No. 23-10362

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.

On Appeal from the United States District Court for the Northern District of Texas, Amarillo Division
No. 2:22-cv-00223-Z, Hon. Matthew J. Kacsmaryk

BRIEF FOR *AMICUS CURIAE* CHARLOTTE LOZIER INSTITUTE IN SUPPORT OF APPELLEES

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SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

No. 23-10362
Alliance for Hippocratic Medicine, et al. v. Food & Drug Administration, et al. v. Danco Laboratories, L.L.C.

Pursuant to 5th Cir. R. 29.2, the undersigned counsel of record hereby certifies that, in addition to the persons and entities listed in the Appellants', Intervenor-Appellant's, and Appellees' Certificates of Interested Persons, and in *amicus curiae*'s accompanying Motion for Leave to File Brief and Exceed Word Limit, the following listed persons and entities as described in the fourth sentence of 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.

Amicus Curiae:
Charlotte Lozier Institute

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In accordance with Federal Rule of Appellate Procedure 26.1, *amicus curiae* Charlotte Lozier Institute states that it is not publicly traded and has no parent corporations. No publicly traded corporation

owns 10% or more of *amicus*. The legal name of *amicus* Charlotte Lozier Institute is the Susan B. Anthony List Inc. Education Fund, a 501(c)(3) charitable nonprofit that is separate from the Susan B. Anthony Pro-Life America, a 501(c)(4) social-welfare entity.

/s/ Gene C. Schaerr
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IDENTITY AND INTEREST OF *AMICUS CURIAE* AND SOURCE OF AUTHORITY TO FILE BRIEF

Charlotte Lozier Institute (CLI) is a nonprofit research and education organization committed to bringing modern science to bear in life-related policy and legal decision-making. CLI believes that laws governing abortion should be informed by the most current medical and scientific knowledge on human development.

Amicus is authorized to file this brief by Fed. R. App. P. 29(a)(2) because all parties have consented to its filing.

RULE 29(a)(4)(e) STATEMENT

Amicus hereby states that no party's counsel authored this brief in whole or in part; that no party or party's counsel contributed money that was intended to fund the preparation or submission of the brief; and that no person other than *amicus* or its counsel contributed money that was intended to fund the preparation or submission of the brief.

SUMMARY OF ARGUMENT

As a matter of sound medical science, the district court's decision was correct, and thus this Court should affirm that decision. Ironically, the U.S. Food & Drug Administration (FDA) claims that it correctly deemed mifepristone and its regulations "safe and effective." FDA Br. at 4.[1] But the data–both available and unavailable–seriously undermine this claim.

FDA and Danco are wrong, for example, in claiming that chemical abortion is generally safe and that adverse events are rare. That conclusion ignores the unavailability of accurate abortion data, the lack of any systematic method for reporting complications, and the documented serious side effects and risks of chemical abortion, including the fact that surgical abortion is actually safer than chemical abortion.

The FDA's 2016 and 2021 changes exacerbate these problems by removing the few protections that previously existed for pregnant women. The FDA's new regulations now allow women to obtain mifepristone via telemedicine and the mail and to use mifepristone up to

[1] U.S. Food & Drug Admin., *Benefit-Risk Assessment In Drug Regulatory Decision-Making: Draft PDUFA VI Implementation Plan (FY 2018-2022)* (Mar. 30, 2018), https://tinyurl.com/5yx2n36k.

70 days' gestation rather than the seven weeks previously allowed. The removal of these protections is not based on a comprehensive risk assessment, or sound science.

First, very few studies support increasing the use of mifepristone to 70 days' gestation. And many studies document higher failure rates of mifepristone at later gestational ages.

Second, the adverse consequences of telemedicine chemical abortion are almost too numerous to count—the lack of necessary ultrasounds to confirm gestational age and rule out ectopic pregnancy; the inability to confirm that a woman is not being coerced to obtain an abortion; the abandonment of women to deal with the medical and psychological repercussions of abortion by herself, with no follow-up; and the grave harm to physicians who are expected to clean up the mess (in the ER and elsewhere) of self-managed abortion.

Third, allowing women to obtain abortion pills by mail ignores the risks that women will not take the pills in the appropriate timeframe and that sex traffickers will confiscate the pills and stockpile them for future, unauthorized use.

In short, the FDA's 2016 and 2021 changes to mifepristone authorization were based on a selective review of the data, not a review of all of "the available scientific evidence." FDA Br. at 47. And it is these changes, not the district court's injunction (*id.* at 2), that harm women. Accordingly, the district court's injunction should be affirmed.

ARGUMENT

I. Contrary to the FDA's claims, the science does not show that chemical abortion is generally safe for women.

The premise of both the FDA's and Danco's brief is that the FDA's determination that mifepristone is "safe and effective" should not be disturbed or even questioned. FDA Br. at 1; Danco Br. at 1. Both the FDA and Danco also emphasize that the district court's order was "unprecedented." FDA Br. at 1; Danco Br. at 1. What the FDA and Danco ignore, however, is that abortion drugs are unlike any other type of drug because they are used to terminate life rather than cure an illness, and because claims about the purported safety of *any* method of abortion rest on a shaky scientific foundation.

A. The prevailing notion that all legal abortion is extremely safe is based on deficient data and skewed studies.

Before discussing the safety claims surrounding chemical abortions, it is important to contextualize the question in this case within the larger framework of the claims about abortion's safety generally.

To start, the pervasive claim that abortion is safer than other commonly performed procedures, such as wisdom tooth extraction and tonsillectomy, relies upon research by an outspoken abortion advocacy organization, Advancing New Standards in Reproductive Health (ANSIRH), who also claims that abortion at any time in pregnancy is safer than childbirth.[2] But these claims, as well as any others concerning the safety of abortion, rely on unreliable studies and deficient data and thus fall apart under scrutiny.[3]

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[2] Advancing New Standards In Reproductive Health (ANSIRH), *Issue Brief #6, December 2014, Safety of abortion in the United States*, https://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf.

[3] James Studnicki et al., *Improving the Metrics and Data Reporting for Maternal Mortality: A Challenge to Public Health Surveillance and Effective Prevention*, 11 Online J. Pub. Health Informatics e17 (2019) (hereinafter "Studnicki et al., *Improving Metrics*"); Ingrid Skop, *Abortion safety at home and abroad*, 34 Issues L. & Med. 43 (2019).

The first data deficiency is that even the number of abortions that take place each year in the United States is unknown. Because of voluntary state reporting, privacy concerns, and the fact that many women pay out of pocket for abortions, there is no accurate central governmental database tracking abortions. In the most recent year calculated (2020), the U.S. Centers for Disease Control (CDC) reported 620,327 abortions based on data from state health departments.[4] But the Guttmacher Institute, based on data directly from abortion providers, reported 930,160 abortions for that same year—about 50% more than the CDC.[5]

Second, the number of abortion-related complications is also unknown. Only about half of the states (28) require abortion providers to report their complications, and in those states, there is rarely robust oversight or an enforced penalty for noncompliance.[6] Just a quarter of

[4] Katherine Kortsmit et al., CDC, *No. SS-10, Abortion Surveillance—United States, 2020*, 71 Morbidity & Mortality Wkly. Rep. 1, 1 (Nov. 25, 2022).

[5] Rachel K. Jones et al., Guttmacher Inst., *Abortion incidence and service availability in the United States, 2020*, 54 Persp. Sexual & Reprod. Health 128, 131 & tbls. 1, 2, 3 (2022), https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12215.

[6] Guttmacher Inst. *Abortion Reporting Requirements* (current as of Feb. 1, 2023), https://www.guttmacher.org/state-policy/explore/abortion-reporting-requirements (last visited Feb. 10, 2023).

the states require other physicians, coroners, or emergency rooms to report abortion-related complications or deaths for investigation.[7] Thus, we can safely assume that abortion complications are substantially underreported.

