Nos. 23-235 & 23-236

IN THE

Supreme Court of the United States

U.S. FOOD & DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF HUMAN COALITION, THE ETHICS AND RELIGIOUS LIBERTY COMMISSION, AND THE NATIONAL ASSOCIATION OF EVANGELICALS AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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 Amici Curiae

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INTEREST OF AMICI 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.

The **Ethics and Religious Liberty Commission** (ERLC) is the moral concerns and public policy entity of the Southern Baptist Convention (SBC), the nation's largest Protestant denomination, with over 13 million members in roughly 50,000 churches and congregations. The ERLC is charged by the SBC with addressing public policy affecting such issues as religious liberty, marriage and family, the sanctity of human life, and ethics. The ERLC affirms that women and their preborn children are made in the image of God and must be protected from harm. Thus, the ERLC has an

[1] Pursuant to Rule 37.6 of this Court, amici state that no counsel for any party authored this brief in whole or in part, and no person or entity, other than amici or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

interest in ensuring that the government protects the lives and wellbeing of women and preborn children.

The **National Association of Evangelicals** (NAE) is the largest evangelical network in the United States. It serves as the convener and collective voice for 40 member denominations, charities, schools, missions, and health ministries, with a constituency of tens of millions. The NAE believes that human life is sacred because all people are made in the image of God, that civil government therefore has no higher duty than to protect human life and health, with a particular concern for women and their children, both before and after birth.

SUMMARY OF THE ARGUMENT

Politics should never trump the lives of women. But the FDA allowed just that to happen when it deregulated the dangerous pregnancy-ending drug mifepristone.

Medication abortion is a procedure that involves taking two prescription drugs: mifepristone[2] and misoprostol. Together, these drugs work to starve and 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 requires "for certain medications with serious safety concerns to help ensure the benefits of the

[2] The brand name of mifepristone is "Mifeprex." It is also referred to as "RU-486."

medication outweigh its risks."[3] REMS requires a drug label to include—among other things—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 direct result of medication abortion. Worse yet, women report that they are often not adequately apprised of the risks of medication abortion or even

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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.

what they will physically experience during their abortions.[6]

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. But even with these modifications, abortion activists continued to pressure the FDA to remove more safeguards 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 doctor during her abortion.

The harms to women will increase now that mothers need not see a physician—or any medical professional—to obtain a medication abortion. Today, medication abortion may be administered without any physical exam or ultrasound to confirm the location and age of the pregnancy, Rhesus antigen

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[6] *See, e.g.*, 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.

(Rh) status testing, or any interaction with a doctor.[7] These important safeguards detect contraindications and prevent complications, many of which can be fatal.

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 since mifepristone was approved in 2000 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.[8]

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

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[7] 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.

[8] *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 Feb. 23, 2024); *with* FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, https://www.fda.gov/media/164331/download (last visited Feb. 23, 2024).

The mental harms inflicted by medication abortion are also grievous. Women who have an abortion of any kind have an increased risk of mental health disorders, such as depression, anxiety, and post-traumatic stress disorder. Women also face an elevated risk of suicide following an abortion. And women's stories show that medication abortion inflicts unique psychological harm.

Removal of the in-person dispensing requirement will increase reproductive coercion and crimes against pregnant women. Medication abortion is an oft-used tool in human trafficking. And the news is replete with stories of criminal convictions of men who have compelled their pregnant partners to have an abortion against their will—by poisoning their food or drink, deceit, or outright force. Deregulation removes already scarce intervention opportunities for victims of human trafficking or abuse.

What's more, amici believe in the inherent dignity and worth of all human beings—including women and unborn children. Amici also affirm that every human is made in the image of God and must be protected from harm. The FDA has placed the incalculably valuable lives of women and their children in harm's way in the pursuit of political favor.[9] Its decision cannot stand.

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[9] *See* Conditional Cross-Petition for a Writ of Certiorari at 11–15, *All. for Hippocratic Med. v. U.S. Food & Drug Adm'n* (U.S. No. 23-395) (filed Oct. 12, 2023) (chronicling the political history of the FDA's deregulation of mifepristone).

