Nos. 22A901, 22A902

In the Supreme Court of the United States

DANCO LABORATORIES, LLC, *Applicant,*

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

FOOD AND DRUG ADMINISTRATION, ET AL., *Applicants,*

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

On Emergency Applications for
Stay of Preliminary Injunction Pending Appeal

BRIEF *AMICUS CURIAE* OF CHARLOTTE LOZIER INSTITUTE IN SUPPORT OF RESPONDENTS AND IN OPPOSITION TO STAY PENDING APPEAL

GENE C. SCHAERR
Counsel of Record
CRISTINA MARTINEZ SQUIERS
SCHAERR | JAFFE LLP
1717 K Street NW, Suite 900
Washington, DC 20006
Telephone: (202) 787-1060
gschaerr@schaerr-jaffe.com

Counsel for Amicus Curiae
Charlotte Lozier Institute

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INTRODUCTION, SUMMARY, AND INTEREST OF *AMICUS CURIAE*[1]

The FDA claims that it based the 2016 and 2021 changes to the mifepristone regulations—the subject of its stay motion in this Court—"on an exhaustive review of" the data. FDA Application at 29. But in fact, the FDA misleadingly cherry-picked certain data to support its changes and ignored the data (or lack thereof) that seriously undermined the rationale for those changes. The FDA's misuse and studied ignorance of the relevant science are of enormous concern to *amicus* Charlotte Lozier Institute (CLI), 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. Yet that is not what the FDA did here.

As a preliminary matter, the FDA claims (at 2, 6, 11, 18) that chemical abortion is generally safe. But 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.

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 70 days' gestation rather than the seven weeks

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, and its counsel, made any monetary contribution toward the brief's preparation or submission.

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 Application at 29. And it is these changes, not the district court's injunction (*id.* at 44), that harm women. Accordingly, the portion of the district court's injunction staying the FDA's 2016 and 2021 actions should not be disturbed.

ARGUMENT

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

In its application, the FDA repeatedly claims that mifepristone is extremely safe. FDA Application at 2, 6, 11, 18. But claims about chemical abortion's purported safety should be viewed with extreme skepticism for several reasons: (1) data about the safety of abortion in general is unreliable, as complications and even deaths are underreported; (2) the effects of chemical abortion are either understudied, because of insufficient data, or unstudied, because of the FDA's own refusal to assess the safety of chemical abortion for minors; and (3) the studies that do exist show that chemical abortions carry significant risks and are, indeed, more dangerous than surgical abortions.

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

As an initial matter, claims about the safety of abortion in general rely on unreliable studies and disregard the inadequate data.[2] Even the number of abortions that take place each year is unknown because of the absence of an accurate central governmental database.[3] The number of abortion-related complications is also

[2] 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).

[3] For example, 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, but the Guttmacher Institute, based on data directly from abortion providers, reported 930,160 abortions in 2020. Katherine Kortsmit et al., *CDC, No. SS-10, Abortion Surveillance—United States, 2020*, 71 Morbidity & Mortality Wkly. Rep. 1, 1 (Nov. 25, 2022); 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.

unknown, as 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.[4] Further, abortion complications are often miscoded as related to miscarriages.[5] Thus, we can safely assume that abortion complications are woefully underreported.[6]

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

Claims about the safety of *chemical* abortion suffer from these same flaws. 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.[7] 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

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[4] 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).

[5] 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*").

[6] The same is true of abortion-related maternal deaths—they are underreported and the quantity of such deaths is unknown. Studnicki et al., *Improving Metrics*, *supra* note 2; 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).

[7] 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.

Information Act (FOIA) requests showed only 3,804 AERs, suggesting the FDA received reports on fewer than five percent of the estimated adverse events.[8] This underestimation of adverse events 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.[9]

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

[8] 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. Further, 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 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. Luu Doan Ireland et al., *Medical Compared With Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 Obstetrics Gyn. 22 (2015); Kelly Cleland et al., *Significant adverse events and outcomes after medical abortion*, 121 Obstetrics Gyn. 167 (2013); 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*").

[9] 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).

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 to answer (or even attempt to answer) these questions. And the FDA does not even acknowledge this shortcoming in its so-called "safety analysis."

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

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.

Indeed, 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 eight percent of women will bleed longer than a month. And most women experience the side effects of cramping, vaginal bleeding, hemorrhage, nausea, weakness, fever, chills, vomiting, headache, diarrhea, and dizziness.[10] On top of these known side effects and risk factors, research suggests that mifepristone itself may cause additional complications of hemorrhage, infection, and depression through direct pharmacologic effects.[11]

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[10] 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.

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

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. International systematic reviews and records-linkage studies in countries with more robust recordkeeping demonstrate high failure rates for chemical abortion.[12] For example, in a study of 18,000 chemical abortions, nearly eight percent of first-trimester abortions and 38% of second-trimester abortions failed, and all of these failures required surgery to complete the abortion.[13]

Finally, there is an alarming increase in the number of women visiting the emergency room following a chemical abortion. One 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).[14] Additionally, by 2015, more than 35% of women who had a chemical abortion had an ER visit within 30 days. This trajectory is especially concerning as chemical abortion becomes more prevalent and easier to access. And it is equally concerning that the FDA does not acknowledge this issue.