Abortion complications are underreported for another reason—improper diagnostic coding. For example, a frequently referenced 2015 study performed by prominent abortion advocates from ANSIRH reported that only 0.87% of 54,911 women receiving abortions financed through California's Medicaid program presented to an emergency room with an abortion complication within six weeks of the abortion.[8] However, a similar but larger records-linkage study of 423,000 Medicaid-financed abortions in 17 states found that by 2015, approximately 2.2% of the women who had a surgical abortion, and 5.2% of the women who

[7] Tessa Longbons, Charlotte Lozier Inst., *Analysis: FDA Decision Ignores Data on Complications, Puts Women at Risk* (Dec. 16, 2021), https://lozierinstitute.org/analysis-fda-decision-ignores-data-on-complications-puts-women-at-risk/.

[8] Ushma D. Upadhyay et al., *Incidence of emergency department visits and complications after abortion,* 125 Obstetrics Gyn. 175, 175 (2015).

had a chemical abortion, presented to an ER with a complication within 30 days of the abortion.[9]

What accounts for the disparity between these two results? ANSIRH's study only recorded complications with a diagnostic code specifically related to abortion.[10] But the researchers in the larger records-linkage study looked at all diagnostic codes related to pregnancy complications.[11] This latter method is much more reliable because all of the women in the study had recent documented abortions, and thus all pregnancy complications within 30 days of that abortion were likely caused by the abortion, even if not specifically coded as such. The researchers in the records-linkage study also documented that 60% of known chemical abortion-related ER visits in 2015 were miscoded as miscarriages, which directly contradicts the FDA's claim that "[t]he rate

[9] James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015*, 8 Health Serv. Rsch. Mgmt. Epidemiology 1 (2021) (hereinafter "Studnicki, *Cohort Study*").

[10] Upadhyay, *supra* note 8.

[11] European Comm'n, *Record linkage* (May 8, 2019), https://ec.europa.eu/eurostat/cros/content/record-linkage_en ("Record linkage is the task of finding records in a data set which refer to the same entity across different Data sources.").

of emergency room presentation" following chemical abortion is "low."[12] FDA Br. at 24.

Even more concerning is that the number of abortion-related maternal deaths (deaths that occur within a year of an abortion) is unknown. It is well established that the CDC has incomplete statistics regarding abortion-related maternal mortality because most of their data come from death certificates, which often fail to document prior pregnancies, especially early pregnancies that end in abortion or miscarriage.[13] Even if related to childbirth, at least 50% of maternal deaths are not reported as pregnancy related on death certificates.[14] Thus, there are deficiencies in the calculations of both maternal deaths and abortion-related maternal deaths.

Even when maternal deaths are properly documented, the numbers are misleading because of differing definitions of the term. For example,

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[12] Studnicki, *Cohort Study*, *supra* note 9.

[13] Studnicki et al., *Improving Metrics*, *supra* note 3; Patrick J. Marmion & Ingrid Skop, *Induced Abortion and the Increased Risk of Maternal Mortality*, 87 Linacre Q. 302 (2020); Tara C. Jatlaoui et al., CDC, *Abortion Surveillance—United States, 2015*, 67 Morbidity & Mortality Wkly. Rep. 1 (Nov. 23, 2018).

[14] Isabelle L. Horon, *Underreporting of maternal deaths on death certificates and the magnitude of the problem of maternal mortality*, 95 Am. J. Pub. Health 478 (2005); Catherine Deneux-Tharaux et al., *Underreporting of pregnancy-related mortality in the United States and Europe*, 106 Obstetrics Gyn. 684 (2005).

the World Health Organization (WHO) and the CDC's National Vital Statistics System (NVSS) define maternal mortality as a pregnancy-related death occurring within six weeks of a pregnancy.[15] But the CDC's Pregnancy Mortality Surveillance System (PMSS) defines maternal mortality as a pregnancy-related death occurring until one year after the pregnancy ends.[16]

Quantifying the more specific number of abortion-related deaths is equally difficult.[17] An "abortion-related death" is defined as any death from a direct complication of an induced abortion (legal or illegal), an indirect complication caused by a chain of events initiated by an abortion, or an aggravation of a preexisting medical condition by the physiologic or psychologic effects of abortion.[18] Unlike maternal deaths that have a

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[15] World Health Org., *The WHO Application of ICD-10 to deaths during pregnancy, childbirth and the puerperium: ICD-MM* 25–27 (2012) (the WHO application of ICD-10 to deaths during pregnancy, childbirth and the puerperium: ICD MM), https://apps.who.int/iris/bitstream/handle/10665/70929/9789241548458_eng.pdf; Donna L. Hoyert, Div. of Vital Stats., Nat'l Ctr. for Health Stats., *Maternal Mortality Rates in the United States, 2020* (Feb. 2022), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/E-stat-Maternal-Mortality-Rates-2022.pdf.

[16] Emily Petersen et al., CDC, *Vital Signs: Pregnancy-Related Deaths, United States, 2011-2015, and Strategies for Prevention*, *13 States, 2013–2017*, 68 Morbidity & Mortality Wkly. Rep. 423 (2019), https://tinyurl.com/377mya5m.

[17] Ingrid Skop, *Handbook of Maternal Mortality: Addressing the U.S. Maternal Mortality Crisis, Looking Beyond Ideology*, Charlotte Lozier Inst. (Jan. 6, 2023) (hereinafter "Skop, *Handbook*").

[18] *Id.*

temporal limitation, however, there is no time limit in the definition of "abortion-related death."[19] There is thus no consistent categorization of these types of deaths.[20]

The poor collection of induced abortion data in the U.S. means that abortion-related deaths are unlikely to be identified, much less thoroughly investigated.[21] As a result, obtaining raw numbers for a proper analysis of the connection between abortion and maternal death is extremely difficult, and the FDA's bold claim about that connection must be viewed with suspicion.[22] *See* FDA Br. at 42 ("As of June 2022, only 28 deaths had been reported among the millions of women who have taken mifepristone.").

All in all, analyzing the safety of abortion is complicated given the significant shortcomings in the data concerning abortion complications and maternal deaths. The most accurate data come from records-linkage

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[19] *Id.*

[20] *Id.*

[21] Katherine Kortsmit et al., CDC, *No. SS-9, Abortion Surveillance—United States, 2019*, 70 Morbidity & Mortality Wkly. Rep. 1 (Nov. 26, 2021), https://www.cdc.gov/mmwr/volumes/70/ss/ss7009a1.htm.

[22] Skop, *Handbook*, *supra* note 17.

studies, and those studies undermine the bold claims about the purported safety of abortion.

B. The effects of chemical abortion are not adequately understood.

The FDA and Danco disregard the myriad problems regarding claims about abortion's safety in general and instead myopically zone in on the supposed safety of chemical abortion. The FDA and Danco claim throughout their briefs (over a dozen times) that serious adverse events following mifepristone use are rare. FDA Br. at 8, 14, 20, 24, 26, 33, 34, 41, 47, 52, and 67; Danco Br. at 9, 17, 18, and 21. But, as with claims about abortion's safety in general, the more specific claims about the safety of chemical abortion are undermined by deficiencies in the data on which these parties rely. There is no accurate tracking of adverse events and complications following chemical abortion**,** and thus the effects of chemical abortion are understudied. And in some cases, the effects have not been studied at all.

As to the understudied effects: An estimated 3.7 million chemical abortions occurred between 2000 and 2018.[23] If the rate of adverse events is conservatively estimated at 2% (as reported by abortion advocates), then one would anticipate approximately 74,000 reported complications. Yet two analyses examining the FDA's mandated adverse event reports (AERs) from 2000 to 2019 obtained by Freedom of Information Act (FOIA) requests showed only 3,804 AERs, suggesting the FDA received reports on fewer than 5% of the estimated adverse events.[24]

Data from Planned Parenthood, which performs approximately 40% of abortions in the U.S., casts further doubt on the accuracy of the FDA's AERs. Planned Parenthood published a study reporting 1,530 significant adverse events following chemical abortion over a two-year period.[25] Planned Parenthood defined "significant adverse events" as emergency room evaluation, hospital admission, blood transfusion,

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[23] U.S. Food & Drug Admin., *RCM# 2007-525, NDA 20-687, Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018*, https://www.fda.gov/media/112118/download.

