Civil Action No. 2:22-CV-00223-Z

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, *ET AL.*,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *ET AL.*,

Defendants,

DANCO LABORATORIES, LLC,

Intervenor-Defendant.

BRIEF FOR *AMICUS CURIAE* CHARLOTTE LOZIER INSTITUTE IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTEREST OF *AMICUS CURIAE*

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

SUMMARY OF ARGUMENT

The U.S. Food & Drug Administration (FDA) claims that "[b]enefit-risk assessment is the foundation for" the agency's "regulatory review of human drugs and biologics."[1] But when it comes to abortion regulation, particularly chemical abortion regulation, that foundation is severely compromised.

The FDA's chemical abortion regulations disregard serious risks and elevate speculative benefits. While the FDA claims that chemical abortion is safe, that conclusion ignores several critical factors. First, claims about abortion's safety in general are unreliable given the lack of accurate abortion data and the misunderstanding of maternal mortality ratios. Second, claims about chemical abortion's safety are equally unreliable given the lack of any systematic method for reporting complications despite the severity of those complications. And the reporting that does happen is underinclusive due to the frequent miscoding of chemical abortion complication as miscarriage.

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

Rather than address these issues, the FDA has exacerbated them by loosening the few restrictions that previously shielded women from some of these risks. The FDA's new regulations now allows women to self-manage their chemical abortions without ever seeing a doctor in person. Yet the consequences of telemedicine chemical abortion are almost too numerous to count—lack of necessary ultrasounds to confirm gestational age and rule out ectopic pregnancy, inability to confirm that a woman is not being coerced to obtain an abortion, abandonment of women to deal with the medical and psychological repercussions of abortion by herself with no follow-up, and grave harm to physicians who are expected to clean up the mess (in the ER and elsewhere) of self-managed abortion.

No benefits outweigh these tremendous risks. While the FDA claims that the availability of chemical abortion is an economic benefit and more convenient for women, the data tell a different story. Although childbirth is costly in the short-term, the long-term economic benefits surpass those initial costs. And convenience and easy access are not a net benefit to women. Rather, the easy access of telemedicine abortion creates further risks for women, particularly those who are abused and disadvantaged. Simply put, there is no justification for the FDA's risk-benefit analysis regarding chemical abortion.

ARGUMENT

I. The prevailing notion that all legal abortion is extremely safe is based on deficient data and skewed studies, and is squarely contradicted by more reliable data and sound studies.

Before discussing the safety claims surrounding chemical abortions, it is important to understand the claims about abortion's safety more generally.[2] The pervasive claim that abortion is safer than other commonly performed procedures, such as wisdom tooth extraction and tonsillectomy, relies upon research by an outspoken abortion advocacy organization, Advancing New Standards in Reproductive Health (ANSIRH), who also claims that abortion at any time in pregnancy is safer than childbirth.[3] But these claims, as well as any others concerning the safety of abortion, rely on unreliable studies and deficient data and thus fall apart under scrutiny.[4]

The first data deficiency is that even the number of abortions that take place each year in the United States is unknown. Because of voluntary state reporting, privacy concerns, and the fact that many women pay out of pocket for abortions, there is no accurate central governmental database that tracks the number of abortions.

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[2] In this brief, the terms "chemical abortion" or "medication abortion" are used for the type of abortion caused by taking the drugs mifepristone then misoprostol.

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

[4] 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).

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.[5] But the Guttmacher Institute, based on data directly from abortion providers, reported 930,160 abortions in 2020.[6]

Second, the number of abortion-related complications is also unknown. Only about half of the states (28) require abortion providers to report their complications, and in those states, there is rarely robust oversight or an enforced penalty for noncompliance.[7] Just a quarter of the states require other physicians, coroners, or emergency rooms to report abortion-related complications or deaths for investigation.[8] Thus, we can safely assume that abortion complications are substantially underreported.

Abortion complications are underreported for another reason—improper diagnostic coding. For example, a frequently referenced 2015 study performed by prominent abortion advocates from ANSIRH reported that only 0.87% of 54,911 women receiving abortions financed through California's Medicaid program

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

[6] 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.