Given all of the complications discussed above, it is unsurprising that the most reliable data show that chemical abortion is more dangerous than surgical abortion.

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[12] 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).

[13] Mentula, *supra* note 12.

[14] Studnicki, *Cohort Study*, *supra* note 5.

A records-linkage review of 42,000 early abortions documented four times as many complications after chemical abortion (20%) than surgical abortion (5.6%).[15] Another study showed that women who had chemical abortions faced complications four times as often as women who had surgical abortion.[16]

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.[17] And abortion complications that are miscoded as miscarriages are nearly four times as high for chemical abortions as for surgical abortions.[18] The FDA's erroneous claim that chemical abortion is "a safe and effective alternative" to surgical abortion ignores these concerns. FDA Application at 4.

The FDA is also incorrect to say that limiting access to mifepristone will "unnecessarily burden[] the healthcare system" because patients who seek surgical abortions "will face long waits." *Id.* at 39. 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.[19] Thus, there are now more providers per abortion than there were before chemical abortion was available. What is more, given the increased

[15] Niinimäki, *supra* note 12.

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

[17] Studnicki, *Cohort Study*, *supra* note 5.

[18] *Id.*

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

medical risks of chemical abortion over surgical abortion, removing 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. And 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 death—even though, as explained above, there was already an underreporting problem for such complications.[20]

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.[21] The drugs can also now be sent to a pregnant woman

[20] 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).

[21] 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.

in the mail rather than obtained in person in a medical setting. While the FDA claims "the available scientific evidence supported each change," FDA Application at 29, these changes were 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 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.[22] 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.[23] Another study, a systematic review of 33,000 chemical abortions, documented fewer than 2% failures under seven weeks' gestation—the cutoff before the 2016 changes. But this number more than tripled (to 7%) by 10 weeks' gestation.[24] Like the FDA's stay application (at 29), the FDA decisions under review here do not address these studies.

The FDA's 2016 rule that prescribers report only deaths exacerbates the problem.[25] 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

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

[23] *Id.*

[24] Chen & Creinin, *supra* note 12.

[25] Aultman, *supra* note 9.

regarding abortion-related complications is already underinclusive, and thus the lack of reporting 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 have an in-person visit with a physician using studies that purportedly found similar outcomes after comparing telemedicine abortions to in-person abortions. See FDA Application at 29–30.

But many of the "telemedicine" abortions in these studies implemented standard pre-abortion screening, including physical exam, ultrasound, and labs.[26] In other words, these studies did not look at true telemedicine abortions (the type that the 2021 changes permit) where the woman is never seen by a physician in person and thus does not have an ultrasound, physical, 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. So the studies capture none of the risks of eliminating the pre-abortion, in-person visit. Of equal concern is

[26] Chong, *Home Use Study*, *supra* note 8; 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).

that the studies often contained large groups of women for whom there was no follow-up, 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 provision of 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 profession. The FDA does not acknowledge and address *any* of these concerns.

1. Eliminating ultrasounds

For at least three reasons, ultrasounds—which are unlikely absent an in-person physician visit—are critical to appropriate abortion counseling and care.

First, ultrasounds are the most accurate way to diagnose ectopic pregnancy. The American College of Obstetricians and Gynecologists' (ACOG) 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.[27] The gold standard for diagnosis of ectopic pregnancy is ultrasound.[28]

If undiagnosed, 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.[29] Studies have documented that a woman is 30% more likely to die from a ruptured ectopic pregnancy while seeking abortion.[30] If the condition remains undiagnosed, a woman may interpret the warning signs of pain and bleeding as signs that the 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

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

[28] 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).

[29] 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).

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

the chemical abortion literature.[31] This same study documented a rate of 10% ongoing living pregnancies in the study population, which is also a number 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.[32]

There can be no doubt that undiagnosed ectopic pregnancy poses a grave risk to a pregnant woman. Indeed, 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."[33] And, while ectopic implantations occur in only 2% of pregnancies, they account for 10-15% of all maternal deaths.[34] Ultrasounds are critical to reducing those risks.

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 procedure, potentially placing the woman's life in danger.[35]

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

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[31] Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 Obstetrics Gyn. 771, 775 (2022); Chen & Creinin, *supra* note 12.

[32] Goldberg, *supra* note 31, at 776.

[33] ACOG, *Practice Bulletin No. 193*, *supra* note 29.

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

[35] ACOG, *Practice Bulletin No. 175*, *supra* note 28.

interventions.[36] 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.[37] And implantation bleeding may lead a woman to assume she had a period when in fact she is already pregnant, and the bleeding is just a sign of that pregnancy.[38] Further, increasing obesity rates have led to a higher incidence of polycystic ovarian syndrome, which causes irregular ovulation and menstruation.[39] 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.

All in all, the many risks of not having an ultrasound, or even the possibility of an ultrasound, are unacceptable.