[24] Am. Ass'n of Pro-Life Obstetricians & Gynecologists, *Comm. Op., No. 9, Dangers of Relaxed Restrictions on Mifepristone* (Oct. 2021), https://aaplog.org/wp-content/uploads/2021/11/CO-9-Mifepristone-Restrictions-1.pdf.

[25] Kelly Cleland et al., *Significant adverse events and outcomes after medical abortion*, 121 Obstetrics Gyn. 167 (2013).

intravenous antibiotics administration, ongoing pregnancy, undiagnosed ectopic pregnancy, and death. The definition did not include failed chemical abortions that require surgery. Nonetheless, the 1,530 adverse events are more than double the total number of adverse events published in the FDA's AERs database in the same two years.[26] Whether Planned Parenthood failed to report all of their complications to the FDA, or whether the FDA failed to provide all of its reports in response to the FOIA request from which the data are derived, remains unknown.

Regardless, even data showing a higher number of adverse events, like the one from Planned Parenthood, are inaccurate. Many studies documenting low complication rates come from high-volume abortionists (like Planned Parenthood) and thus fail to reflect the quality of all abortion providers in the U.S. Many of these researchers also make the

[26] U.S. Food & Drug Admin., *TTT# 2022-2468, NDA 020687, ANDA 091178, Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022*, https://www.fda.gov/media/164331/download; Christina A. Cirucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Serv. Rsch. Managerial Epidemiology 233339282110689 (2021); Kathi Aultman et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 Issues in L. & Med. 3 (2021); Margaret M. Gary & Donna J. Harrison, *Analysis of severe adverse events related to the use of mifepristone as an abortifacient*, 40 Annals Pharmacotherapy 191 (2006).

unsupported assumption that the large number of women lost in follow-up have had uncomplicated abortions, which likely leads to an underestimation of abortion complications.[27]

This underestimation is also due in part to the many women who are treated in an emergency room following a chemical abortion but not accounted for in statistics regarding complications. The FDA's complication data show that abortion providers performed less than 40% of the surgeries required for failed chemical abortions,[28] demonstrating that many women in medical distress do not return to their abortion provider and instead have subsequent care in emergency rooms or by other providers. Thus, abortion providers are likely unaware of these complications. And, even if abortion providers are aware of complications, most of them do not maintain hospital admitting privileges and thus would be unable to care for hospitalized women.[29]

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[27] Luu Doan Ireland et al., *Medical Compared With Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 Obstetrics Gyn. 22 (2015); Cleland, *supra* note 25; Erica Chong et al., *A prospective, non-randomized study of home use of mifepristone for medical abortion in the U.S.*, 92 Contraception 215 (2015) (hereinafter "Chong, *Home Use Study*").

[28] Aultman, *supra* note 26; Gary & Harrison, *supra* note 26.

[29] James Studnicki et al., *Doctors Who Perform Abortions: Their Characteristics and Patterns of Holding and Using Hospital Privileges*, 6 Health Servs. Rsch. & Managerial Epidemiology 1 (2019).

The result of all of this is that a woman needing care from a different provider is likely to have her complications go unreported. And therefore, it is of little comfort for Danco to say that it is bound "to report serious, unexpected adverse events to FDA," and that providers "can voluntarily report adverse events directly to FDA." Danco Br. 47; *see also* FDA Br. at 53. The reality is that, given present data collection efforts, neither Danco nor abortion providers will ever know about many of these complications.

An additional defect in claims about chemical abortion's safety is that, for certain populations, complications are completely unstudied, not just understudied. Mifepristone, the first drug used in a chemical abortion, is a synthetic steroid that blocks progesterone receptors in the uterus of the woman or girl who consumes it. Although the FDA is required to test medications that are used in children and adolescents, the agency ignored its own rules in its approval of mifepristone, performing no studies focused on girls under the age of 18. Even today, more than two decades after the FDA approved the drug for abortion, no studies specific to the pediatric population have been performed. What is the effect of using an endocrine disruptor that blocks progesterone in a

developing adolescent? Could this impair sexual development or lead to impaired fertility later in life? Does it work differently in an adolescent than an adult woman? No one knows, since the FDA has failed in its duty to answer (or even attempt to answer) these questions.

Although much is unknown about the number of complications following chemical abortion and what specific complications affect adolescents, we do know that the drugs can have devastating and dangerous consequences. And, as discussed next, these consequences merit a more rigorous review.

C. Chemical abortions carry tremendous risks, can result in serious complications, and are more dangerous than surgical abortions.

The FDA and Danco downplay the risks of chemical abortion and claim that chemical abortion is a preferable alternative to surgical abortion. FDA Br. 10, 45, 63–64; Danco Br. 5, 51. But chemical abortions are inherently risky, and surgical abortion is, in fact, safer.

To fairly assess the risks from chemical abortions, it is important to recognize at the outset that even the "normal" side effects of chemical abortion are serious. After taking chemical abortion drugs, the average woman bleeds for nine to sixteen days, and 8% of women will bleed longer

than a month. The side effects of cramping, vaginal bleeding, hemorrhage, nausea, weakness, fever, chills, vomiting, headache, diarrhea, and dizziness occur in most women.[30]

Beyond these "normal" side effects, prevailing practices fail to account for known risk factors and thus endanger women. The American College of Obstetricians and Gynecologists (ACOG) lists the following situations where chemical abortion may be dangerous: hemoglobin < 9.5 g/dL, severe liver, renal, or respiratory disease, uncontrolled hypertension, or cardiovascular disease.[31] In fact, many women suffer from anemia, and these women are likely to have a baseline hemoglobin below the 9.5 g/dL cutoff suggested by ACOG. Yet most chemical abortion protocols do not screen for these disorders and state that blood work is not indicated.[32] The extreme blood loss that can occur with a

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[30] U.S. Food & Drug Admin., *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (current to Jan. 24, 2023), https://tinyurl.com/4fab24zf.

[31]ACOG, *Practice Bulletin No. 225, Medication Abortion Up to 70 Days of Gestation,* 136 Obstetrics Gyn. e31 (2020), https://tinyurl.com/r4cuwyhe.

[32] Ingrid Skop, *The "No-Test Medication Abortion" Protocol: Experimenting with Women's Health*, Charlotte Lozier Inst. (July 30, 2020), https://lozierinstitute.org/the-no-test-medication-abortion-protocol-experimenting-with-womens-health/. *See also* U.S. Food & Drug Admin., *Approved Risk Evaluation and Mitigation Strategies (REMS), Mifepristone, REMS Materials*, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.

chemical abortion may bring an anemic patient perilously close to hemodynamic compromise—that is, an inability for her compromised blood supply to sustain her body.

On top of these known side effects and risk factors, research suggests that mifepristone itself may cause additional complications of hemorrhage, infection, and mental health issues through direct pharmacologic effects. Mifepristone impairs the ability of the spiral arterioles in the uterus to contract, predisposing women to excessive blood loss.[33] The drug also blocks glucocorticoid receptors, which may contribute to an impaired inflammatory response, increasing the risk of infection and sepsis.[34] In addition, mifepristone releases inflammatory cytokines, which have been identified as contributing to depression. In a rat model, the group of pregnant rats given mifepristone had significantly decreased body weight, food intake, locomotor-related activity, and

[33] Malin Helmestam et al., *Mifepristone-Exposured Human Endometrial Endothelial Cells In Vitro*, 21 Repro. Scis. 408 (2014).

