-abortion counseling and decision conflict as predictors of subsequent relationship difficulties and psychological stress in men and women*, TRAUMATOLOGY Vol. 16, No. 1, 16–30 (2010), https://doi.org/10.1177/1534765609347550).

[52] *Id.*

For some women who have abortions, their mental suffering leads to a far greater risk of suicide. Medical research shows that U.S. women face nearly double the risk for suicide compared to women who carry their pregnancies to term. In one study of 173,279 low-income women in California, researchers "found that women who underwent abortions had nearly double the chance of dying in the following two years, and 'had a 154 percent higher risk of death from suicide' than if they gave birth."[53] This study concluded that "[h]igher death rates associated with abortion persist over time and across socioeconomic boundaries," which "may be explained by self-destructive tendencies, depression, and other unhealthy behavior aggravated by the abortion experience."[54]

Foreign studies show an even bleaker picture. When Italian researchers studied suicide rates "during pregnancy or within 1 year after giving birth," they "concluded that—of the maternal suicides [studied]—the suicide rate of women who underwent an abortion "was *more than double* the suicide rate of women who gave

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[53] Hannah Howard, *New Study: Elevated Suicide Rates Among Mothers after Abortion*, CHARLOTTE LOZIER INSTITUTE (Sept. 10, 2019), https://lozierinstitute.org/new-study-elevated-suicide-rates-among-mothers-after-abortion/ (last accessed Feb. 1, 2023) (citing Elliot Institute, *New Study Shows Abortion Death Rate Higher Than Previously Known* (July-September 2002), https://afterabortion.org/new-study-shows-abortion-death-rate-higher-than-previously-known/); *see also* David C. Reardon et al., *Deaths associated with pregnancy outcome: a record linkage study of low income women*, SOUTHERN MED. J. Vol. 95, No. 8, 834–41 (Aug. 2002), https://pubmed.ncbi.nlm.nih.gov/12190217/ (last accessed Feb. 1, 2023).

[54] David C. Reardon et al., *Deaths associated with pregnancy outcome: a record linkage study of low income women*, SOUTHERN MED. J. Vol. 95, No. 8, 834–41 (Aug. 2002).

birth."[55] In a similar study, Finnish researchers found that within one year of an abortion, "women were *three times* more likely to commit suicide than the general population, and *nearly six times* more likely to [do so] than women who gave birth," while most of these deaths occur in the first two months.[56]

b. Medication abortion inflicts unique psychological harm on women and girls.

Medication abortion plagues the mental health of mothers undergoing the procedure. Although many studies outline the psychological consequences of underdoing an abortion generally, there are few studies that speak to the psychological effects unique to medication abortion. One study examined the effects of medication abortion on women and showed that: 83% of women reported that their medication abortion changed them (77% reported being changed in a *negative* way); 77% explicitly stated that they regretted their decision; and 38% reported issues with anxiety, depression, drug abuse, and suicidal thoughts because of the abortion.[57]

The physical experience of medication abortion can be traumatizing. During medication abortion, women often experience severe cramping, contractions, and bleeding. The entire process can be a psychologically taxing ordeal, as bleeding can

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[55] Hannah Howard, *supra* note 53 (citing Ilaria Lega, et al., *Maternal suicide in Italy*, ARCHIVES OF WOMEN'S MENTAL HEALTH 23, 199–206 (2020) https://doi.org/10.1007/s00737-019-00977-1) (emphasis added).
[56] *Id.* (citing M. Gissler, et al., *Suicides after pregnancy in Finland, 1987-94. register linkage study*, THE BMJ Vol. 313, 1431–34 (Dec. 1996) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2352979/pdf/bmj00571-0021.pdf) (emphasis added).
[57] Rafferty & Longbons, *supra* note 36.

last from several hours to several *weeks*.[58] In a space where there are few scientific studies, most sources on the psychological harm of medication abortion discuss the various responses of traumatized women and their account of the psychologically taxing event.[59] For example, one woman described her experience:

