No. 23-395

IN THE

Supreme Court of the United States

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Cross-Petitioners,

v.

U.S. FOOD & DRUG ADMINISTRATION, ET AL.,
Cross-Respondents,

and

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Cross-Petitioners,

v.

DANCO LABORATORIES, L.L.C.,
Cross-Respondent.

On Conditional Cross-Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF AMICUS CURIAE ON BEHALF OF HUMAN COALITION IN SUPPORT OF CROSS-PETITIONERS

Elissa M. Graves
Counsel of Record
THE LAW OFFICE OF ELISSA GRAVES
1907 Bonanza Dr.
Sachse, TX 75048
(214) 733-3213
elissamgraves@gmail.com

Chelsey D. Youman
HUMAN COALITION
P.O. Box 5347
Frisco, TX 75035
(214) 295-7301

Counsel for Amicus Curiae

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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. 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 harm that medication abortion causes the mothers who enter their facilities.

SUMMARY OF THE ARGUMENT

Politics should never trump the lives of women. 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.

Medication abortion is a procedure that involves taking two prescription drugs: mifepristone[2] and misoprostol. Together, these drugs work to starve and

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[1] Amicus states that 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. Counsel of record for all parties received timely notice of the intention to file this brief.

[2] The brand name of mifepristone is "Mifeprex."

expel a developing human during pregnancy. Mifepristone is approved for use 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."[3] REMS requires 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).[4] Among other necessary safeguards for women, the mifepristone ETASU required that the drug be dispensed only in clinics, medical offices, and hospitals by an approved medical provider.[5] Thus, before receiving mifepristone, a woman seeking medication abortion needed to be seen in person at a medical facility to evaluate for possible contraindications that could lead to complications, injury, or death.

But even with the REMS restrictions in place, women experienced severe injury to their health as a

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[3] FDA, *Risk Evaluation and Mitigation Strategies* (May 16, 2023), https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems.

[4] FDA, *What's in a REMS?* (Jan. 26, 2018), https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems.

[5] FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Sept. 1, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

direct result of medication abortion. Worse yet, women are often not adequately apprised of the risks of medication abortion or even what they will physically experience during their abortions.

Despite these harms, the FDA removed necessary safeguards designed to protect women from serious complications beginning in 2016. Among other changes, the FDA eliminated two of the three visits required during the medication abortion process, increased the maximum gestational age at which the drug could be used, and eliminated the requirement that prescribers report non-fatal adverse events. Despite these changes, abortion activists continued to pressure the FDA to further deregulate mifepristone to allow for easy access to the dangerous drug. And in 2021, the FDA caved to that pressure, eliminating the requirement that a mother visit the abortion provider in-person to receive the life-ending medication—leaving her alone at home without a physician during her abortion.

The harms to women will increase now that mothers need not see a physician to obtain a medication abortion. 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."[6] These important

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[6] American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), *Dangers of Relaxed Restrictions on Mifepristone* at 1 (Oct. 2021), https://aaplog.org/wp-content/uploads/2022/07/CO-9-Mifepristone-restrictions-update-Jul-22.pdf.

safeguards detect contraindications and prevent complications, many of which can be fatal. But now the entire abortion process can take place without any physician interaction or oversight, at the expense of the health of women and their unborn children.

The FDA's removal of the in-person dispensing requirement has already led to increased harm to women. The FDA data shows that 12.5% of the total deaths reported to the FDA were recorded during the last 6 months of 2022. During this period, women were not required to visit an abortion provider to obtain a medication abortion.[7]

Human Coalition sees firsthand the damage medication abortion causes to the physical health of women. It serves mothers who report they were ill-informed about the severe risks involved with undergoing medication abortion. Human Coalition clinics also assist women who suffered life-threatening complications due to medication abortion.