[34] Marc Fischer et al., *Fatal toxic shock syndrome associated with Clostridium sordellii after medical abortion*, 353 New Eng. J. Med. 2352 (2005); Ralph P. Miech, *Pathophysiology of mifepristone-induced septic shock due to Clostridium sordellii*, 39 Annals Pharmacotherapy 1483 (2005); David M. Aronoff et al., *Misoprostol impairs female reproductive tract innate immunity against Clostridium sordellii*, 180 J. Immunology 8222 (2008).

sucrose consumption, which are all animal proxies for depression and anxiety.[35]

Another serious complication of chemical abortion is abortion failure—when the abortion pills fail to kill the embryo/fetus or fail to expel all of the embryo/fetus and placenta from the uterus. And international systematic reviews and records-linkage studies in countries with more robust recordkeeping demonstrate high failure rates for chemical abortion. For example, a systematic review of 45,000 abortions documented that almost 5% of chemical abortions failed, requiring surgery, and 1% of chemical abortions failed to kill the fetus.[36] In another review of 18,000 chemical abortions, nearly 8% of first-trimester abortions and 38% of second-trimester abortions failed, and all of these failures required surgery to complete the abortion.[37]

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[35] Christina Camilleri et al., *Biological, Behavioral and Physiological Consequences of Drug-Induced Pregnancy Termination at First-Trimester Human Equivalent in an Animal Model*, 13 Frontiers in Neurosci. 544 (2019).

[36] Elizabeth G. Raymond et al., *First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review*, 87 Contraception 26 (2013). *See also* Maarit J. Mentula et al., *Immediate adverse events after second trimester medical termination of pregnancy: Results of a nationwide registry study*, 26 Hum. Reproduction 927 (2011); Melissa J. Chen & Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, 126 Obstetrics Gyn. 12 (2015); Maarit Niinimäki, *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics Gyn. 795 (2009).

[37] Mentula, *supra* note 36.

The FDA argues (at 41) that abortion failure is not "a complication" but rather "ineffective treatment" that requires surgery as an "alternative treatment." But surgical intervention following a failed abortion is vastly different from having a surgical abortion in the first instance. If a woman first pursues a medication abortion then has surgery, her fetus will have a higher gestational age because of the lapse in time. And abortion becomes more dangerous as the gestational age increases. One study documented a 38% increase in the risk of maternal death for each additional week of gestation.[38] Further, retained pregnancy tissue can contribute to infection, potentially leading to scar tissue development (Asherman's Syndrome), which may lead to future infertility or pregnancy complications.[39] Similarly, women who need surgical completion of medical abortion face an increased risk of early delivery of a subsequent pregnancy.[40] Additionally, if the medication abortion fails and the woman decides to continue her pregnancy, her

[38] Linda A. Bartlett et al., *Risk Factors for Legal Induced Abortion-Related Mortality in the United States,* 103 Obstetrics & Gynecology 729, 729 (2004), https://pubmed.ncbi.nlm.nih.gov/15051566/.

[39] Collin Smikle et al., *Asherman Syndrome* (2022), https://www.ncbi.nlm.nih.gov/books/NBK448088/.

[40] Hua Liao et al., *Repeated Medical Abortions and the Risk of Preterm Birth in the Subsequent Pregnancy*, 284 Archives of Gynecology & Obstetrics 579 (2011).

fetus faces a higher risk of having birth defects due to exposure to misoprostol (the drug taken after mifepristone for a medication abortion).[41]

It is not just the medical risks that are higher for women who need surgery following medication abortion. Surgical intervention also increases the cost of abortion. One international study found that required surgical removal of retained pregnancy tissue doubled the cost of the abortion.[42] And one-third of the women who had medication abortions in that same study needed additional medications due to continued bleeding, which increased the cost of the abortion by 62%.[43] Given the serious medical risks and increased costs of failed chemical abortion, the FDA's callous dismissal of surgical intervention as simply an alternative treatment is deeply concerning.

Finally, there is an alarming increase in the number of women visiting the emergency room following a chemical abortion. One

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[41] Catherine Vauzelle et al., *Birth Defects After Exposure to Misoprostol in the First Trimester of Pregnancy: Prospective Follow-Up Study*, 36 Reproductive Toxicology 98 (2012).

[42] Wei Xia et al., *Medical versus Surgical Abortion Methods for Pregnancy in China: A Cost-Minimization Analysis*, 72 Gynecologic & Obstetric Investigation 257, 260 tbl. 4 (2011).

[43] *Id.* at 262.

longitudinal study showed a 507% increase in the rate of incidents related to chemical abortion from 2002 to 2015 (the period when chemical abortions were penetrating the Medicaid population).[44] Additionally, by 2015, more than 35% of chemical abortions resulted in an ER visit within 30 days. This trajectory is cause for alarm, especially as chemical abortion becomes more prevalent and easier to access.

Given all of the complications discussed above, it is unsurprising that the most reliable data available show that chemical abortion is more dangerous than surgical abortion. Indeed, a records-linkage review of 42,000 early abortions documented four times as many complications after chemical abortion (20%) than surgical abortions (5.6%). The most common complications were hemorrhage (15.6% for chemical abortion and 2.1% for surgical abortion) and retained pregnancy tissue (6.7% for chemical abortion and 1.6% for surgical abortion). And 5.9% of the

[44] Studnicki, *Cohort Study*, *supra* note 9. In response to Plaintiffs' motion for preliminary injunction, the FDA criticizes this study by stating that "[t]here are many reasons why patients seek ER care." Defs.' Opp'n to Pls.' Mot. for Prel. Inj. at 36, *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223-Z (N.D. Tex.), ECF No. 28. The FDA ignores that (1) these ER visits occurred within 30 days of the chemical abortion, making it highly unlikely that the visit was unrelated to the abortion, and (2) the steep increase in the number of women seeking ER care following a chemical abortion over the 16-year period of the study is by itself concerning.

women undergoing chemical abortions required surgery to complete the abortion.[45] Another study also showed that women who had chemical abortions faced complications four times as often as women who had surgical abortion.[46]

When it comes to ER visits, chemical abortion is also more dangerous than surgical abortion. ER visits properly coded as abortion related are twice as high for chemical abortions as for surgical abortions.[47] And abortion complications that are miscoded as miscarriages are nearly four times as high for chemical abortions as for surgical abortions.[48] Miscoded women in the ER following a chemical abortion who are subsequently admitted to the hospital are also more than twice as likely to be admitted for surgical removal of "retained products of conception" (86.4% for miscoded chemical abortion versus 34.2% for miscoded surgical abortion).[49]

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[45] Niinimäki, *supra* note 36.

[46] Upadhyay, *supra* note 8.

[47] Studnicki, *Cohort Study*, *supra* note 9.

[48] *Id.*

[49] James Studnicki et al., *A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization*, 9 Health Servs. Rsch. Managerial Epidemiology 1 tbl. 1 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9130799/.

Without acknowledging any of these data, the FDA and Danco *assume* that chemical abortion is preferable simply because it is not a surgery. FDA Br. at 46, 63–64; Danco Br. at 51. Indeed, it is telling that, rather than engaging with these data, the FDA only claims that surgical abortion might be unavailable for "some patients" who are allergic to anesthesia and that surgical abortion may be impractical because of "travel costs." FDA Br. 63–64. An argument based on speculation and convenient access is not a sound safety determination. Additionally, when incomplete abortion occurs requiring surgery, the surgery is often performed in emergent conditions which will cause the procedure to be more difficult than if it were performed non-emergently. The presumed contraindications to surgery will still exist and may be more likely to cause harm when addressed in an emergency.

The FDA and Danco are also incorrect to say that limiting access to mifepristone will burden the healthcare system because patients who seek surgical abortions will "face long waits." FDA Br. at 65; Danco Br. at 60. The number of providers per abortion has significantly increased over the past few decades and remains much higher than pre-*Roe* or even

pre-*Casey* levels.[50] Thus, there are now more providers per abortion than there were before chemical abortion was available. And, given the increased medical risks of chemical abortion over surgical abortion, removing or limiting chemical abortions may put *less* of a strain on the healthcare system overall.

In sum, chemical abortions present significant safety concerns—even greater than for surgical abortions. For that reason alone, the district court was right to enjoin the FDA's 2016 and 2021 relaxations of its prior regulatory regime.