[7] 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).

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

presented to an emergency room with an abortion complication within six weeks of the abortion.[9] However, a similar but larger records-linkage study of 423,000 Medicaid-financed abortions in 17 states found that, within 30 days of the abortion, 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.[10]

What accounts for the disparity between these two results? ANSIRH's study only recorded complications with a diagnostic code specifically related to abortion.[11] But the researchers in the larger records-linkage study looked at all diagnostic codes related to pregnancy complications.[12] This latter method is much more reliable because all of the women in the study had recent documented abortions, and thus all pregnancy complications within 30 days of that abortion were likely caused by the abortion, even if not specifically coded as such. The researchers in the records-linkage study also documented that 60% of known chemical abortion-related ER visits in 2015 were miscoded as miscarriages, further evidencing deficiencies in the detection of abortion complications.[13]

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

[10] 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*").

[11] Upadhyay, *supra* note 9.

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

[13] Studnicki, *Cohort Study*, *supra* note 10.

Similarly, the number of abortion-related maternal deaths (deaths that occur within a year of an abortion) is unknown. It is well established that the CDC has incomplete statistics regarding abortion-related maternal mortality because most of their data comes from death certificates, which 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] One study from Finland documented that 73% of all maternal deaths and 94% of abortion-related deaths are not documented as such on the death certificate.[16] Thus, there are deficiencies in the calculations of both maternal deaths and abortion-related maternal deaths.

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[14] Studnicki et al., *Improving Metrics*, *supra* note 4; 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-Tharaux et al., *Underreporting of pregnancy-related mortality in the United States and Europe*, 106 Obstetrics Gyn. 684 (2005).

[16] Mika Gissler et al., *Methods for identifying pregnancy-associated deaths: population-based data from Finland 1987-2000*, 18 Paediatric Perinatal Epidemiology 448 (2004); Mika Gissler et al., *Pregnancy-associated mortality after birth, spontaneous abortion, or induced abortion in Finland, 1987-2000*, 190 Am. J. Obstetrics Gyn. 422 (2004). Further compromising the data is the fact that mental health complications remote from the end of a pregnancy are unlikely to be detected or attributed to pregnancy or childbirth. So there is no accurate data that links mental health complications, such as the increasing "deaths of despair" (substance abuse and overdose, suicides, homicides, and excessive risk-taking behavior), to pregnancy and the type of pregnancy outcome (abortion, miscarriage, or childbirth); Claire E. Margerison et al., *Pregnancy-Associated Deaths Due to Drugs, Suicide, and Homicide in the United States, 2010-2019*, 139 Obstetrics Gyn. 172 (2022).

Regarding maternal deaths, even when they are properly documented, the numbers are misleading due to differing definitions of the term. For example, the World Health Organization (WHO) and the CDC's National Vital Statistics System (NVSS) define maternal mortality as a pregnancy-related death occurring within six weeks of a pregnancy.[17] But the CDC's Pregnancy Mortality Surveillance System (PMSS) defines maternal mortality as a pregnancy-related death occurring until one year after the pregnancy ends.[18]

Another reason the number of maternal deaths can be misleading is the subjectivity involved in categorizing deaths following pregnancy.[19] In describing maternal mortality, the broadest category is a "pregnancy-associated death," which is the death of a woman while pregnant or within 365 days (one year) of the end of pregnancy from any cause. *Id.* This includes both deaths due to complications of the pregnancy or its management and deaths due to seemingly unrelated events, such as a car accident, cancer, or homicide, within a year of the pregnancy outcome. *Id.*

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

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

[19] Ingrid Skop, *Handbook of Maternal Mortality: Addressing the U.S. Maternal Mortality Crisis, Looking Beyond Ideology*, Charlotte Lozier Inst. (Jan. 6, 2023), https://lozierinstitute.org/handbook-of-maternal-mortality-addressing-the-u-s-maternal-mortality-crisis-looking-beyond-ideology/ (hereinafter "Skop *Handbook*").

