Nos. 23-235, 23-236

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL., *Petitioners*,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

DANCO LABORATORIES, L.L.C., *Petitioner*,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

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

MOTION FOR LEAVE TO FILE BRIEF OUT OF TIME AND BRIEF AS *AMICUS CURIAE* OF CHARLOTTE LOZIER INSTITUTE SUPPORTING RESPONDENTS AND AFFIRMANCE

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MOTION FOR LEAVE TO FILE *AMICUS* BRIEF

The Charlotte Lozier Institute (CLI) respectfully requests leave to submit an out-of-time brief as *amicus curiae* in support of Respondents. *Amicus* respectfully submits that the unusual circumstances here merit the Court's consideration of this motion.

1. Plaintiffs' failure to submit its brief on the due date resulted from *amicus* counsel's being unaware of the Petitioners' decision to file their opening briefs earlier than the original due date set by the Court's rules. Pursuant to Rule 25.1, Petitioners' merits briefs were *originally* due on January 29, 2024, and Respondents' briefs were due on February 28, 2024, meaning that *amicus* briefs supporting Respondents would have been due on March 6. See S. Ct. R. 37.3. However, unbeknownst to counsel for *amicus,* Petitioners filed their briefs six days early, on January 23, therefore accelerating the timelines for Respondents' brief, as well as *amicus* briefs supporting Respondents, by six days. And, although CLI had participated as an *amicus* in both the district court and court of appeals, Petitioners' counsel—as is their right—apparently elected not to serve CLI's counsel when they filed their opening briefs in this Court.

As a result of Petitioners' timing decision, under the Court's rules the due date for *amicus* briefs supporting Respondents shifted from March 6 to February 29, 2024. And counsel for *amicus* did not become aware of this revised deadline until March 1, 2024—five days before the original due date but one day after the new due date.

2. Apart from the shifting due dates resulting from the operation of the Court's rules, there are good grounds for granting the motion. *First,* the Court's acceptance of CLI's *amicus* brief will not prejudice any party, as this proposed brief (if the motion is granted) will be filed just four days after it was due under the latest briefing timetable. That will give Petitioners ample time to respond to the points raised in the *amicus* brief. Indeed, if the motion is granted, CLI's brief will still be filed before the deadline for *amicus* briefs that do not support either party. S. Ct. R. 37.3.

Second, CLI's brief will be of substantial value to the Court as it considers the scientific questions that lie at the heart of this case. CLI's proposed brief draws on its expertise as the nation's leading pro-life scientific, statistical, and research center and provides important information about the data and scientific research underlying the FDA's decisions at issue in this case.

CLI is thus uniquely positioned to explain the scientific data—available and unavailable—that seriously undermine the FDA's assertions that mifepristone is "safe and effective." Pet. Br. 4. CLI is also uniquely qualified to explain why the FDA's modifications to mifepristone's conditions of use were scientifically unsound.

In fact, the lower courts relied on research from CLI scholars in reaching that very conclusion. *Alliance for Hippocratic Med.* v. *U.S. Food & Drug Admin.*, 668 F. Supp. 3d 507, 524 n.9 (N.D. Tex. 2023). The district court cited CLI scholar James Studnicki five separate times, *id.* at 524 n.9, 537 n.22, 547 n.37, 548 n.45, and

CLI scholar Kathi Aultman three separate times, *id.* at 548 n.44, 552 nn.56-57. The court also cited a study co-authored by CLI researchers Katherine Rafferty and Tessa Longbons three times. *Id.* at 524, 547 n.40, 548 n.41. Much of this scholarship focuses on adverse events, including emergency room visits, following mifepristone use, which affects both the standing and merits issues in this case. *Id.* at 524, 527, 547-548, 552.

3. This request is also supported by the limited available precedent. In this very case, the Court has already granted one request—by several former FDA commissioners—to file an *amicus* brief out of time. Like CLI, the former FDA commissioners had not filed a brief at the certiorari stage and were therefore unaware of the revised deadlines. Further, the former commissioners offered their unique scientific expertise to assist the Court in evaluating the merits, just as CLI does here.

For all these reasons, CLI respectfully asks the Court to grant leave to file the attached *amicus* brief.