II. The FDA's 2016 and 2021 changes pose additional dangers to women.

Given the deficiencies in the studies the FDA has relied on to claim these drugs are safe, the history of the FDA's regulation of chemical abortion drugs from 2016 on is even more troubling. In 2016, the FDA extended use of chemical abortion drugs until 70 days' gestational age and changed the reporting requirements so that abortion providers no longer need to report *any* complication unless it resulted in a woman's

[50] Jeff Diamant & Besheer Mohamed, Pew Rsch. Ctr., *What the data says about abortion in the U.S.* (Jan. 11, 2023), https://tinyurl.com/2yfff6kp.

death—even though, as explained above, there was already an underreporting problem for such complications.[51]

In December 2021, the FDA permanently removed the requirement that a pregnant woman see a physician in person before and after obtaining the chemical abortion drugs. Under the new rules, a woman can obtain mifepristone without in-person examination, sonogram, or laboratory analysis, and physicians can prescribe the drugs via telemedicine.[52] The drugs can also now be sent to a pregnant woman in the mail rather than obtained by her in person in a medical setting. While the FDA claims "the available scientific evidence supported each change," FDA Br. at 47, these changes were scientifically *unjustified* and pose unacceptable dangers to pregnant women.

A. Allowing women to use abortion drugs past 7 weeks' gestation is dangerous.

Starting with the 2016 changes, the FDA decided to increase the

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[51] U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (current as of Jan. 4, 2023), available at https://tinyurl.com/4jx2vdrx (last visited Feb. 9, 2023); U.S. Gov't Accountability Off., *GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (Mar. 2018), https://www.gao.gov/assets/gao-18-292.pdf (report to Congressional Requesters).

[52] Pam Belluck, *F.D.A. Will Permanently Allow Abortion Pills by Mail*, N.Y. Times (Dec. 16, 2021), https://www.nytimes.com/2021/12/16/health/abortion-pills-fda.html.

timeframe in which women can take abortion drugs to 70 days' gestational age despite very few studies supporting such a change and the documented higher failure rates in later gestational ages.[53] One study showed that extending chemical abortion to 10 weeks results in far higher failure rates in the higher gestational ages because of the increased amount of pregnancy tissue (i.e., a larger developing fetus) that must be expelled from the uterus.[54] Another study, a systematic review of 33,000 chemical abortions, documented fewer than 2% failures under 7 weeks' gestation—the cutoff before the 2016 changes. But this number more than tripled (to 7%) by 10 weeks' gestation.[55]

The FDA's 2016 rule that prescribers report only deaths exacerbates the problem.[56] As a result of that rule, any increase in failure rates will not be adequately documented. Nor will other complications, even the most serious ones. The data regarding abortion-related complications is already underinclusive, and thus the lack of reporting

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[53] Beverly Winikoff et al., *Extending outpatient medical abortion services through 70 days of gestational age*, 120 Obstetrics Gyn. 1070 (2012) (hereinafter "Winikoff, *Extending Services*").

[54] *Id.*

[55] Chen & Creinin, *supra* note 36.

[56] Aultman, *supra* note 26.

requirements for chemical abortions only makes it harder to assess their safety.

B. Allowing women to obtain abortion drugs without an in-person visit with a physician is dangerous.

The FDA's 2021 changes are even more problematic. The FDA justified the removal of the requirement that a pregnant woman undergo an in-person visit with a physician using studies that purportedly found similar outcomes after comparing telemedicine abortions to in-person abortions. *See* FDA Br. at 54; Danco Br. at 47–48. But many of the "telemedicine" abortions in these studies implemented standard pre-abortion screening, including physical exam, ultrasound, and labs.[57] In other words, these studies did not look at true telemedicine abortions (the type that the 2021 changes permit), i.e., where the woman is never seen by a physician in person and thus does not have an ultrasound, physical,

[57] Chong, *Home Use Study*, *supra* note 27; Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130 Obstetrics Gyn. 778 (2017); Elizabeth Raymond et al., *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*, 100 Contraception 173 (2019); Erica Chong et al., *Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*, 104 Contraception 43 (2021) (hereinafter "Chong, *Telemedicine Abortion*"); Ushma D. Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, 4 JAMA Network Open e2122320 (2021); Daniel Grossman et al., *Medication Abortion With Pharmacist Dispensing of Mifepristone*, 137 Obstetrics Gyn. 613 (2021).

or labs. The supposed "telemedicine abortions" in the studies only differed from in-person abortion in that the abortion pills were provided to the woman by mail or through a local pharmacy instead of directly from the abortion provider during an in-person visit. Accordingly, the studies capture none of the risks of eliminating the pre-abortion, in-person visit. Of equal concern is that the studies often contained large groups of women for whom there was no follow-up,[58] and thus any subsequent complications went undocumented. Despite their numerous flaws, these studies are often cited as proof that the lack of in-person screening is safe.

Further, as shown below, telemedicine chemical abortion removes the necessary ultrasounds, compromises informed consent, amplifies concerns about coercion, abandons women to self-manage their abortions and any resulting complications, and harms physicians and the medical

[58] For example, in many of the studies the FDA relied on for the 2016 and 2020 changes, a substantial number of women were lost to follow up. Philip Goldstone et al., *Early Medical Abortion Using Low-Dose Mifepristone Followed by Buccal Misoprostol: A Large Australian Observational Study*, 197 Med. J. Austl. 282 (2012) (17% of women lost to follow up); Chong, *Telemedicine Abortion, supra* note 57 (13% of women lost to follow up); Mary Gatter et al., *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days,* 91 Contraception 269, 273 tbl. 5 (2015) (16% of women lost to follow up); Dina Abbas et al., *Outpatient Medical Abortion Is Safe and Effective Through 70 Days Gestation*, 92 Contraception 197, 198 tbl. 1 (2015) (14% of women lost to follow up).

profession. Neither the FDA nor Danco acknowledges or addresses *any* of these concerns.

1. *Eliminating ultrasounds*

The FDA, for example, claims that it justifiably decided to defer to medical providers regarding whether to date a pregnancy or diagnose ectopic pregnancy via ultrasound. FDA Br. at 44. But this deference is problematic for at least three reasons.

First, ultrasounds are the most accurate way to diagnose ectopic pregnancy, which pose perhaps the greatest health risk to women receiving chemical abortions. ACOG's website lists many common risk factors for ectopic pregnancies: previous pelvic or abdominal surgery, sexually transmitted infections, pelvic inflammatory disease, endometriosis, cigarette smoking, age older than 35 years, history of infertility, and use of artificial reproductive technology. Yet the website also states that half of women with ectopic pregnancies do not have any of these risk factors, so ectopic pregnancy cannot be ruled out merely by

taking a history via telemedicine.[59] And the gold standard for diagnosis of ectopic pregnancy is ultrasound.[60]

If undiagnosed, moreover, ectopic pregnancy poses the most serious complication following unsupervised chemical abortion. Mifepristone and misoprostol will not resolve an ectopic pregnancy because these medications exert their actions on the uterus, allowing the ectopic pregnancy, which exists outside of the uterus, to continue to grow, possibly to the point of tubal rupture, which can lead to catastrophic bleeding and death.[61] Studies have documented that a woman is 30% more likely to die from a ruptured ectopic pregnancy while seeking abortion.[62] If the condition remains undiagnosed, a woman may interpret the warning signs of pain and bleeding as signs that the

[59] ACOG, *FAQs: Ectopic Pregnancy* (Feb. 2018), https://www.acog.org/womens-health/faqs/ectopic-pregnancy.

[60] Jean Bouyer et al., *Risk factors for ectopic pregnancy: a comprehensive analysis based on a large case-control, population-based study in France*, 128 Am. J. Epidemiology 185 (2003); ACOG, *Practice Bulletin No. 175: Ultrasound in Pregnancy*, 128 Obstetrics Gyn. 1459 (2016).

[61] ACOG, *Practice Bulletin No. 193: Tubal Ectopic Pregnancy*, 131 Obstetrics Gyn. 91 (2018); Paul Bryde Axelsson et al., *A ruptured ectopic pregnancy during early termination of pregnancy before ultrasound confirmation*, 182 Ugeskrift Laeger V11190651 (2020).