The FDA's removal of important safeguards for mothers harms the physical and mental well-being of women and ends human lives. Amici urge this Court to invalidate the FDA's arbitrary deregulation of medication abortion.

I. Medication abortion causes 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 removed important safeguards designed to protect women from the dangers of mifepristone. In doing so, the FDA chose political favor over the health of women, neglecting those it endangers and making them the living victims of abortion.

According to the FDA, mifepristone has caused at least 32 maternal deaths[10] since its approval.[11] Along

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

[11] 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*

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.[12] Second, a medication abortion may cause a ruptured ectopic pregnancy.[13] "An ectopic pregnancy occurs when a fertilized egg grows outside of the uterus," in most cases within the fallopian tube.[14] "As the pregnancy grows, it can cause the tube to burst," resulting in "major internal bleeding" that "can be a life-threatening emergency that needs immediate surgery."[15] The FDA reported 97 known cases in which women with ectopic pregnancies took mifepristone.[16]

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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/.

[12] 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), https://pubmed.ncbi.nlm.nih.gov/33939340/.

[13] *Id*.

[14] American College of Obstetricians and Gynecologists (ACOG), *FAQs: Ectopic Pregnancy*, https://www.acog.org/womens-health/faqs/ectopic-pregnancy (last visited Feb. 23, 2024).

[15] *Id*.

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

Medication abortion results in other serious complications, most commonly excessive bleeding, infection, and ongoing pregnancy.[17] 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.[18] 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 mifepristone.[19] 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."[20]

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[17] FDA, *Highlights of Prescribing Information: Mifeprex (mifepristone) Tablets, 200 mg*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (last visited Feb. 23, 2024); *see also* AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 7 at 2–4 (internal citations omitted).

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

[19] FDA, *Mifeprex clinical review* at 48–49, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (last visited Feb. 23, 2024); 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.

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

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.[21] 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 may fail to report serious complications simply because they are not required to do so.

Data from abortion providers shows that mifepristone causes more complications than the FDA data suggests. In 2010, Planned Parenthood recorded 1,530 adverse events in relation to medication abortion.[22] But the FDA reported only 664 adverse events for *all providers nationwide* that year.[23]

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[21] Aultman, et al., *supra* note 12 (Concluding that only 39.75% of follow-up D&C procedures after a failed medication abortion are done by abortion providers).

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

[23] *Id.*

A recent study of telemedicine medication abortion in the United States revealed that 5% of participants required surgical intervention following the procedure.[24] And 6% of study participants required "unplanned visits to emergency rooms or urgent care centers for reasons related to the abortion."[25]

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.[26] 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.[27] The data also revealed that 3%

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[24] 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.

[25] *Id*.

[26] 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)).

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

of women who took the life-ending medications required surgical intervention to complete the 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 research from Canada further suggests that medication abortion in

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[28] Percuity Limited, *supra* note 27.

[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.

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]

Along with the lives of millions of children extinguished, the FDA sacrificed women in pursuit of political approval by ignoring available data exposing women to the known dangers of mifepristone.

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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.* at 229 (internal citations omitted).

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 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

[38] Br. for Respondents at 6 (internal citations omitted).

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.

With no in-person visit to a medical professional, there are severe contraindications or complications that may be missed. First, 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 abortion procedure. But the FDA's elimination of the in-person dispensing requirement means that a woman may not even be offered an ultrasound.

Additionally, 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

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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.

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] If an Rh-negative woman becomes pregnant after having an abortion and did not receive Rh treatment before the abortion, "a future fetus may be at risk of problems if [the child] is Rh positive."[44] 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.[45] ACOG recommends that this medication be given to Rh-

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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 Feb. 23, 2024).

[42] *Id*.

[43] *Id*.

[44] *Id*.

[45] 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)).

negative women before a medication abortion.[46] ACOG further notes that Rh testing and treatment (if needed) is the standard of care.[47] But eliminating the in-person dispensing requirement means this test may never happen.

What's more, 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%.[48] And in the second trimester, the failure rate reaches 40%.[49] 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

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[46] 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)).