The mental harms inflicted by medication abortion are likewise grievous. Women who have an abortion of any kind face an increased risk of mental health disorders, such as depression, anxiety, and post-traumatic stress disorder. Women also face an

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[7] *Compare* FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 6/30/2022*, https://web.archive.org/web/20230105005608/https:/www.fda.gov/media/164331/download (last visited Nov. 5, 2023); *with* FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, https://www.fda.gov/media/164331/ download (last visited Nov. 5, 2023).

increased risk of suicide following an abortion. And women's stories collected by Human Coalition show that medication abortion inflicts unique psychological harm.

The FDA's approval of mifepristone and its subsequent removal of important safeguards for mothers harms the physical and mental well-being of women.

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

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

Medication abortion physically harms women, even causing death. The FDA and Danco admit they are aware of the serious harms associated with mifepristone. But the FDA chose to ignore these harms when it first illegally approved the drug and with every amendment to mifepristone's approval. In doing so, the FDA chose political favor over the health of women, neglecting the women it places in harm's way and making them the living victims of abortion.

According to the FDA, mifepristone has caused at least 32 maternal deaths[8] since its approval.[9] Along with causing the death of a child, there are two primary ways a medication abortion can be fatal for the mother. 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-threatening infection.[10] Second, a medication abortion may cause a ruptured ectopic pregnancy.[11] "An ectopic 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), resulting in "major internal bleeding" that "can be a life-threatening emergency that needs immediate

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[8] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, https://www.fda.gov/media/164331/download.

[9] 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/.

[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*.

[12] American College of Obstetricians and Gynecologists (ACOG), *FAQs: Ectopic Pregnancy*, https://www.acog.org/womens-health/faqs/ectopic-pregnancy (last visited Oct. 30, 2023).

surgery."[13] The FDA reported 97 known cases in which women with ectopic pregnancies took mifepristone.[14]

Medication abortion results in other serious complications, most commonly excessive bleeding, infection, and ongoing pregnancy.[15] As of December 2022, 1,049 hospitalizations, 604 blood transfusions, and 418 infections (including 75 severe infections)—with a total of 4,218 adverse events—were reported.[16] But the FDA data is likely incomplete.

The rate of severe complications is likely higher than the FDA data suggests. The FDA only requires deaths to be reported and thus physicians need not report other serious adverse events associated with

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[13] American College of Obstetricians and Gynecologists (ACOG), *FAQs: Ectopic Pregnancy*, https://www.acog.org/womens-health/faqs/ectopic-pregnancy.

[14] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, 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 visited Oct. 30, 2023); *see also* AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 6 at 2–4 (internal citations omitted).

[16] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, https://www.fda.gov/media/164331/download.

mifepristone.[17] The FDA admits that the data submitted to it "cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population."[18] For many reasons, the FDA data does not provide the full picture of the rate of complications associated with mifepristone. First, the abortion provider may not be the same doctor treating a woman's medication abortion complications. One study suggests clinicians other than the abortion provider often manage emergency complications.[19] For this reason, treating providers may not know about the relationship between the adverse event and mifepristone. In the same vein, the abortionist 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

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[17] FDA, *Mifeprex clinical review* at 48–49, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (last visited Nov. 3, 2023); Tessa Longbons, *Analysis: FDA Decision Ignores Data on Complications, Puts Women at Risk*, CHARLOTTE LOZIER INSTITUTE (Dec. 16, 2021), https://lozierinstitute.org/analysis-fda-decision-ignores-data-on-complications-puts-women-at-risk/.

[18] *All. for Hippocratic Med. v. U.S. Food & Drug Adm'n.*, 78 F.4th 210, 249 (5th Cir. 2023) (internal citations omitted).

[19] 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).

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 FDA data suggests. It found the rate of abortion-related emergency room visits following medication abortion increased over 500% from 2002 through 2015.[20] 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.[21] 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.[22] Data obtained from abortion providers supports this. In 2010, Planned Parenthood recorded 1,530 adverse events in relation to medication abortion.[23] But the FDA reported only 664 adverse events for *all providers nationwide* that year.[24]

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[20] 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.

[21] *Id.*

[22] *Id.*

[23] *All. for Hippocratic Med.*, 78 F.4th at 249 (internal citations omitted).