Respectfully submitted,

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QUESTIONS PRESENTED

Amicus addresses the second question presented in this case:

2. Whether FDA's 2016 and 2021 actions were arbitrary and capricious.

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INTRODUCTION AND INTEREST OF *AMICUS CURIAE*[1]

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 and policies governing abortion should be informed by the most current medical and scientific knowledge on human development. Yet that is not how the FDA has made decisions regarding mifepristone.

As a preliminary matter, the FDA claims that chemical abortion is generally safe. See FDA Br. 4, 6, 12. But that conclusion ignores the unavailability of accurate or complete 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. Those changes now allow women to obtain mifepristone via telemedicine, the mail, and certified pharmacies without seeing a physician in person and to use mifepristone up to 70 days' gestation rather than the previous 49-day limit. These changes removed critical protections for women and are not based on a comprehensive risk assessment, or sound science.

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[1] This brief was not authored in whole or in part by counsel for any party and no person or entity other than *amicus* has made a monetary contribution toward the brief's preparation or submission.

SUMMARY OF ARGUMENT

The FDA and Danco claim that because mifepristone is "safe and effective," the Fifth Circuit was wrong in holding that plaintiffs have standing (injury) and that the changes to the REMS were arbitrary and capricious. See, *e.g.*, FDA Br. 4, 6, 12, 14; Danco Br. 4, 8, 25, 47. But the data–both available and unavailable–seriously undermine this claim.

First, accurate abortion data, including data surrounding complications, is often unavailable, and thus broad claims about abortion's safety are suspect. Further, the more inclusive, records-linkage studies, which accurately detect all medical events following abortion, reveal that chemical abortion carries tremendous risks and needs further examination. Studies also reveal that surgical abortion is safer than chemical abortion, and thus it is inaccurate for the FDA and Danco to say that more women obtaining surgical abortion would be a net harm.

Second, the FDA's continued relaxation of mifepristone's restrictions exacerbates these concerns. Specifically, the available data do not support permitting mifepristone use through 70 days' gestation or removing the requirement for an in-person visit with a physician. The lack of an in-person visit with a physician is particularly harmful, as it often removes the woman's ability to get an ultrasound to confirm the fetus's age and health and thus rule out a dangerous ectopic pregnancy, and it prevents an abortion provider from determining whether the pregnant woman is being coerced, abused, or trafficked.

Third, the FDA and Danco make the erroneous claim that physicians, and plaintiffs in particular, are not harmed by these inadequate mifepristone regulations. Many physicians who oppose abortion will inevitably have to provide care for women with mifepristone complications and thus lose the opportunity to care for both the mother and child and face a moral crisis for being complicit in elective abortion.

Collectively and individually, these considerations demonstrate the arbitrary and capricious character of the FDA decisions at issue in this case, and thus militate strongly in favor of affirming the Fifth Circuit's decision.

ARGUMENT

I. Contrary to the FDA's and Danco's Claims, the Science Does Not Show that Chemical Abortion Is Generally Safe for Women.

The FDA and Danco argue that mifepristone is "safe and effective" and that adverse events are "exceedingly rare." See, *e.g.*, FDA Br. 4, 6, 12, 14; Danco Br. 4, 8, 25, 47. But this claim ignores (1) the unavailability of accurate or complete abortion data, (2) the lack of any systematic method for reporting complications, and (3) the documented serious side effects and risks of chemical abortion, including the fact that surgical abortion is actually safer than chemical abortion.

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

First, even the number of abortions that take place each year in the United States is unknown. 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.[2] But the Guttmacher Institute, based on data obtained directly from abortion providers, reported 930,160 abortions for that same year—about 50% more abortions than the CDC.[3]

Second, the number of abortion-related complications is also unknown. Only about half of the states require abortion providers to report their complications, and only a quarter of states require other physicians, coroners, or emergency rooms to report abortion-related complications.[4] There are few enforcement mechanisms or penalties for noncompliance. Thus, we can safely assume that

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

[3] 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://tinyurl.com/2s3hznp9.

[4] Guttmacher Inst., *Abortion Reporting Requirements* (current as of Sept. 1, 2023), https://tinyurl.com/yxvrp5c8; Tessa Longbons, Charlotte Lozier Inst., *Analysis: FDA Decision Ignores Data on Complications, Puts Women at Risk* (2021), https://tinyurl.com/27rdfdmz.