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

[48] *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)).

[49] *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)).

trimester.[50] Without an in-person visit before medication abortion, an ultrasound will not be administered to determine whether the gestational age is too late for medication abortion.

Eliminating the in-person dispensing requirement for mifepristone dangerously isolates women from preventive testing and medical oversight. As a result, women will suffer grave injury and even death.

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.[51] In one study, 14% of women reported being inadequately prepared about what to expect during their medication abortion

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[50] AAPLOG, *Dangers of Relaxed Restrictions on Mifepristone*, *supra* note 7 at 7 (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)).

[51] 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.

and many felt openly deceived.[52] 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.[53]

Unfortunately, these experiences are consistent among women obtaining a medication abortion. Amicus Human Coalition served around 35,000 pregnant women last year. Among these women, those who underwent medication abortion report that they were not provided adequate information about the 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 the abortion industry's failure to provide informed consent to medication abortion. 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."[54] Some

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[52] Rafferty & Longbons, *supra* note 51.

[53] *Id.*

[54] *Id.*

women expressed that the abortion provider told them "it is as easy as taking Advil."

Many women are horrified that they were not warned about seeing their child's remains. Traumatized mothers 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 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 taking the abortion-inducing 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 jeopardized the health of this client.

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 emergency surgery. 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 and their unborn children should have received quality prenatal care.

In the now largely deregulated field of medication abortion, women and their children need more safeguards, not less. Women deserve basic protections that require abortion providers to have accountability. And women are owed complete and accurate 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.[55] The data and stories of post-abortive 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 having an abortion.[56] These women also face a 34% increased risk of anxiety, 37% increased risk of depression, and 155% increased risk of suicidal behavior.[57] "[M]ost social and medical science scholars [agree] that a minimum of 20% to 30% of

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[55] 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. (Oct. 29, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207970/ (internal citations omitted).

[56] 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/).

[57] *Id.*

women who abort suffer from serious, prolonged negative psychological consequences, yielding at least 260,000 new cases of mental health problems each year."[58] Many studies also reflect that "abortion significantly increases [the] risk" that a woman will engage in substance abuse.[59]

Abortion also places women at risk of suffering post-traumatic stress disorder. PTSD is often seen in "people who have experienced or witnessed a traumatic event, series of events or set of circumstances."[60] Women who suffer from PTSD experience "intense, disturbing thoughts and feelings related to their experience that last long after the traumatic event has ended."[61] 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

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[58] 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/).

[59] *Id*.

[60] American Psychiatric Association, *What Is Posttraumatic Stress Disorder?,* https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd (last visited Feb. 23, 2024).

[61] *Id*.

diagnostic criteria for PTSD."[62] 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. [63]

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."[64] 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

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[62] AAPLOG, *Practice Bulletin: Abortion and Mental Health*, *supra* note 58 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).

[63] *Id*.

[64] 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).

unhealthy behavior aggravated by the abortion experience."[65]

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."[66] 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.[67]

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

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[65] 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/.

[66] Howard, *supra* note 64 (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).

[67] *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).

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.[68]

Most sources on the psychological harm of medication abortion discuss the various responses of traumatized women and their account of the psychologically taxing event. 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*.[69] In a space where there are few scientific studies, most sources on the mental harm of medication abortion discuss the various responses of traumatized women and their account of the psychologically taxing event. 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

[68] Rafferty & Longbons, *supra* note 51.

[69] 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 visited Feb. 23, 2024).

> 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. [70]

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.'"[71]

- "Another woman . . . said, 'There was so much pain and blood I

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[70] 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.

[71] 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.

> 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[.]"[72]

- "'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.'"[73]

And unlike surgical abortions, a mother sees the remains of her aborted child. These factors add to the psychological pain that is unique to medication

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[72] McGovern, *supra* note 71.

[73] *Id.*

abortion.[74] To compound this pain, women are often alone when they experience the effects of the medication abortion. With the elimination of the in-person dispensing requirements and follow-up care, the FDA further isolates women from in-person physician interaction.