[24] *Id.*

A recent study of telemedicine medication abortion in the United States revealed that 5% of participants required surgical intervention following medication abortion.[25] And 6% of study participants required "unplanned visits to emergency rooms or urgent care centers for reasons related to the abortion."[26]

Data from other countries aligns with these conclusions. In a study from the United Kingdom examining medication abortions between 1994 and 2001, approximately 1% of women were hospitalized.[27] And results of recent freedom of information requests to the U.K.'s National Health Service show that 5.9% of women who attempted a medication abortion were later treated at an NHS hospital for complications resulting from an incomplete abortion. The data also revealed that 3% of women who took the life-ending medications required surgical intervention to complete the

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[25] Gynuity Health Projects, *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience during the COVID-19 Pandemic* (Mar. 26, 2021), https://gynuity.org/resources/expansion-of-a-direct-to-patient-telemedicine-abortion-service-in-the-united-states-and-experience-during-the-covid-19-pandemic.

[26] *Id*.

[27] AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone, supra* note 6 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)).

abortion.[28] And 2.3% of women were later treated for post-abortive hemorrhage.[29]

Another study from Finland affirmed that medication abortion leads to *more* complications than surgical abortion.[30] The study found that women undergoing medication abortion experienced adverse events at a rate *four times higher* (20% vs. 5.6%) than women who had a surgical abortion. In the study, women aborting with mifepristone experienced significantly higher rates of hemorrhage (15.6%, compared to 2.1% for surgical abortion), incomplete abortion (6.7% vs. 1.6%), as well as unplanned surgical evacuation of their child (5.9% vs. 1.8%).[31] Abortion provider MSI Australia (also known as Marie Stopes Australia) reported that medication abortions provided by their staff in 2020 resulted in serious complications in 6.37% of cases, with a 4.95% rate of incomplete abortion.[32] And recent research from Canada further suggests that medication

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[28] Percuity Limited, *FOI Investigation into Medical Abortion Treatment Failure* (2021), https://percuity.blog/foi-investigation-into-medical-abortion-treatment-failure/.

[29] *Id*.

[30] 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/.

[31] *Id*.

[32] MSI Australia, *Impact Report 2020* (2021), https://resources.msiaustralia.org.au/MSA-Impact-Report-2020.pdf.

abortion in the first trimester leads to more adverse events than surgical abortion during the same timeframe.[33]

The FDA and Danco know of the dangerous complications arising from the use of mifepristone in women. They "do not dispute that a significant percentage of women who take mifepristone experience adverse effects."[34] The 2011 REMS warn that "about 5–8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding."[35] The patient agreement admits that "the treatment will not work" in "about 2 to 7 out of 100 women."[36] And the most recent REMS medication guide notes that "between 2.9% and 4.6% of women visited the emergency room after taking mifepristone."[37]

In addition to the millions of children extinguished, the FDA sacrificed women in pursuit of political favor by ignoring available data and illegally

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[33] 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.

[34] *All. for Hippocratic Med.*, 78 F4th at 229 (internal citations omitted).

[35] *Id.* (cleaned up).

[36] *Id.* (internal citations omitted).

[37] *Id*. (internal citations omitted).

approving mifepristone. And when it later removed necessary safeguards to protect women from the known dangers associated with the drug, the FDA discarded women as easily as the children they carry.

b. Eliminating necessary safeguards for the use of mifepristone will lead to more physical harm to women.

Beginning in 2016, the FDA removed several necessary safeguards designed to protect women from dangerous complications associated with mifepristone. The FDA's 2016 changes, as relevant here, (1) eliminated the in-person examination following the medication abortion, (2) increased the maximum gestational age from seven to ten weeks, (3) removed the in-person dispensing requirement for misoprostol, and (4) eliminated the reporting requirement for non-fatal adverse events.[38] And in 2021, the FDA eliminated the in-person dispensing requirement for mifepristone. Now, medication abortion can be administered without any preventive testing such as a physical exam, diagnostic ultrasound, blood tests, or interaction with the abortion provider. The entire abortion can now 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. Such complications can be avoided if a

[38] Conditional Cross-Petition for a Writ of Certiorari at 7 (citing C.A. Add. 697–725).

woman visits a physician in-person before and after her medication abortion.

