No. 23-10362

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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

Plaintiffs-Appellees

v.

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

Defendants-Appellants

v.

Danco Laboratories, L.L.C.,

Intervenor-Appellant

Appeal from the United States District Court
for the Northern District of Texas
No. 2:22-cv-00223-Z

BRIEF AMICUS CURIAE ON BEHALF OF HUMAN COALITION IN SUPPORT OF APPELLEES AND IN OPPOSITION TO APPELLANTS' EMERGENCY MOTION FOR A STAY PENDING APPEAL

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Dated: April 11, 2023

CORPORATE DISCLOSURE STATEMENT

Under Fed. R. App. P. 26.1 and 5th Cir. R. 26.1, Amicus Curiae Human Coalition states that it is a non-profit organization, has no parent corporation, and does not issue stock.

Dated: April 11, 2023

Respectfully submitted,

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CERTIFICATE OF INTERESTED PARTIES

The undersigned counsel of record certifies that the following listed persons and entities—as described in the fourth sentence of Circuit Rule 28.2.1—have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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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.

INTRODUCTION

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 to end a pregnancy: mifepristone and misoprostol. When mifepristone was first approved, it gained approval only under the

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), 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. All parties have consented to the filing of this brief.

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."[2] Initially, the drug could be dispensed only in medical facilities by an approved medical provider.[3] But even with the REMS restrictions in place, women experienced injury to their physical and mental health as a result of medication abortion. And in 2021, the FDA eliminated the in-person safety protocols. Now, the entire abortion process can take place without any physician interaction or oversight. Women will be harmed by the FDA's reckless removal of these important safeguards.

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[2] FDA, *Risk Evaluation and Mitigation Strategies*, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems.

[3] 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-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

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

a. Medication abortion causes serious complications.

Medication abortion physically harms women. According to the FDA, mifepristone caused 28 deaths since its approval.[4] Medication abortion results in other serious complications, most commonly bleeding, infection, and ongoing pregnancy.[5] 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.[6] But the FDA data is likely incomplete. Despite the risks associated with mifepristone, the FDA only requires deaths to be reported.[7] For this

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

[5] FDA, *Highlights of Prescribing Information: Mifeprex (mifepristone) Tablets, 200 mg*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf; *see also* AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 7 at 2–4 (internal citations omitted).

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

[7] FDA, *Mifeprex clinical review* at 48–49, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf; 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/.

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.[8] Thus, treating providers may not know about the relationship between the adverse event and mifepristone. Second, medical professionals may be unable to trace every deadly infection back to the use of these drugs, as there are potential intervening causes. 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 FDA data suggests. It found the rate of abortion-related emergency room visits following medication abortion increased over

[8] 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).

500% from 2002 through 2015.[9] 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.[10] 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.[11]

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.

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[9] 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.

[10] *Id.*

[11] *Id.*

b. Human Coalition's clients are misinformed about risks associated with medication abortion and are therefore 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.[12] In one study, 14% of women reported being inadequately prepared about what to expect during their medication abortion and many felt openly deceived.[13] 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.[14]

Unfortunately, these experiences are pervasive. Human Coalition served approximately 45,000 pregnant women last year. Women who visit Human Coalition's care clinics and call their help line consistently

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[12] 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 .

[13] *Id.*

[14] *Id.*

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.

Informed consent is "fundamental in both ethics and law."[15] 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."[16] In seeking informed consent, a physician should:

> Present relevant information accurately and sensitively[.] 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...[17]

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[15] American Medical Association Code of Medical Ethics, *Opinion 2.1.1: Informed Consent*, https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent.

[16] *Id.*

[17] *Id.*

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

Human Coalition's clinics often serve women who were not provided accurate information about medication abortion and its risks. Abortion providers are reported to minimize concerns or side effects—"easy process," "quick recovery," and "like taking over the counter meds." Or—as one study found—material misrepresentations: "it's just a pill" and "if you by chance are in pain."[18] 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. Women call Human Coalition nurses panicking in the middle of their abortions, shocked by the reality of what they experience

Human Coalition has served many women whose medication abortions failed and found themselves still pregnant. Several clients were unknowingly ectopic when they arrived at Human Coalition with

[18] Rafferty & Longbons, *supra* note 12.

abortion pills in hand. Human Coalition sonographers provided potentially life-saving ultrasounds.

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. And now these patients may never see the abortion provider.

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.

Abortion—whether it be by medication or surgery—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.[19] The data

[19] 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),

and stories of post-abortive women shows 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.[20] These women also face a 34% increased risk of anxiety, 37% increased risk of depression, and 155% increased risk of suicidal behavior.[21] "[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."[22]

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207970/ (internal citations omitted).

[20] 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 (internal citations omitted).

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

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

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 "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."[23] 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."[24]

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[23] 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); *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/.

[24] 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).

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.[25]

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 last from several hours to several *weeks*.[26] In a space where there are few scientific studies, most

[25] Rafferty & Longbons, *supra* note 12.
[26] 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.

sources on the psychological harm of medication abortion discuss the various responses of traumatized women and their account of the psychologically taxing event.[27] For example, one source gathered 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.'"[28]
>
> - "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 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[.]"[29]
>
> - "'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," . . .

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[27] Newsweek Staff, *Blood and Tears*, NEWSWEEK (September 17, 1995), https://www.newsweek.com/blood-and-tears-183058.
[28] 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.
[29] *Id.*

> '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.'"[30]

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.[31] 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.

CONCLUSION

Amicus Human Coalition accordingly requests that this Court deny Appellants' request for a stay pending appeal.

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[30] Celeste McGovern, *Study Confirms Women's Testimonies About Abortion Pill's Link to Depression, Anxiety*, *supra* note 28.
[31] 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.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 27(d)(2) because it contains 2,465 according to the word count feature in Microsoft Word, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally-spaced typeface using Microsoft Word in 14-point Century Schoolbook font.

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Dated: April 11, 2023

CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2023, the foregoing amicus brief was filed electronically with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit through the Court's CM/ECF system. I certify that all participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

/s/ Elissa M. Graves