> I knew to expect blood clotting, but nothing could've prepared me for seeing her body. It was the color of my own skin and was actually starting to look like a person…I thought maybe after the due date I would feel better, but it doesn't end there. It never ends! The pain and emptiness stays there forever. [60]

Another source gathered more in-depth responses from women stating:

- "'I looked down and screamed,' she said. 'It was not just a blob of tissue. I had given birth to what looked like a fully formed, intact 14-week-old fetus covered in blood.' The court document says she 'endured eight years of alcoholism, divorce, suicidal thoughts, rage-filled outbursts and debilitating depression.'"[61]

- "Another woman . . . said, 'There was so much pain and blood I thought I might die' before she passed a gestational sac about the size of a tennis ball in which

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[58] Women on Web, *When will you start bleeding and how long will it last?,* https://www.womenonweb.org/en/page/484/when-will-you-start-bleeding-and-how-long-will-it-last (last accessed Feb. 1, 2023).

[59] Newsweek Staff, *Blood and Tears*, NEWSWEEK (September 17, 1995), https://www.newsweek.com/blood-and-tears-183058 (An account of the entire medication abortion process with testimony such as, "The following Sunday—nine days after the misoprostol—she is taking a shower when she suddenly expels the pregnancy sac. It doesn't go down the drain. She scoops it up, wraps it carefully in toilet paper and flushes it away. 'It really emotionally hit me,' she says later.").

[60] Kim Hayes, "*The Pain and Emptiness Stay There Forever"- #Abortionchangesyou Study Looks at Personal Chemical Abortion Experiences*, PREGNANCY HELP NEWS (July 22, 2020), https://pregnancyhelpnews.com/the-pain-and-emptiness-stay-there-forever-abortionchangesyou-study-looks-at-personal-chemical-abortion-experiences.

[61] Celeste McGovern, *Study Confirms Women's Testimonies About Abortion Pill's Link to Depression, Anxiety*, NAT'L CATHOLIC REG. (July 30, 2019), https://www.ncregister.com/daily-news/study-confirms-womens-testimonies-about-abortion-pills-link-to-depression-a (last accessed Feb. 6, 2023).

> she could see her baby. 'I sat and held him and cried.' She later suffered from anorexia, abusive relationships and post-traumatic stress disorder, which a counselor traced directly to her abortion[.]"[62]
>
> - "'I feel like I lost a part of my soul with that baby,' another woman . . . said. "The [abortion] pill is so easy it doesn't give the mother time to truly reflect on what her actions will be doing and the lifelong consequences it can cause," she testified to the court. 'To me, it seems a very easy way for the business to make a quick buck by feeding on the fear of the scared and naive mother, who will be the one that is forced to live with the consequences, while the business profits and moves on to the next mother.'"[63]

Unlike surgical abortions, a mother sees the remains of her aborted child. These factors add to the psychological pain that is unique to medication abortion.[64] To compound this pain, women are often alone when they experience the effects of the medication abortion. The FDA further isolates women from in-person physician interaction—a relationship already tenuously attended to in the abortion industry.

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[62] Celeste McGovern, *Study Confirms Women's Testimonies About Abortion Pill's Link to Depression, Anxiety*, *supra* note 61.

[63] *Id*.

[64] Pauline Slade, et al., *Termination of pregnancy: Patient's perception of care*, J. OF FAMILY PLANNING & REPRODUCTIVE HEALTH CARE Vol. 27, No. 2, 72–77 (2001), https://srh.bmj.com/content/familyplanning/27/2/72.full.pdf ("Seeing the foetus, in general, appears to be a difficult aspect of the medical termination process which can be distressing, bring home the reality of the event and may influence later emotional adaptation"); Pauline Slade, et al., *A comparison of medical and surgical termination of pregnancy: choice, emotional impact and satisfaction with care*, BRITISH J. OBSTETRICS & GYNAECOLOGY Vol. 105 ,No. 12, 1288–95 (Dec. 1998), https://pubmed.ncbi.nlm.nih.gov/9883920/ ("Those having the medical procedure rated it as marginally more stressful and experienced more post-termination physical problems and disruption to life. Seeing the fetus was associated with more intrusive events (nightmares, flashbacks, unwanted thoughts related to the experience).").

c. Women's stories demonstrate the deep, negative psychological impact that medication abortion can have on mothers.