Removal of the in-person dispensing requirement has already resulted in more deaths. The most recent FDA data shows that 32 deaths are attributed to mifepristone.[39] But in the FDA data ending June 31, 2022, only 28 deaths had been reported. This means that 4 additional deaths were reported between July 1 and December 31, 2022.[40] Thus, over 22 years, 12.5% of the deaths logged by the FDA were reported in a period during which the in-person dispensing requirement had been abandoned.

Failure to diagnose an ectopic pregnancy can result in life-threatening complications for a woman undergoing medication abortion. As noted in Section I.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 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.

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[39] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 6/30/2022*, https://web.archive.org/web/20230105005608/https:/www.fda.gov/media/164331/download.

[40] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, https://www.fda.gov/media/164331/download.

Failure to test the mother's rH factor before medication abortion can lead to grave complications. "The Rh factor is a protein that can be found on the surface of red blood cells," and its presence indicates that someone is Rh positive—its absence, Rh negative.[41] 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."[42] "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."[43] A simple blood test performed during pregnancy can determine whether a woman is Rh-negative and medication can be administered to prevent antibodies from forming.[44] ACOG recommends that this medication be given to Rh-negative women before a

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[41] ACOG, *FAQs: 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 visited Oct. 30, 2023).

[42] *Id*.

[43] *Id*.

[44] AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 6 at 7 (citing ACOG, *Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, OBSTETRICS & GYNECOLOGY Vol. 130, No. 2, e57–e70 (2017)).

medication abortion.[45] ACOG further notes that Rh testing and treatment (if needed) is the standard of care.[46] 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%.[47] And in the second trimester, the failure rate reaches 40%.[48] While it is possible to guess 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.[49] Without an in-

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[45] AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 6 at 7 (citing ACOG, *Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, OBSTETRICS & GYNECOLOGY Vol. 130, No. 2, e57–e70 (2017)).

[46] *Id*. (internal citations omitted).

[47] *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)).

[48] *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)).

[49] *Id*. (citing Kelly A. Bennett, et al., *First trimester ultrasound screening is effective in reducing postterm labor induction rates:*

person visit before medication abortion, an ultrasound will not be administered to determine whether the gestational age is too late for medication abortion.

The cumulative effect of eliminating necessary safeguards for mifepristone dangerously isolates women from preventive testing and medical oversight. The results may be deadly.

c. Human Coalition serves women who are misinformed about risks associated with medication abortion.

The FDA's diminished protocols leave women in the dark about their abortions. Despite the risk of serious harm, abortion providers already give insufficient, limited, or misleading information to women seeking medication abortion.[50] In one study, 14% of women reported being inadequately prepared about what to expect during their medication abortion and many felt openly deceived.[51] In their own words,

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a randomized controlled trial, AM. J. OBSTETRICS & GYNECOLOGY Vol. 190, No. 2, 1077–81 (2004)).

[50] 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.

[51] *Id*.

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.[52]

Unfortunately, these experiences are consistent among women obtaining a medication abortion. Human Coalition served around 40,000 pregnant women last year. Among those who had a medication abortion, many contact Human Coalition reporting that they were not provided adequate information about their abortion—not knowing that they will see the remains of their child and can experience significant pain and bleeding. Women report abortion providers fail to: (1) inform them about medication abortion complications, and (2) respond when they experience a complication.

Human Coalition nurses see firsthand how women become the living victims of these failures. Abortion providers are reported to minimize concerns or side effects and focus on the positive—"easy process," "quick recovery," and "like taking over-the-counter meds." Or even provide—as one study found—material misrepresentations: "It's just a pill" and "if you by chance are in pain."[53] Some women expressed that the abortion provider told them "it is as easy as taking Advil."

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[52] Rafferty & Longbons, *supra* note 50.