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 Advancing New Standards In Reproductive Health ("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.[5] However, a similar but larger records-linkage study published in 2021 that examined 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 had a chemical abortion, presented to an ER with a complication within 30 days of the abortion.[6]

What accounts for the disparity between these two results? ANSIRH's study recorded only complications with a diagnostic code specifically related to abortion.[7] But the researchers in the larger records-linkage study looked at all diagnostic codes related to pregnancy complications.[8] This latter method is much

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

[6] 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*").

[7] Upadhyay, *supra* note 5, at 175.

[8] Studnicki, *Cohort Study, supra* note 6, at 2.

more reliable because all 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.

In the final year of this study, moreover, 60% of known chemical abortion complications and 40% of known surgical abortion complications were miscoded—not, as they should have been, as arising from an abortion, but instead as arising from a "miscarriage." This obviously further complicates data interpretation.

These differences in method matter, as the FDA and Danco claim that one of the Fifth Circuit's critical errors was holding that plaintiffs faced an imminent injury because of the risk that women who take mifepristone would present to the emergency room for care. See FDA Br. 17-20; Danco Br. 16, 24. In making that determination, the lower courts relied on the 2021 records-linkage study above. And that study, along with a follow-up study published in 2022, have been unfairly criticized in the media and recently retracted—by the journal, not the authors—for unwarranted, ideological reasons.[9]

For example, one of the media's and journal's concerns is the affiliation of the 2021 study authors

[9] Sofia Resnick, *Study cited by Texas judge in abortion-pill case under investigation*, Wis. Exam'r (Aug. 4, 2023), https://tinyurl.com/y3k5d3xn.

with CLI given CLI's pro-life positions.[10] Yet neither the media nor the journal mentions that the opposing studies touting mifepristone's safety were funded by ANSIRH—a vocal pro-abortion advocacy group.[11] And the media and journal mention nothing about the general benefits of a records-linkage study and why ANSIRH's recording of only diagnostic codes specifically related to abortion would be severely underinclusive given the shortcomings, discussed above, related to documenting abortion-related complications.

The media and journal also claim that the 2021 study looked at all emergency room visits and "does not distinguish between routine medical care and adverse events" that are "not necessarily related to having taken abortion drugs."[12] This is a curious statement, considering that the 2021 study looked at both "all-cause" ER visits, as well as abortion-related ER visits. Furthermore, given that the ER visits occurred within 30 days of the chemical abortion, making it highly unlikely that the visit was unrelated to the abortion. Plus, the steep increase in the number of women seeking ER care following a chemical abortion over the 17-year period of the study is itself concerning.

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[10] *Id.*; *CLI Authors' Responses to Sage Concerns and Retractions*, Charlotte Lozier Inst. (Feb. 21, 2024), https://tinyurl.com/5feb38kr.

[11] *About*, ANSIRH, https://www.ansirh.org/about (last visited Mar. 2, 2024).

[12] Resnick, *supra* note 9.

CLI has provided comprehensive answers to every supposed concern with the 2021 study, yet the journal has not offered a single word in response.[13] In fact, the authors communicated the appropriateness of all their methods to the journal before the retraction, and the journal never responded. The journal has yet to identify any problem with methodology or any breach of the Committee on Publication Ethics ("COPE") guidelines that would justify retractions of any of the papers. Nor has the journal invalidated any of the papers' findings. All in all, then, the suspicious timing of the journal's retraction—long after publication and while this case is pending before the Court—speaks for itself.

Finally, the number of abortion-related maternal deaths (deaths that occur within a year of an abortion) is also unknown and likely underinclusive. Death certificates often fail to document prior pregnancies, especially early pregnancies that end in abortion or miscarriage.[14] Even if related to childbirth, at least 50% of maternal deaths are not reported as pregnancy related on death certificates.[15] Thus, there are

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[13] Charlotte Lozier Inst., *supra* note 10.

[14] 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); 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).

[15] 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-

deficiencies in the calculations of both maternal deaths and abortion-related maternal deaths. And for abortion-related maternal deaths, there is no consistent definition of that term and therefore no consistent categorization of these types of deaths.[16]

Given these data deficiencies, it is of little comfort that Danco claims prescribers will report mifepristone-related deaths to track the drug's safety. Danco Br. 10-11. The reality is that many of these deaths go and will continue to go undocumented. It is telling that the FDA and Danco fail to acknowledge any of these issues in the underreporting of both complications and deaths related to abortion generally and mifepristone specifically.