[62] H.K. Atrash et al., *Ectopic pregnancy concurrent with induced abortion: Incidence and mortality*, 162 Am. J. Obstetrics Gyn. 726 (1990).

chemical abortion pills are working rather than as a sign that her life is in danger.

Undiagnosed ectopic pregnancy leads to many other complications. One study showed that women who received chemical abortion pills outside a medical setting (despite the inability to document pregnancy location and rule out ectopic pregnancy) had a failure rate of 14.6%, which is far higher than the 3-7% generally reported in the chemical abortion literature.[63] This same study documented a rate of 10% ongoing living pregnancies in the study population, which is also far higher than the commonly reported rate of 1%. Additionally, 16.8% of women in the study were lost to follow-up so the complication rates could be under-documented and thus understated.[64]

There can be no doubt that undiagnosed ectopic pregnancy poses a grave risk to a pregnant woman. ACOG's practice bulletin on ectopic pregnancy states: "[T]ubal ectopic pregnancy in an unstable patient is a medical emergency that requires prompt surgical intervention."[65] And,

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[63] Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 Obstetrics Gyn. 771, 775 (2022); Chen & Creinin, *supra* note 36.

[64] Goldberg, *supra* note 63, at 776.

[65] ACOG, *Practice Bulletin No. 193*, *supra* note 61.

while ectopic implantations occur in only 2% of pregnancies, they account for 10-15% of all maternal deaths.[66] Ultrasounds are critical to reducing those risks.

Indeed, a recent publication in the New England Journal of Medicine describes a case of a woman who "presented to the emergency department with severe abdominal pain."[67] She had procured mifepristone and misoprostol from the internet, and then presented at the ER with an undiagnosed ectopic pregnancy. "The patient returned 6 days later with increased pain. Diagnostic laparoscopy revealed a ruptured right tubal ectopic pregnancy."[68] Thus, the risk of undiagnosed ectopic pregnancy is not speculative.

Second, ultrasounds are the only way to detect certain maternal anatomic abnormalities, such as uterine fibroids, septum or unusual orientation, and abnormal placentation. These conditions could complicate the abortion process, potentially placing the woman's life in

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[66] Josie L. Tenore, *Ectopic Pregnancy*, 61 Am. Fam. Physician 1080 (2000), https://www.aafp.org/pubs/afp/issues/2000/0215/p1080.html.

[67] Isabel Beshar et al., *Discovery of an Ectopic Pregnancy after Attempted Self-Managed Abortion*, 388 New Eng. J. Med. 278, 278 (2023), https://www.nejm.org/doi/pdf/10.1056/NEJMc2214213.

[68] *Id.*

danger.[69]

Finally, an ultrasound is generally needed to accurately determine not only gestational health, but also gestational age, underestimation of which will lead to far higher failure rates, resulting in additional complications and medical or surgical interventions.[70] Abortion advocates often assume that a woman will be able to determine her fetus's gestational age based on her last menstrual period, but women frequently miscalculate their fetus's gestational age.[71] And implantation bleeding may lead a woman to assume she had a period when in fact she

[69] ACOG, *Practice Bulletin No. 175*, *supra* note 60.

[70] Mentula, *supra* note 36; Chen & Creinin, *supra* note 36; Winikoff, *Extending Services*, *supra* note 53; Raymond, *supra* note 36. Ultrasounds also detect fetal well-being. That is important because approximately 15% of recognized pregnancies result in early miscarriages. An ultrasound may document the lack of a fetal heartbeat and thus spare a woman an unnecessary abortion.

[71] C. Ellertson et al., *Accuracy of assessment of pregnancy duration by women seeking early abortions*, 355 Lancet 877 (2000); P. Taipale & V. Hiilesmaa, *Predicting delivery date by ultrasound and last menstrual period in early gestation*, 97 Obstetrics Gyn. 189 (2001); David A. Savitz et al., *Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination*, 187 Am. J. Obstetrics Gyn. 1660 (2002). Plus, ACOG cites numerous studies that have documented that ultrasound dating is more accurate than recollection of last menstrual period. ACOG, *Committee Opinion No. 700, Methods for Estimating the Due Date* (May, 2017), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date.

is already pregnant, and the bleeding is just a sign of that pregnancy.[72] Further, increasing obesity rates have led to a higher incidence of polycystic ovarian syndrome, which causes irregular ovulation and menstruation.[73] Because of the inability of many women to determine their gestational age, ultrasound is the most accurate way to lower the risks of complications related to any miscalculations.

One recent lawsuit demonstrates the danger of not confirming gestational age via ultrasound. The plaintiff sued Planned Parenthood because they assumed she was 6 weeks pregnant following a telehealth visit with no physical exam or ultrasound.[74] Planned Parenthood provided the plaintiff with the abortion pills and after taking them, the plaintiff quickly became very ill and then "gave birth to a fully-formed, stillborn baby" "in the toilet covered in mucous, blood, and the

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[72] Mary Marnach, *Is implantation bleeding common in early pregnancy?*, Mayo Clinic (Apr. 19, 2022), https://www.mayoclinic.org/healthy-lifestyle/pregnancy-week-by-week/expert-answers/implantation-bleeding/faq-20058257.

[73] Thomas M. Barber et al., *Obesity and Polycystic Ovary Syndrome: Implications for Pathogenesis and Novel Management Strategies*, 13 Clinical Med. Insights Reproductive Health 1179558119874042 (2019), https://tinyurl.com/5n7kd45m.

[74] Summons & Verified Compl. 5, *Jane Doe v. Meera Shah, M.D., et al.*, Index No. 501531/2021 (N.Y. Sup. Ct., Kings Cnty., Jan. 20, 2021), NYSCEF No. 1, https://www.liveaction.org/news/wp-content/uploads/2022/10/Kings-Co-501531_2021_JANE_DOE_v_MEERA_SHAH.pdf

placenta."[75]

Despite these risks, the FDA now, ironically, justifies the 2016 change to allow mifepristone use through 10 weeks' gestation by relying on studies that confirmed gestational age via ultrasound. FDA Br. at 50. Thus, even if the 2016 change to increase the gestational age was scientifically justified (it was not), the 2021 changes substantially undermine the very safety claims about the 2016 changes on which the FDA now relies.

All in all, the many risks of not having an ultrasound, or even the possibility of an ultrasound, are unacceptable to anyone who truly cares about women's health.

2. *Informed Consent*

In-person visits are also essential to obtaining informed consent. Abortion is unique in that it is a medical procedure that rarely addresses a medical disease. Only 1-3% of abortions are performed to protect the "life or health" of the mother.[76] Nevertheless, because abortion is a medical procedure, it is subject to the doctrine of informed consent, which

[75] *Id.* at 10.

[76] Tessa Longbons, Charlotte Lozier Inst., *Fact Sheet: Reasons for Abortion* (Aug. 17, 2022), https://lozierinstitute.org/fact-sheet-reasons-for-abortion/.

requires a physician to disclose enough about the risks and benefits of proposed treatments that the patient becomes sufficiently informed to participate in shared decision making.[77]

As noted above, the prevailing studies do not recognize the serious risks and complications of chemical abortion. Thus, even before the FDA's relaxation of the rules, women were not hearing the full story of complications and risks. And now, with telemedicine chemical abortion, the FDA has implied to women that abortion is not just safe, but so safe that they do not even need to see a physician in person and can manage their own abortion at home. The availability of telemedicine abortion turns a blind eye to the gravity of abortion and its serious risks, placing a woman's pregnancy on par with the common cold. Then the woman, without ever seeing a doctor, is left alone to deal with the consequences, which are potentially far more severe than a cold.