Amicus Human Coalition runs the website "The Abortion Memorial," where individuals can post their abortion experiences. Many of these stories detail the psychological harm that mothers suffer following medication abortion. Many mothers give their child a name, write directly to them and express regret at never meeting them.

One mother, who posted anonymously and writing to the child she had named "Zion," describes her medication abortion experience and the trauma she has endured since her abortion in 2013:

> My little Zion, If I were to write a letter to you it would sound more like an apology. 7 weeks of bad nausea and headaches, it would've all been worth it for you. I was only 13 when I got pregnant with you and I couldn't dare bring you into this world unprepared to give you what you deserved. I still have nightmares & flashbacks of the day I took those second set of pills, crying and screaming on the toilet while your grandma rubbed my back. It's been 5 years now and it's still very hard to bear the image of you dying and still shaming myself for never thinking of you. I'm so sorry my sweet Zion. I love you so much.[65]

Another woman, writing to the child she named "Gabriel," writes of immediately regretting her decision and seeking to undo the harmful effects of mifepristone:

> Gabriel, I agonized over this decision for such a long time. When I finally took that evil pill, I knew I had made a mistake. I called the abortion reversal line and took a huge dose of progesterone to counter it but it didn't save you. I miss you so much my baby boy. I wish I could take back

[65] Zion, *The Abortion Memorial*, https://abortionmemorial.com/zion/ (last accessed Feb. 1, 2023) (cleaned up).

> that day and hold you in my arms. It hurts me deeper than you can imagine. . . I'm so sorry, Gabriel. Mommy will love you forever.[66]

And a young mother wrote of the deep regret she felt after her medication abortion:

> I was 22 years old, already a mother of a 2 year old that had to be raised in a broken home. I was engaged to my now husband when I found out I was expecting. I cried because it wasn't suppose to happen . . . I was scared to have to tell my parents that here I was pregnant out of wedlock with my second baby from a different relationship. I was scared of my father's reaction to this the most. I quickly looked into Planned Parenthood about having an abortion. I was early enough to have the abortion pill because if I were further along I would have not gone through the other type of abortion . . . I regret that decision every single day. . .[67]

The psychological toll that medication abortion takes on mothers is devastating. The FDA has a duty to consider these harms rather than turn a blind eye towards the women suffering them.

III. Unfettered access to mifepristone will likely increase reproductive coercion and crimes against pregnant women and girls.

Increased access to medication abortion will also likely lead to increases in reproductive coercion and crimes against women. Without the in-person requirement, *anyone* can obtain the abortion pills for a woman, even someone who seeks to cause her harm by coercing—or even *forcing*—her to have an abortion.

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[66] I miss you, and regret my decision, *The Abortion Memorial,* https://abortionmemorial.com/i-miss-you-and-regret-my-decision/ (last accessed Feb. 1, 2023).

[67] I was scared to be a shame to my parents, *The Abortion Memorial*, https://abortionmemorial.com/i-was-scared-to-be-a-shame-to-my-parents/ (last accessed Feb. 1, 2023).