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

As noted above, the FDA and Danco claim throughout their briefs that serious adverse events following mifepristone use are rare. FDA Br. 2, 6, 12, 14, 21, 40-41; Danco Br. 8, 10, 25, 47. 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

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Tharaux et al., *Underreporting of pregnancy-related mortality in the United States and Europe*, 106 Obstetrics Gyn. 684 (2005).

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

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.[17] If the rate of adverse events is conservatively estimated at 2% (as reported by abortion advocates), 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.[18]

Further, many studies documenting low complication rates come from high-volume

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[17] 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 (last accessed Mar. 3, 2024).

[18] Am. Ass'n of Pro-Life Obstetricians & Gynecologists (AAPLOG), *Comm. Op., No. 9, Dangers of Relaxed Restrictions on Mifepristone* (Oct. 2021), https://tinyurl.com/yz6x39yr. And, even for the events that the FDA knows about, it attempts to downplay them despite how serious they are. See FDA Br. 44. These events include the "occurrence of uterine/vaginal bleeding and uterine/vaginal bleeding and sepsis," as well as "the occurrence of ongoing pregnancy, drug intoxication and death approximately 5 months after ingestion of mifepristone, death [cause of death is currently unknown] , sepsis and death, and pulmonary embolism." Ctr. for Drug Eval. & Rsch., U.S. Food & Drug Admin., *NDA & ANDA Appl. Nos. 020687 & 91178, REMS Modification Rationale Review* 22 (2021) (omitting case number citations), https://www.accessdata.fda.gov/drugsatfda_docs/summary_review/2023/020687Orig1s025SumR.pdf [https://perma.cc/W4U3-L38P] (document at pp. 41-90 of pdf).

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.[19]

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 as a result of failed chemical abortions.[20] This shows 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. And, even if abortion providers are aware of complications, most of

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[19] 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); see also Ingrid Skop, *What is the Truth about the* Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration *lawsuit?*, Charlotte Lozier Inst. (June 13, 2023), https://tinyurl.com/2y4z45p2.

[20] 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).

them do not maintain hospital admitting privileges and thus would be unable to care for hospitalized women.[21]

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, Danco's claims that it is bound to report adverse events to the FDA and that providers can voluntarily report adverse events directly to the FDA are of little utility. Cf. Danco Br. 45-46; see also FDA Br. 41-42. The reality is that, given present data collection efforts, Danco, and therefore the FDA, will likely never 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 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 used in children and adolescents, the agency ignored its own rules in its approval of mifepristone, performing no studies focused on girls under 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?

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[21] 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).

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 critical questions.

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

The FDA further claims that restricting mifepristone's use "would be damaging for women and healthcare providers" because for many women, a medication abortion is preferable over a surgical abortion, and a surgical abortion "can have greater health risks for some patients, such as those who are allergic to anesthesia." FDA Br. 47. Danco similarly claims that the Fifth Circuit's decision warrants reversal because limiting mifepristone would result in more women needing surgical abortion. Danco Br. 52. But the FDA and Danco disregard the evidence that chemical abortions are inherently risky, and surgical abortion is, in fact, safer.

1. First, 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.[22]

2. Further, current clinical guidelines fail to account for known risk factors. 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.[23] 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.[24] The extreme blood loss that can occur with a 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.

Research also suggests that mifepristone itself may cause additional complications of hemorrhage, infection, and mental health issues through direct

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[22] U.S. Food & Drug Admin., *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (current to Mar. 23, 2023), https://tinyurl.com/4fab24zf.

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

[24] Ingrid Skop, *The "No-Test Medication Abortion" Protocol: Experimenting with Women's Health*, Charlotte Lozier Inst. (July 30, 2020), https://tinyurl.com/5e2ah4p7. See also U.S. Food & Drug Admin., *Approved Risk Evaluation and Mitigation Strategies (REMS), Mifepristone, REMS Materials* (Mar. 23, 2023), https://tinyurl.com/mryhbmat.

pharmacologic effects. Mifepristone impairs the ability of the spiral arterioles in the uterus to contract, predisposing women to excessive blood loss.[25] The drug also blocks glucocorticoid receptors, which may contribute to an impaired inflammatory response, increasing the risk of infection and sepsis.[26] In addition, mifepristone releases inflammatory cytokines, which have been identified as contributing to depression.[27]

3. 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 in a manner that required surgery, and 1% of

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

[26] 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).