[53] *Id*.

Many report they were not warned about seeing human remains. Traumatized women call Human Coalition lamenting that "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." Women also call Human Coalition nurses panicking in the middle of their abortions. The nurses support them over the phone, so they are not alone.

Several women were also unknowingly ectopic when they arrived at Human Coalition with abortion pills in hand. Human Coalition sonographers provided life-saving ultrasounds. Basic safeguards, like ultrasounds and in-person physician consultations, are appreciated by women, especially those whose lives are saved by them. As one ectopic client said, "I did go to the hospital. I ended up having to get my tube removed so I had surgery the same day. I would like to say thank you for convincing me to get checked. You literally saved my life and I am thankful."

Ultrasounds also inform women how far along women are in their pregnancies to avoid sepsis, hemorrhage, and other complications from medication abortion. For example, one client that Human Coalition served had been encouraged by her mother to get an abortion. After going to her abortion provider and receiving pills, she remained pregnant. The ultrasound she received at Human Coalition revealed her pregnancy to be too far along to use the

pills she had taken. Negligent abortion practices unnecessarily placed this client in harm's way.

In-person follow-up care is vital to women and their children. Abortion providers do not always return patients' calls or schedule appointments when complications arise. One Human Coalition client received abortion pills online. She estimated she was ten weeks pregnant. The abortion provider inaccurately assured her the pills would be effective through 12 weeks. The woman endured a painful and difficult abortion experience. She bled heavily for three weeks, finally calling Planned Parenthood for help. Planned Parenthood refused to see her. When she managed to find medical treatment, the doctors discovered retained placenta, a potentially life-threatening condition.

Another client was a flight attendant. Because her abortion provider failed to warn her about the pain and bleeding she would experience, she planned to work the day she took the second pill. When she began vomiting and feeling sick, she called the abortion clinic, concerned about her symptoms. They dismissed her, telling her it was "just a stomach bug." She then sought care at an emergency room where she underwent an emergency surgical procedure. Her doctors told her that, if she had waited 24 hours, she would have died from the sepsis that had developed.

Human Coalition also serves women whose medication abortions have "failed." One client took the abortion pills but felt that something was wrong. For two months, she reached out to the abortion clinic

seeking follow-up care. When she persuaded them to see her, her ultrasound revealed she was pregnant with twin boys. Another woman continued to have positive pregnancy tests for two months after completing the medication abortion regimen. During that time, Planned Parenthood refused to schedule a follow-up appointment. Human Coalition nurses located a provider who would accept her insurance and could see her that day. As a result, the patient discovered that she was still pregnant. Instead of neglect, these women should have received quality prenatal care to ensure the health of these mothers and their unborn children.

In the now deeply unregulated field of medication abortion, women and their children need more safeguards, not less. Women deserve basic safeguards that require abortion providers to have accountability. Women deserve accurate and complete information instead of material omissions or mistruths.

II. Abortion psychologically damages women.

Abortion causes significant mental health problems in women, increasing the risk of depression, anxiety, substance abuse, and suicide. Mothers who choose abortion often experience grief, sadness, and feelings of loss.[54] The data and stories of post-abortive

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[54] David C. Reardon, *The abortion and mental health controversy: A comprehensive literature review of common ground agreements, disagreements, actionable*

women show that medication abortion inflicts unique psychological pain on mothers.

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.[55] These women also face a 34% increased risk of anxiety, 37% increased risk of depression, and 155% increased risk of suicidal behavior.[56] "[M]ost social and medical science scholars [agree] that a minimum of 20% to 30% of women who abort suffer from serious, prolonged

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recommendations, and research opportunities, SAGE OPEN MED. (Oct. 29, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207970/ (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).

[55] AAPLOG, *Committee Opinion 6: Induced Abortion & the Increased Risk of Maternal Mortality* at 8 (Aug. 13, 2019), https://aaplog.org/wp-content/uploads/2020/01/FINAL-CO-6-Induced-Abortion-Increased-Risks-of-Maternal-Mortality.pdf (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/).