3. *Coercion*

Telemedicine abortion is also problematic because it is far less effective than in-person consultation to determine that a woman is

[77] Am. Med. Ass'n, *Ch. 2: Opinions on Consent, Communication & Decision Making, in* The AMA Code of Medical Ethics (2019), available at https://www.amaassn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf.

voluntarily taking the abortion pills. Counseling a woman via telemedicine video, or in some cases via audio only, cannot establish that a woman is requesting the abortion pills without coercion. With limited visibility and an inability to detect unspoken body language, there is no way to ensure that an abuser standing off-screen is not pressuring the woman to request an action that she does not desire.[78] Nor is there any way to document that the woman making the request is actually the person who will receive the abortion, or even to document that she is pregnant.[79]

The FDA based its dangerous decision to remove in-person supervision on four telemedicine studies. Of the studied abortions, 92% were performed in the United Kingdom (UK), which preceded the FDA

[78] Ingrid Skop, *Chemical Abortion: Risks Posed by Changes in Supervision*, 27 J. Am. Ass'n Physicians & Surgeons 56 (2022) (hereinafter "Skop, *Chemical Abortion*").

[79] John Joseph Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: A prospective observational cohort study during the COVID-19 pandemic*, BMJ Sex Reprod. Health 1 (2021), https://pubmed.ncbi.nlm.nih.gov/33542062/; Abigail R.A. Aiken et al., *Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study*, 10 Lancet Reg'l Health Am. 100200 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9223776/.

in loosening restrictions.[80] The FDA should have continued to monitor events abroad because, shortly after relaxing restrictions, the UK had a dramatic reversal in its telemedicine abortion policy. On February 24, 2022, the UK's government ended its approval of chemical abortion "pills by post" when it learned of concerns about remote abortion providers' decreased ability to identify domestic abuse and coercion.[81] About 70% of public commenters were concerned that remote provision of abortion pills would have a negative impact on the safety of women seeking abortion, particularly the "risk of women being coerced into an abortion when they are not physically being seen in a service."[82] This concern seemed to be validated when a BBC poll of over 1,000 women ages 15-44 documented that 15% of respondents said they experienced pressure to

[80] Chong, *Telemedicine Abortion*, *supra* note 57; Reynolds-Wright, *supra* note 79; Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 Contraception 49 (2021); A.R.A. Aiken et al., *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: A national cohort study*, 128 BJOG 1464 (2021).

[81] U.K. Dep't of Health & Social Care, *Consultation Outcome, Home use of both pills for early medical abortion (EMA) up to 10 weeks gestation: summary of consultation responses* (Mar. 10, 2022), https://tinyurl.com/49wwc4wz.

[82] Denis Campbell, *England abortion 'pills by post' scheme to be scrapped in September*, The Guardian (Feb. 24, 2022), https://tinyurl.com/4mx8mxdy.

terminate a pregnancy when they did not want to, and 3% reported being given something to cause an abortion without their consent.[83]

A recent U.S. study on abortion and pressure paints an even grimmer picture. The study found that over 60% of women who had abortions reported high levels of pressure to choose abortion from one or more sources, and those same women reported higher levels of mental health and quality of life issues.[84] Another study of the same group found that two-thirds of the women described their abortions as coerced, unwanted, or inconsistent with their values or preferences.[85] Only 33% described their abortions as "wanted."[86]

Telemedicine abortion also raises serious concerns about coercion for victims of sex trafficking. Medical professionals are positioned to

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[83] Alys Harte & Rachel Stonehouse, *Reproductive coercion: 'I wasn't allowed to take my pill'*, BBC (Mar. 14, 2022), https://www.bbc.com/news/newsbeat-60646285; Savanta ComRes for BBC Radio 4, Reproductive Coercion Poll–BBC Radio 4–8 March 2022 (Aug. 3, 2022), https://savanta.com/knowledge-centre/poll/reproductive-coercion-poll-bbc-radio-4-8-march-2022.

[84] David C. Reardon & Tessa Longbons, *Effects of Pressure to Abort on Women's Emotional Responses and Mental Health*, 15 Cureus, (2023), https://www.cureus.com/articles/124269-effects-of-pressure-to-abort-on-womens-emotional-responses-and-mental-health.

[85] David C. Reardon et al., *The Effects of Abortion Decision Rightness and Decision Type on Women's Satisfaction and Mental Health*, 15 Cureus e38882 (2023), https://www.cureus.com/articles/146123-the-effects-of-abortion-decision-rightness-and-decision-type-on-womens-satisfaction-and-mental-health#!/.

[86] *Id.*

serve as first responders when they encounter trafficking victims: they can observe a woman's demeanor, identify signs of trafficking, ask questions, and offer support and resources to help a victim escape.[87] Making abortion pills available via telehealth allows traffickers to limit trafficking victims' access to healthcare professionals, removing this crucial protection for victims.

4. *Follow-up visits*

For all of the reasons above, telemedicine chemical abortion increases risks to women because an in-person consultation with a doctor before obtaining abortion pills and in-person receipt of the pills are much safer. But the dangers of telemedicine abortion do not end with the ingestion of abortion pills; the lack of follow-up visits with a physician further endangers women.

Abortion advocates assert that a follow-up visit following chemical abortion is medically unnecessary. But it is difficult to reconcile that position with ACOG's guidance on chemical abortion, which states that

[87] Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, 23 Health Consequences 61, 87 (2014), https://lawecommons.luc.edu/annals/vol23/iss1/5.

women may not be good candidates for chemical abortion if, among other things, "they are unable or unwilling to adhere to care instructions, desire quick completion of the abortion process, [or] *are not available for follow-up contact or evaluation …*"[88]

In addition, fetal survival continues in 1-3% of women consuming the chemical abortion pills.[89] Prompt diagnosis that the medical abortion did not work will allow these women to obtain a surgical abortion earlier (and more safely) than if there is no follow-up and the diagnosis is made belatedly. Plus, providers prescribing abortion pills should have the ability to treat this frequent complication rather than leaving women to rush to the emergency room. It is patient abandonment to force these women to obtain this care from the overworked emergency room system.

Further, a provider is required to have the ability to conduct surgical intervention in the 3.4–7.9% of cases where chemical abortion fails to expel all of the pregnancy tissue.[90] Without a physician-patient relationship, a woman experiencing these common complications after

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[88] ACOG, *Practice Bulletin No. 225, supra* note 31.

[89] Raymond, *supra* note 36; Winikoff, *Extending Services*, *supra* note 53.

[90] U.S. Food & Drug Admin., *Approved Risk Evaluation and Mitigation Strategies (REMS), Mifepristone, REMS Full* (mod. Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

chemical abortion is likely to find herself abandoned and at high risk for adverse outcomes.[91]

5. *Harms to physicians*

Finally, contrary to the FDA's and Danco's argument that the plaintiffs have only demonstrated speculative injuries, FDA Br. 67, Danco Br. 61, telemedicine chemical abortion results in serious harm to physicians and the medical profession.

When their patients have chemical abortions, obstetricians lose the opportunity to provide professional services and care for the woman and child through pregnancy. Most obstetricians operate under a "two-patient paradigm" because "a physician's ethical duty toward the pregnant woman clearly requires the physician to act in the interest of the fetus as well as the woman."[92] Abortion advocates, however, follow a "one-patient paradigm," whereby the fetus is their second patient only if the mother desires him to be so. These advocates appear to consider pregnancy as a disease and recommend abortion as its treatment because

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[91] Ingrid Skop, *Medical Abortion: What Physicians Need to Know*, 24 J. Am. Physicians & Surgeons 109 (2019); Skop, *Chemical Abortion, supra* note 78.

[92] Helene Cole, *Legal Interventions During Pregnancy: Court-Ordered Medical Treatments and Legal Penalties for Potentially Harmful Behavior by Pregnant Women*, 264 J. Am. Med. Ass'n 2663 (1990).

it eliminates the disease. If this were truly the case, every OBGYN would recommend abortion as an alternative to every pregnant woman, and all OBGYNs would perform abortions. But only a small minority (7-14%) of OBGYNs perform elective abortions.[93] That small number is unsurprising given that treating pregnancy as a disease is contrary to the practice of Hippocratic medicine and the ethical principle that sees every human life as inherently valuable.