[27] 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).

chemical abortions failed even to kill the fetus.[28] 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.[29]

This is important because women who need surgical completion of medical abortion face an increased risk of early delivery of a subsequent pregnancy.[30] Additionally, if the medication abortion fails and the woman decides to continue her pregnancy, her fetus faces a higher risk of having birth defects due to exposure to misoprostol—the drug taken after mifepristone for a chemical abortion.[31]

4. Yet another concern is the alarming increase in the number of women visiting the emergency room following a chemical abortion. The records-linkage

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[28] 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).

[29] Mentula, *supra* note 28.

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

[31] 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).

study discussed above 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).[32] Additionally, by 2015, more than 35% of chemical abortions resulted in an ER visit within 30 days. The FDA is well aware of this problem, as mifepristone is the only drug with a REMS for which the FDA provides a table tracking the ER visits it knows about on its approved label.[33]

This trajectory in increased ER visits is itself cause for alarm, especially as chemical abortion becomes more prevalent and easier to access. ER visits properly coded as abortion related are twice as high for chemical abortions as for surgical abortions.[34] And abortion complications that are miscoded as miscarriages are nearly four times as high for chemical abortions as for surgical abortions.[35] 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"—specifically, 86.4% for miscoded chemical

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[32] Studnicki, *Cohort Study*, *supra* note 6.

[33] Compare U.S. Food & Drug Admin., *Mifeprex (mifepristone) Medication Guide* (rev. Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf, with U.S. Food & Drug Admin., *Mifepristone, Approved Risk Evaluation and Mitigation Strategies (REMS)* (Mar. 23, 2023), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.

[34] Studnicki, *Cohort Study*, *supra* note 6.

[35] *Ibid.*

abortion versus 34.2% for miscoded surgical abortion.[36]

Given all 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 women undergoing chemical abortions required surgery to complete the abortion.[37] Another study also showed that women who had chemical abortions faced complications four times as often as women who had surgical abortion.[38]

Without acknowledging any of these data, the FDA and Danco *assume* that chemical abortion is preferable simply because it is not surgery. FDA Br. 46-47; Danco Br. 52-53. And rather than engaging with these data, the petitioners only claim that surgical abortion might be unavailable for "some patients" allergic to anesthesia and that surgical abortion may be

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[36] 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/.

[37] Niinimäki, *supra* note 28.

[38] Upadhyay, *supra* note 5.

impractical for women living in rural areas. *Ibid*. An argument based on speculation and convenient access is not a sound safety determination. Additionally, when incomplete abortion occurs and requires 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's failure to adequately address these issues in the decisions under review make those decisions arbitrary and capricious—just as the Fifth Circuit (preliminarily) concluded.

II. The FDA's 2016 and 2021 Decisions Fail to Account for Significant Dangers They Pose to Women.

Given the deficiencies in the studies the FDA has relied on, and the data the FDA and Danco have ignored, the FDA's mifepristone regulation from 2016 on is even more troubling—and even more arbitrary and capricious. These changes, discussed below, 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 timeframe in which women can take abortion drugs to 10 weeks' gestational age despite very few studies supporting such a change and the documented higher failure rates in later gestational ages. 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. 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.[39]

The FDA's 2016 rule that prescribers report only patient deaths exacerbates the problem.[40] 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 requirements for chemical abortions only makes it harder to assess their safety. And this problem exacerbates the arbitrariness of the FDA's 2016 rule.

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 and arbitrary. As shown below, not only did the FDA rely upon obviously biased and unrepresentative studies, but it failed to address important safety issues outright: that telemedicine chemical abortion removes necessary ultrasounds, compromises informed consent, amplifies concerns

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[39] Chen & Creinin, *supra* note 28.

[40] Aultman, *supra* note 20.

about coercion, abandons women to self-manage their abortions and any resulting complications, and harms physicians and the medical profession. Neither the FDA nor Danco acknowledged or addressed any of these concerns before the Fifth Circuit, and so unsurprisingly, their briefs before this Court continue to ignore these serious safety issues.

1. Reliance upon biased and inadequate studies

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. 35-37; Danco Br. 8-10. But many of the "telemedicine" abortions in these studies implemented standard pre-abortion screening, including physical exam, ultrasound, and labs. 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, or labs.