Abortion is often used as a tool in human trafficking. And easy access to medication abortion increases the availability of these pills to predators. Intimate partner violence is of particular concern in the population of women seeking abortions, who are at increased risk for reproductive coercion.[68] This is particularly true for women and girls who are victims of sex-trafficking.[69] In a study examining reproductive harm in survivors of sex trafficking, 55.2% of the 67 survivors examined for the study reported at least 1 abortion—29.9% reported multiple abortions.[70] Over the 67 survivors participating in the study, 114 abortions were reported.[71] This study noted the disturbing prevalence of forced abortions in victims of sex trafficking: "Prior research noted that forced abortions were a reality for many victims of sex trafficking outside the United States and at least one study noted forced abortions in domestic trafficking."[72] "The survivors in this study similarly reported that they often did not freely choose the abortions they had while being trafficked."[73] "*More than half* (eighteen) of [the responsive] group indicated that one or more of their abortions was

[68] AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 7 at 10 (citing Elizabeth Miller, et al., *Reproductive coercion: connecting the dots between partner violence and unintended pregnancy*, CONTRACEPTION Vol. 81, No. 6, 457–59 (June 2010); ACOG, *Committee opinion no. 554: reproductive and sexual coercion*, OBSTETRICS & GYNECOLOGY Vol. 121, No. 2 Pt. 1, 411–15 (2013)).
[69] Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, 23 ANNALS HEALTH L. 61 (2014), https://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1410&context=annals.
[70] *Id.* at 73.
[71] *Id.*
[72] *Id.*
[73] *Id.*

at least partly forced upon them."[74] One woman reported having 17 total abortions and noted that some were forced upon her.[75] Medication abortion enables sex traffickers to continue perpetuating their crimes against women, ensuring their victims continue to work. The FDA eliminated one of the few intervention opportunities a human trafficking victim has—meeting a physician face to face.

A second criminal concern unique to medication abortion is the prevalence of male sexual partners who use abortion-causing medications (either mifepristone or misoprostol) to kill their unborn children covertly. There have been several reports over the years of men who purchase abortion drugs illegally and then place them in the mother's drink or secretly insert it inside her vagina without her consent.[76] Recently, a man in Texas was charged with felony assault after allegedly placing abortion drugs in his pregnant wife's glass of water.[77]

The in-person dispensing requirements served an important gatekeeping function to ensure abortion pill recipients voluntarily receive medication abortion themselves. Now the FDA has made it much easier for abusers and criminals to access abortion-causing drugs and continue perpetuating their crimes, including

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[74] Lederer & Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, *supra* note 69 at 73.
[75] *Id*. at 73–74.
[76] CWALAC Staff, *Drug Like RU-486 May Be Approved as Morning-After Pill*, CONCERNED WOMEN OF AMERICA LEGISLATIVE ACTION COMMITTEE (June 25, 2010), https://concernedwomen.org/drug-like-ru-486-may-be-approved-as-morning-after-pill/ (last accessed Feb. 1, 2023) (listing criminal incidents involving abortion drugs)
[77] Emma Colton, *Texas lawyer charged after allegedly drugging pregnant wife with abortion pill*, FOX NEWS (Nov. 16, 2022), https://www.foxnews.com/us/texas-lawyer-charged-allegedly-drugging-pregnant-wife-abortion-pill (last accessed Feb. 1, 2023).

forced abortions. The FDA negligently places these women in harm's way without properly vetting intended and unintended consequences of medication abortion.

CONCLUSION

Decades of medication abortion marred women and girls into living victims of abortion. It caused severe damage to their physical and mental health, including death. These grievous lessons were learned as the FDA failed to fulfill its duty under the law to ensure basic safety measures for women. And now that the FDA has caved to political pressure and removed any semblance of safety protocols for medication abortion, women and girls unknowingly face even greater physical and mental risks. The FDA will survive this catastrophe but unfortunately the living victims of medication abortion may not. The FDA callously dismisses women's real experiences and traumas, wielding its incomplete data as a shield. But Human Coalition believes their voices matter. Women and children in the womb deserve better. Amicus Human Coalition accordingly requests that this Court grant Plaintiffs' motion for preliminary injunction.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 10, 2023, this document was electronically filed and served via the Court's CM/ECF system.

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