This principle, held by the plaintiffs in this case, is not undercut by the fact that leadership at several larger progressive medical organizations support expansive abortion availability. Historical examples demonstrate that large medical organizations are not always the bearers of scientific or moral truth. In the early 1900s, for example, the American Psychological Association (APA) created a Committee on Measurement, which consisted of many psychologists who supported "racial hierarchy and/or eugenics."[94] And the American Medical

[93] Sheila Desai et al., *Estimating abortion provision and abortion referrals among United States obstetrician-gynecologists in private practice*, 97 Contraception 297 (2018); Debra B. Stulberg et al., *Abortion provision among practicing obstetrician-gynecologists*, 118 Obstetrics Gyn. 609 (2011).

[94] Am. Psych. Ass'n, *Historical Chronology* (2023), https://www.apa.org/about/apa/addressing-racism/historical-chronology.

Association (AMA) previously opposed the creation of Medicare.[95] Thus, while abortion advocates point to these organizations as the leaders for acceptable views within the medical community, their history demonstrates that, in many instances, it is appropriate and even necessary to hold contrary views.

Regarding ACOG, its pro-abortion positions are inherently contradictory. For example, ACOG's *Committee Opinion 390*, *Ethical Decision Making in Obstetrics and Gynecology*, reinforces the ethical principle of beneficence, which "requires a physician to act in a way that is likely to benefit the patient. Nonmaleficence is the obligation not to harm or cause injury."[96] It is difficult to understand why ACOG does not apply these principles to fetuses, especially considering that many OBGYNs believe in avoiding harm to a fetus whenever possible—evidenced by the fact that only 7-14% of them will perform elective

[95] Max J. Skidmore, *Ronald Reagan and "Operation Coffeecup": A Hidden Episode in American Political History*, 12 J. Am. Culture 89 (1989), DOI: 10.1111/j.1542-734x.1989.1203_89.x.

[96] ACOG, *Committee Opinion No. 390: Ethical Decision Making in Obstetrics and Gynecology*, 110 Obstetrics Gyn. 1479 (2007, reaff'd 2016), https://tinyurl.com/zzkdhe76.

abortions at all.[97] The chasm between ACOG's pro-abortion statements[98] and their membership's actual medical care and willingness to perform abortions undermines the weight one should attribute to ACOG's pro-abortion position.

In addition, ACOG provides clinical practice guidelines for members that are developed through a peer-review process that generally ensures that the recommendations are based on science.[99] But ACOG has not abided by that standard in its guidance about abortion. ACOG's publications on abortion are crafted by prominent abortion advocates, such as Mitchell Creinin (consultant for Danco,[100] the manufacturer of mifepristone and intervenor in this case) and Daniel Grossman (Director of ANSIRH, a vocal abortion advocacy organization), who collaborated on *Practice Bulletin No. 225 Medical Management Up*

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[97] Desai, *supra* note 93; Stulberg, *supra* note 93.

[98] ACOG, *Statement of Policy, Abortion Policy* (reviewed 2022), https://tinyurl.com/3c53znrz.

[99] ACOG, *Clinical Practice Guideline Methodology*, 138 Obstetrics Gyn. 518 (2021), https://tinyurl.com/2hfxuxct.

[100] Shelly Kaller et al., *Pharmacists' knowledge, perspectives, and experiences with mifepristone dispensing for medication abortion*, 61 J. Am. Pharmacists Ass'n 785 (2021). See Disclosure, *id.* at 785.

to 70 Days Gestation,[101] and (in Grossman's case) who cowrote *Practice Bulletin No. 135: Second-Trimester Abortion.*[102]

For the numerous physicians and pharmacists who disagree with ACOG's pro-abortion position, the FDA's loosened restrictions on mifepristone will pressure, or perhaps force, them to participate in a life-ending action. Even if they decline to prescribe mifepristone, many doctors will be unable to avoid caring for women who have been harmed by chemical abortions when they present to emergency rooms or obstetricians' offices. The consequent feeling of complicity in the act of an elective chemical abortion often causes great emotional suffering, mental anguish, and spiritual distress among these doctors. These objections are both ethical and medical, as they stem from the purpose of medicine itself, which is to heal and not to electively kill human beings, regardless of their location.

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[101] ACOG, *Practice Bulletin No. 225* at e71, *supra* note 31.

[102] ACOG, *Practice Bulletin No. 135: Second-Trimester Abortion*, 121 Obstetrics Gyn. 1394, 1394 (2013). Mr. Grossman is also the Principal Investigator of the clinical trials to test pharmacy dispensation of mifepristone for abortion. U.S. Nat'l Libr. of Med., *NCT03320057, Medication Abortion Via Pharmacy Dispensing*, ClinicalTrials.gov, https://clinicaltrials.gov/ct2/show/NCT03320057 (accessed May 12, 2023).

C. Allowing women to obtain abortion drugs via the mail is dangerous.

Finally, the FDA claims that its decision to remove the in-person dispensing requirement was "the result of a thorough scientific review." FDA Br. at 9; *see also* Danco Br. at 47–48. But once again, the FDA ignores that the mailing of abortions pills, instead of receiving the pills directly from a physician, creates additional risks, as remote distribution fails to account for transit time, the possibility that a woman may wait to take the pills, and the condition of the pills on arrival.

For instance, a woman may decide not to take the pills when they finally arrive (which could be days or weeks after ordering), but then change her mind again and take them later, when the risks of abortion failure and its corresponding complications are much higher. That example is not far-fetched. One study on abortion pills obtained from international distributors found that the pills took on average two weeks to arrive, that some misoprostol pills contained only 15% of the advertised amount of misoprostol, that the packages often arrived damaged, and that none of the packages contained instructions.[103]

[103] Chloe Murtagh et al., *Exploring the feasibility of obtaining mifepristone and misoprostol from the internet*, 97 Contraception 287 (2018).

Abortion pills via the mail also make it easier for traffickers to force women to have unwanted abortions. In one survey of sex trafficking survivors, 55.2% reported having at least one abortion and nearly 30% reported having multiple abortions.[104] Moreover, more than half of the survivors who responded "indicated that one or more of their abortions was at least partly forced upon them."[105] Because under the FDA's 2021 rule the abortion can now happen at home, no medical professionals are present to ensure that a woman is not coerced into the abortion, perhaps even through violent means. And, as noted above, the medical professional who prescribes an abortion pill cannot even guarantee that the pill is ultimately taken by the woman who asked for it. Traffickers could force women to obtain prescriptions so that the traffickers can stockpile abortion pills and coerce other women into taking the pills against their will. Thus, the ability to receive abortion pills by mail puts some of the most vulnerable women at the most risk.

[104] Lederer & Wetzel, *supra* note 87, at 73.

[105] *Id.*

CONCLUSION

In relaxing the regulation of chemical abortion, the FDA has disregarded what is both known and unknown—by dismissing the serious risks and complications of chemical abortion and by relying on flawed studies that do not account for the deficiencies in abortion-complication data—to the detriment of both women and physicians. Thus, contrary to the FDA here, the district court's order was not based "on its own lay interpretation of the scientific evidence." FDA Br. at 40. Rather, the district court took into account the evidence—and the absence of evidence—that the FDA has persistently ignored. For all these reasons, *amicus* respectfully urges the Court to affirm the district court's injunction.

May 12, 2023

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CERTIFICATE OF SERVICE

Pursuant to Fed. R. App. P. 25(d) and 5th Cir. R. 25.2.5, I hereby certify that on May 12, 2023, I filed the foregoing Brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the Court's CM/ECF system; service on counsel for all parties was accomplished by electronic mail or by service through the Court's electronic filing system.

/s/ Gene C. Schaerr
Gene C. Schaerr

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No. 23-10362 Alliance Hippocratic Medicine v. FDA
USDC No. 2:22-CV-223

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Ms. Delia Scoville
Mr. Jordan Dentler Segall
Ms. Shannon Rose Selden
Mr. Michael Francis Smith
Mr. Samuel Spital
Ms. Danielle Desaulniers Stempel
Ms. Catherine Emily Stetson
Mr. Christian D. Stewart
Ms. Simona Strauss
Ms. Eva Temkin
Mr. John F. Walsh III
Mr. John Marc Wheat
Mr. Edward Lawrence White
Ms. Grace Zhou
Ms. Allison M. Zieve