[56] *Id*. at 8 (internal citations omitted).

negative psychological consequences, yielding at least 260,000 new cases of mental health problems each year."[57] Many studies also reflect that "abortion significantly increases [the] risk" that a woman will engage in substance abuse.[58]

Abortion places women at risk of suffering post-traumatic stress disorder. PTSD is often seen in "people who have experienced or witnessed a

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[57] AAPLOG, *Practice Bulletin: Abortion and Mental Health* at 6 (Dec. 30, 2019), https://aaplog.org/wp-content/uploads/2019/12/FINAL-Abortion-Mental-Health-PB7.pdf (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/).

[58] *Id*. (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 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/).

traumatic event, series of events or set of circumstances."[59] Women who suffer from PTSD experience "intense, disturbing thoughts and feelings related to their experience that last long after the traumatic event has ended."[60] 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."[61] 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. [62]

For some women who have abortions, their mental suffering leads to a 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

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[59] American Psychiatric Association, *What Is Posttraumatic Stress Disorder?,* https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd (last visited Oct. 30, 2023).

[60] *Id*.

[61] AAPLOG, *Practice Bulletin: Abortion and Mental Health*, *supra* note 57 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).

[62] *Id*.

"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."[63] 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."[64]

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 the suicide rate of women who underwent an abortion "was more than double the suicide rate of women who gave birth."[65] 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

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[63] 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/ (internal citations omitted).

[64] 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).

[65] Howard, *supra* note 63 (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).

who gave birth," while most of these deaths occur in the first two months.[66]

b. Medication abortion inflicts unique psychological harm on women.

Medication abortion plagues the mental health of mothers undergoing the procedure. Although many studies outline the psychological consequences of undergoing 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.[67]

Most sources on the psychological harm of medication abortion discuss the various responses of traumatized women and their account of the psychologically taxing event. 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.

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[66] Howard, *supra* note 63 (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).

[67] Rafferty & Longbons, *supra* note 50.

One mother, who posted anonymously, describes her medication abortion experience and the trauma she has endured since her abortion:

> My little Zion, If I were to write a letter to you it would sound more like an apology. . . 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.[68]

Another woman, speaking to her unborn child, writes of immediately regretting her decision and seeking to undo the 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

[68] Zion, *The Abortion Memorial* (May 13, 2016), https://abortionmemorial.com/zion/ (cleaned up).

> 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 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.[69]

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[d] to happen . . . I was scared to have to tell my parents that here I was pregnant out of wedlock . . . I quickly looked into Planned Parenthood about having an abortion. I was early enough to have the abortion pill . . . I regret that decision every single day. . .[70]

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[69] I miss you, and regret my decision, *The Abortion Memorial* (Sept. 30, 2019), https://abortionmemorial.com/i-miss-you-and-regret-my-decision/.

[70] I was scared to be a shame to my parents, *The Abortion Memorial* (Nov. 17, 2020), https://abortionmemorial.com/i-was-scared-to-be-a-shame-to-my-parents/.

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 from them.

CONCLUSION

The FDA failed millions of women and their unborn children when it approved mifepristone, choosing politics over the health and safety of mothers. Medication abortion has caused severe damage to the physical and mental health of women. These grievous lessons were learned as the FDA failed to fulfill its duty to ensure basic safety measures for women. And now that the FDA has removed any semblance of safety protocols for medication abortion, mothers unknowingly face even greater risks. The FDA dismisses women's real experiences and traumas, wielding its incomplete data as a shield. Women and their unborn children alone will bear the costs of the FDA's continuing approval of mifepristone.

Respectfully submitted,

Elissa M. Graves
Counsel of Record
THE LAW OFFICE OF ELISSA GRAVES
1907 Bonanza Dr.
Sachse, TX 75048
(214) 733-3213
elissamgraves@gmail.com

Chelsey D. Youman
HUMAN COALITION
P.O. Box 5347
Frisco, TX 75035
(214) 295-7301

Counsel for Amicus Curiae

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