As a result, the supposed "telemedicine abortions" in the studies often 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, 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.

Additionally, the largest of the peer-reviewed studies that the FDA referenced in its 2021 decision to remove the in-person prescribing requirements on mifepristone—allowing mail-order and other medically unsupervised chemical abortions—was performed by pro-abortion researcher Abigail Aiken and had fatal flaws.[41] This study encompassed 92% of the abortions examined by the FDA and was drawn from the United Kingdom's ("UK") data from its "pills-by-post" policy. Further review of the data from the UK's reporting systems revealed serious underreporting issues due to discrepancies in coding as well as the exclusion of serious complications such as incomplete medical abortions resulting in retained tissue.[42] Not surprisingly, Aiken's team used the less inclusive reporting data from the UK's ANS (Abortion Notification System) records system as opposed to the more inclusive HES (Hospital Episodes Statistics) system. The HES system documented approximately two percent complications after medical abortions,

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[41] See 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).

[42] See Off. for Health Improvement & Disparities, U.K. Gov't, *Complications from abortions in England, 2017 to 2021* (2023), https://tinyurl.com/3pk55m9z; see also Right to Life UK, *Complications Rates 160 Times Higher for Medical Abortions at 20 Weeks and After Compared to Before 10 Weeks, According to Gov. Review*, Right to Life News (Dec. 12, 2023), https://tinyurl.com/23yw3p65.

which is ten times higher than the rate reported by ANS.[43]

Freedom of Information requests to the UK Government also revealed a shocking 5.5-6.2% rate of women presenting for emergency care following a medication abortion due to retained tissue, and half of those women required surgery.[44] When applied to the number of women requesting abortion "pills-by-post," this means that more than 10,000 women a month sought emergency services after chemical abortion.[45] The FDA thus acted arbitrarily by relying on compromised UK data misrepresented by a biased U.S. pro-abortion researcher in order to justify removing critical in-person safeguards on medical abortion.

2. Eliminating ultrasounds

Without an in-person clinical visit, pregnant women are much less likely to receive an ultrasound. Yet ultrasounds are the most accurate way to diagnose ectopic pregnancy, which poses 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,

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[43] *Ibid.*

[44] See Right to Life UK, *supra* note 42; see also Percuity Ltd., *FOI Investigation into Medical Abortion Treatment Failure* (Oct. 27, 2021), https://percuity.files.wordpress.com/2021/10/foi-ma-treatment-failure-211027.pdf.

[45] *Ibid.*

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.[46] And the gold standard for diagnosis of ectopic pregnancy is ultrasound.[47]

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.[48] Studies have documented that a woman is 30% more likely to die from a ruptured ectopic pregnancy while seeking abortion.[49] If the condition remains undiagnosed, a woman may interpret the

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

[47] 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).

[48] 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).

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

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.

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 interventions.[50] 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.[51] 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

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[50] Mentula, *supra* note 28; Chen & Creinin, *supra* note 28; Beverly Winikoff et al., *Extending outpatient medical abortion services through 70 days of gestational age*, 120 Obstetrics Gyn. 1070 (2012); Raymond, *supra* note 28. 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.

[51] 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://tinyurl.com/5n6px6y6.

a sign of that pregnancy.[52] Further, increasing obesity rates have led to a higher incidence of polycystic ovarian syndrome, which causes irregular ovulation and menstruation.[53] Because of the inability of many women to determine their fetus's gestational age, ultrasound is the most accurate way to lower the risks of complications related to any miscalculations.

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. 5, 40. 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.

3. Coercion

Telemedicine abortion is also problematic because it is far less effective than in-person consultation in determining whether a woman is voluntarily taking the abortion pills. 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. Nor is there any way to document that

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[52] Mary Marnach, *Is implantation bleeding common in early pregnancy?*, Mayo Clinic (Apr. 19, 2022), https://tinyurl.com/dhxe7rdd.

[53] 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.

the woman making the request is actually the person who will receive the abortion, or even to document that she is pregnant.

The FDA based its dangerous decision to remove in-person supervision on four telemedicine studies. As previously discussed, 92% of the abortions studied were performed in the UK, which preceded the FDA in loosening restrictions.[54] 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.[55] 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

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[54] 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); 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/; 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); Aiken et al., *supra* note 41.