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

Amicus Human Coalition runs the website "The Abortion Memorial," where individuals post their abortion experiences. Many of these stories detail the psychological harm that mothers suffer following medication abortion.

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

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[74] 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");

> 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.[75]

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 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

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

> so sorry, Gabriel. Mommy will love you forever.[76]

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. . .[77]

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.

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

[77] 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/.

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

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

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.[78] This is particularly true for women who are victims of sex-trafficking.[79] In a study examining reproductive harm in survivors of sex trafficking, 55.2% of the 67

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[78] 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)).

[79] 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.

survivors examined for the study reported at least 1 abortion—29.9% reported multiple abortions.[80] Over the 67 survivors participating in the study, 114 abortions were reported.[81]

This study further 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."[82] "The survivors in this study similarly reported that they often did not freely choose the abortions they had while being trafficked."[83] "More than half (eighteen) of [the responsive] group indicated that one or more of their abortions was at least partly forced upon them."[84] One woman reported having 17 total abortions and noted that some were forced upon her.[85] Medication abortion enables sex traffickers to continue perpetuating their crimes against women, ensuring their victims continue to work. But the FDA eliminated one of the few

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[80] Lederer & Wetzel, *supra* note 79 at 73.

[81] *Id*.

[82] *Id*.

[83] *Id*.

[84] *Id*.

[85] *Id*. at 73–74.

intervention opportunities a human trafficking victim has—meeting a physician face to face.

Another criminal concern is the prevalence of male sexual partners who use abortion-causing medications—mifepristone or misoprostol—to kill their unborn children. There have been reports over the years of men who buy abortion drugs and then put them in the mother's drink, place it in her food, or insert it inside her vagina without her consent.[86] Just this month, a man in Texas pled guilty to injury and assault charges after he repeatedly poisoned his pregnant wife's water with abortion drugs.[87] A Wisconsin man was sentenced to 5 years in prison for attempted murder of an unborn child after he put mifepristone in his girlfriend's water bottle.[88] Similarly, a physician in Virginia pled guilty to fetal homicide after he placed abortion-inducing

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[86] 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/ (listing criminal incidents involving abortion drugs).

[87] Minyvonne Burke, *Texas attorney who poisoned pregnant wife with abortion medication sentenced to 180 days in jail*, NBC NEWS (Feb. 9, 2024), https://www.nbcnews.com/news/us-news/texas-attorney-poisoned-pregnant-wife-abortion-medication-sentenced-18-rcna 138065.

[88] Mason Dowling, *Wisconsin Rapids man sentenced to five years for abortion scheme*, WAOW 9 NEWS (Apr. 29, 2022), https://www.waow.com/news/top-stories/wisconsin-rapids-man-sentenced-to-five-years-for-abortion-scheme/article_4ed1eb9c-c7dd-11ec-a75b-732ab9730380.html.

medication in his pregnant girlfriend's tea causing her to miscarry within hours.[89] She was 17 weeks pregnant at the time.[90] Another man covertly administered misoprostol to his pregnant girlfriend *three times* after she refused to have an abortion.[91] In Kansas, a man was sentenced to nearly 10 years in prison after he killed his girlfriend's unborn child by lacing her food with mifepristone.[92] Another man used the drug in his partner's drink; he was later sentenced to 22 years in prison for attempted murder of an unborn child.[93]

Men have also coerced women to take pregnancy-ending medications by deceit and force. A Florida doctor tricked his girlfriend into taking pregnancy-

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[89] Associated Press, *Doctor Who Spiked Girlfriend's Drink with Abortion Drug Sentenced to 3 years in Jail*, CNN NEWS 18 (May 22, 2018), https://www.news18.com/news/world/doctor-who-spiked-girlfriends-drink-with-abortion-drug-sentenced-to-3-years-in-jail-1755035.html.

[90] *Id*.

[91] Marc Cota-Robles, *Restaurateur sentenced to 9 years in prison for 2009 miscarriage*, ABC 13 EYEWITNESS NEWS (Jan. 30, 2016), https://abc13.com/restaurant-owner-joshua-woodward-attempted-murder-misoprostol-gail-greaves/1180368/.