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[36] Mentula, *supra* note 12; Chen & Creinin, *supra* note 12; Winikoff, *Extending Services*, *supra* note 22; Raymond, *supra* note 12. 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.

[37] 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.

[38] 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.

[39] 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.

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.[40] Nevertheless, because abortion is a medical procedure, it is subject to the doctrine of informed consent, which 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.[41]

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 regarding 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.

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

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

3. Coercion

Telemedicine abortion is also problematic because it is far less effective than in-person consultation to determine that a woman is 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.[42] Nor is there any way to document that the woman making the request is the person who will receive the abortion or to document that she is even pregnant.[43]

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 in loosening restrictions.[44] 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,

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

[43] 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/.

[44] Chong, *Telemedicine Abortion*, *supra* note 26; John Joseph Reynolds-Wright et al., *Telemedicine medical abortion at home under twelve weeks' gestation: A prospective observational cohort study during the COVID-19 pandemic*, BMJ Sex Reprod. Health 1 (2021), http://dx.doi.org/10.1136/bmjsrh-2020-200976; 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).

2022, the UK's government ended its approval of chemical abortion "pills by post" when it heard concerns about remote abortion providers' decreased ability to identify domestic abuse and coercion.[45] 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."[46] 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 terminate a pregnancy when they did not want to, and 3% reported being given something to cause an abortion without their consent.[47]

A recent U.S. study on abortion and coercion paints an even grimmer picture. The study found that over 60% of women who had abortions "report high levels of pressure to abort from one or more sources, and those same women report higher levels of subsequent mental health and quality of life issues."[48]

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

[45] 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.

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

[47] 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.

[48] David C. Reardon & Tessa Longbons, *Whose Choice? Pressure to Abort Linked to Worsening of Subsequent Mental Health*, Charlotte Lozier Inst. (Feb. 7, 2023), https://lozierinstitute.org/whose-choice-pressure-to-abort-linked-to-worsening-of-subsequent-mental-health/.

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.[49] 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 women may not be good candidates for chemical abortion "if they are unable or unwilling to adhere to care instructions, desire quick completion of the abortion, *are not available for follow-up contact or evaluation*, or cannot understand the instructions because of comprehension barriers."[50]

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[49] 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.

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

In addition, fetal survival continues in 1-3% of women consuming the chemical abortion pills.[51] 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 provide surgical intervention in the 3.4-7.9% of cases where chemical abortion fails to expel all of the pregnancy tissue.[52] Without a physician-patient relationship, a woman experiencing these common complications after chemical abortion is likely to find herself abandoned and at high risk for adverse outcomes.[53]

5. Harms to physicians

Finally, contrary to the FDA's argument that the plaintiffs have only demonstrated speculative injuries, FDA Application at 43, 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"

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[51] Raymond, *supra* note 12; Winikoff, *Extending Services*, *supra* note 22.

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

[53] Ingrid Skop, *Medical Abortion: What Physicians Need to Know*, 24 J. Am. Physicians & Surgeons 109 (2019); Skop, *Chemical Abortion, supra* note 42.

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."[54] 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 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.[55] 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 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." And the American Medical Association (AMA) previously

[54] 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).

[55] 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).

opposed the creation of Medicare.[56] 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."[57] 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 abortions at all.[58] The chasm between ACOG's pro-abortion statements[59] 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

[56] 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.

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

[58] Desai, *supra* note 55; Stulberg, *supra* note 55.

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

recommendations are based on science.[60] 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,[61] the manufacturer of mifepristone) and Daniel Grossman (Director of ANSIRH, a vocal abortion advocacy organization), who collaborated on *Practice Bulletin No. 225 Medical Management Up to 70 Days Gestation*,[62] and (in Grossman's case) who cowrote *Practice Bulletin No. 135: Second-Trimester Abortion*.[63]

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

[61] 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.

[62] ACOG, *Practice Bulletin No. 225* at e71, *supra* note 50.

[63] ACOG, *Practice Bulletin No. 135: Second-Trimester Abortion*, 121 Obstetrics Gyn. 1394, 1394 (2013).

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 App at 36. 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.[64]

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.[65] Moreover, more than half of the survivors who responded "indicated that one or more

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

[65] 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, 73 (2014), https://lawecommons.luc.edu/annals/vol23/iss1/5.

of their abortions was at least partly forced upon them."[66] 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 given to the woman who asked for it. Traffickers could force women to obtain prescriptions so that the traffickers can then 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.

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 articles, studies, and websites identified by respondents, their amici, or the court itself." FDA Application at 35 n.5. Rather, the district court, and then the Fifth Circuit, took into account all of the evidence (or lack thereof) that the FDA has ignored. For all these reasons, *amicus* respectfully urges the Court to deny Applicants' motions.

[66] *Id.*

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Respectfully submitted,

/s/ Gene C. Schaerr
Gene C. Schaerr
Counsel of Record
Cristina Martinez Squiers
SCHAERR | JAFFE LLP
1717 K Street NW, Suite 900
Washington, DC 20006
Telephone: (202) 787-1060
gschaerr@schaerr-jaffe.com

Counsel for Amicus Curiae
Charlotte Lozier Institute