[55] 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.

physically being seen in a service."[56] 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.[57]

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 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.[58] 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.[59] Only 33% described their abortions as "wanted."[60]

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

[57] Alys Harte & Rachel Stonehouse, *Reproductive coercion: 'I wasn't allowed to take my pill'*, BBC (Mar. 14, 2022), https://tinyurl.com/mr2sd5yt; Savanta ComRes for BBC Radio 4, Reproductive Coercion Poll–BBC Radio 4–8 March 2022 (Aug. 3, 2022), https://tinyurl.com/3bwtvzy2.

[58] David C. Reardon & Tessa Longbons, *Effects of Pressure to Abort on Women's Emotional Responses and Mental Health*, 15 Cureus (2023), https://tinyurl.com/3e9ux6au.

[59] 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://tinyurl.com/yu6ywnpn.

[60] *Ibid.*

Telemedicine abortion also raises serious concerns for victims of sex trafficking. Medical professionals are positioned to 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.[61] Making abortion pills available via telehealth allows traffickers to limit trafficking victims' access to healthcare professionals, removing this crucial protection for victims. Neither the FDA nor Danco addresses this significant safety issue for some of the most vulnerable women.

4. Follow-up visits

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, 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*[.]"[62] Danco ignores these guidelines and claims that follow-

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[61] 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.

[62] ACOG, *Practice Bulletin No. 225, supra* note 23.

up visits should be determined on a case-by-case for chemical abortion. Danco Br. 9.

In addition, fetal survival continues in 1–3% of women consuming the chemical abortion pills.[63] Prompt diagnosis that the medical abortion did not work will allow these women either to decide to keep their babies or 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 the pregnancy tissue.[64] 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.[65]

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[63] Raymond, *supra* note 28; Winikoff, *supra* note 50.

[64] U.S. Food & Drug Admin., *Approved Risk Evaluation and Mitigation Strategies (REMS), Mifepristone, REMS Full* (mod. Mar. 2023), https://tinyurl.com/3ntxfjbj.

[65] Ingrid Skop, *Medical Abortion: What Physicians Need to Know*, 24 J. Am. Physicians & Surgeons 109 (2019); Ingrid Skop, *Chemical Abortion: Risks Posed by Changes in Supervision*, 27 J. Am. Ass'n Physicians & Surgeons 56 (2022).

5. Obtaining abortion pills in the mail

The FDA also claims that its decision to remove the in-person dispensing requirement was "the result of a thorough scientific review." FDA Br. 49; see also Danco Br. 9. 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.[66]

All of these problems strongly support the Fifth Circuit's (preliminary) conclusion that the FDA decisions at issue here were arbitrary and capricious.

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

III. The FDA's 2016 and 2021 Decisions Fail to Account for Harms They Impose on Physicians and the Medical Profession.

Finally, contrary to the FDA's and Danco's argument that the plaintiffs have only demonstrated speculative injuries, FDA Br. 13, Danco Br. 20, 24, telemedicine chemical abortion undoubtedly 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."[67] Abortion advocates, however, follow a "one-patient paradigm," whereby the fetus is their second patient *only* if the mother desires her to be so. These advocates appear to consider "unwanted" pregnancy 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.[68] That small number is unsurprising given

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[67] 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).

[68] Sheila Desai et al., *Estimating abortion provision and abortion referrals among United States obstetrician-gynecologists in private practice*, 97 Contraception 297 (2018); Debra B.

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 leaders at several larger progressive medical organizations support expansive abortion availability. 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."[69] It is difficult to understand why ACOG does not apply these principles to fetuses. The chasm between ACOG's pro-abortion statements[70] and its membership's actual medical care undermines the weight one should attribute to ACOG's pro-abortion position.

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. And even if they decline to prescribe

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Stulberg et al., *Abortion provision among practicing obstetrician-gynecologists*, 118 Obstetrics Gyn. 609 (2011).

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

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

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.

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, in making a preliminary finding that the FDA had acted arbitrarily, the Fifth Circuit's opinion was not based on a mere "second-guessing [of the] FDA's expert judgment." FDA Br. 12; see also Danco Br. 50. Rather, the Fifth Circuit considered the evidence—and the absence of evidence—that the FDA has persistently and arbitrarily ignored.

Respectfully submitted,

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