[92] Brian Dulle, *Kansas man gets nearly 10 years in prison in fetus' death*, KSNT NEWS (Feb. 23, 2016), https://www.ksnt.com/news/kansas-man-gets-nearly-10-years-in-prison-in-fetus-deat h/.

[93] Pafoua Yang, *Patel sentenced to prison in attempted forced-abortion case*, FOX 11 NEWS (Oct. 9, 2018), https://fox11online.com/news/local/patel-sentenced-to-prison-in-forced-abortion-case.

ending medication by forging a prescription for misoprostol, placing the drugs in a bottle labeled for an antibiotic, and telling his pregnant partner that she had an infection requiring treatment.[94] Because of this elaborate deception, her unborn child died soon after she took the drug.[95] In another instance, a man entered the home of his former partner, held a gun to her, and forced her to take abortion-inducing drugs, killing the child.[96] The woman had ended the romantic relationship after he repeatedly insisted that she have an abortion—and he then forcefully took away her choice.[97]

Despite these many crimes, the FDA chose to make the mifepristone even more accessible to predators by eliminating important safeguards designed to protect women from harm. The in-person dispensing requirements served an important gatekeeping function to ensure abortion pill recipients voluntarily receive medication abortion

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[94] Michael Winter, *Fla. man gets prison for abortion-pill miscarriage*, USA TODAY (Jan. 27, 2014), https://www.usatoday.com/story/news/nation/2014/01/27/florida-prison-abortion-pill-deception/4948947/.

[95] *Id.*

[96] Jason Kotowski, *'I never even got the chance to listen to the heartbeat;' Victim statement read at sentencing in forced miscarriage case*, KGET NEWS (Sept. 1, 2022),https://www.kget.com/news/crime-watch/jagmeet-sandhu-forced-miscarriage-manslaughter-sala-bakersfield-sentencing/.

[97] *Id.*

themselves. Without these requirements, the FDA negligently places women in harm's way.

IV. All human life is valuable and must be protected from the dangers of mifepristone.

Amici believe, as a matter of religious conviction, that every human life has dignity and worth. The Southern Baptist statement of faith asserts that "Children, from the moment of conception, are a blessing and heritage from the Lord."[98] And the NAE holds that "[b]ecause God created human beings in his image, every human life from conception to death bears the image of God and has inestimable worth[.]"[99] Because of these beliefs, amici affirm that all lives deserve protection from harm. But the FDA imperiled women and their unborn children when it ignored the dangers of mifepristone and largely deregulated the life-ending drug.

The Bible makes clear that *all* human beings are made in God's image and worthy of protection.[100] This means that all life—regardless of age, ability, gender,

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[98] S. Baptist Convention, *Baptist Faith & Message 2000*, art. XVIII, The Family, https://bfm.sbc.net/bfm2000/#xviii (last visited Feb. 26, 2024).

[99] Nat'l Ass'n of Evangelicals, *For the Health of the Nation*, https://www.nae.org/wp-content/uploads/2018/09/For-the-Health-of-the-Nation_pages.pdf (last visited Feb. 27, 2024).

[100] Genesis 1:27.

race, religion, or any other characteristic—has infinite value. This value cannot be invalidated. Scripture also commands that Christians love their neighbors as themselves.[101] Amici accordingly believe that all women and their unborn children deserve protection from the deadly abortion drug regimen. Thus, these women and children must be protected from the dangers of mifepristone. But the FDA instead abandoned them when it arbitrarily removed vital safeguards for the dispensing of the drug. This must be remedied.

CONCLUSION

The FDA failed millions of women and their unborn children when it eliminated necessary safeguards for mifepristone at the insistence of the abortion industry. Even with safeguards in place, medication abortion caused severe damage to the physical and mental health of women, while ending the lives of children. It also allowed criminals to access pregnancy-ending medications for their unwilling victims. And now that the FDA has removed any semblance of safety protocols for medication abortion, women face even greater risks. Women and their unborn children alone will bear the costs of the FDA's irresponsible deregulation of medication abortion.

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[101] Mark 12:31.

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 Amici Curiae

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