Organizations take this broad category and determine if any deaths should be subcategorized as pregnancy related, which is the death of a woman while pregnant or within 365 days (one year) of the end of pregnancy, irrespective of the duration or site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, excluding accidental or incidental causes. *Id.* This subcategory excludes deaths the organization determines are not caused by the pregnancy or its sequelae. *Id.* Thus, there can be subjectivity involved in this decision, and the protocols used to make these decisions are not publicly available. *Id.*

Quantifying the more specific number of abortion-related deaths is equally difficult. *Id.* An "abortion-related death" is defined as any death from a direct complication of an induced abortion (legal or illegal), an indirect complication caused by a chain of events initiated by an abortion, or an aggravation of a preexisting medical condition by the physiologic or psychologic effects of abortion. *Id.* Unlike maternal deaths that have a temporal limitation, there is no time limit in the definition of "abortion-related death." *Id.* So there is no consistent categorization of these types of deaths. *Id.* The poor collection of induced abortion data in the U.S. means that abortion-related deaths are unlikely to be identified, much less thoroughly investigated.[20] As a result, obtaining raw numbers for a proper analysis

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

of the connection between abortion and maternal death is extremely difficult, and any claim about that connection must be closely scrutinized.[21]

Yet, without acknowledging or addressing these data deficiencies, studies continue to claim that childbirth causes higher maternal mortality rates than abortion does. One such study states that deaths from childbirth occur 14 times as often as deaths following abortion. The study compared the abortion-related mortality rate (abortion-related deaths divided by 100,000 legal abortions) with the maternal mortality ratio (the number of all maternal deaths, including abortion-related deaths, divided by 100,000 live births).[22] But each of these four numbers is difficult to calculate, and the rates are not comparable because of the tremendous deficiencies in maternal mortality data.

In particular, the maternal mortality ratio is deeply flawed because the numerator (maternal deaths) is overinflated by the lack of differentiation between pregnancy outcomes.[23] Put differently, no matter whether the mother died within a year of an abortion or live childbirth, the death is counted as a "maternal death." So the category of "maternal deaths" actually encompasses many abortion-related deaths. Thus, comparing a maternal mortality rate to an abortion mortality rate using "maternal deaths" is a meaningless exercise. Accordingly, confident assertions

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[21] Skop, *Handbook*, *supra* note 19.

[22] Elizabeth G. Raymond & David A. Grimes, *The comparative safety of legal induced abortion and childbirth in the United States*, 119 Obstetrics Gyn. 215 (2012); *David A. Grimes*, HuffPost, https://www.huffpost.com/author/david-a-grimes (last visited Feb. 9, 2023).

[23] Studnicki et al., *Improving Metrics*, *supra* note 4.

about mortality from the various pregnancy outcomes (abortion, miscarriage, or live birth) just cannot be made with certainty in the U.S. given that the category of maternal deaths is overinclusive and the category of abortion-related deaths is underinclusive.[24]

However, using records-linkage studies, where all deaths in reproductive aged women are linked to records on all pregnancy outcomes, provides a more accurate picture of maternal outcomes following abortion versus childbirth. Using this more accurate method, studies in both the U.S. and other countries show that maternal deaths are more frequent in the year following abortion than childbirth.[25]

For example, an eight-year retrospective California study showed that women who aborted had significantly higher age-adjusted risks of death from all causes (162%) and suicide (254%) compared to those who delivered a baby.[26] Comprehensive studies from Finland also found that, compared to women who carried to term, women who had an abortion were two to four times more likely to die within a year, six times more likely to commit suicide, four times more likely to die from an accident, and fourteen times more likely to be murdered.[27] Danish studies have documented

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[24] David C. Reardon et al., *Deaths Associated with Abortion Compared to Childbirth-A Review of New and Old Data and the Medical and Legal Implications*, 20 J. Contemp. Health L. & Pol'y 1 (2004) (hereinafter "Reardon et al., *Deaths Associated with Abortion*"); Mark Crutcher, *Lime 5: Exploited by Choice* (1996).

[25] Reardon et al., *Deaths Associated with Abortion*, *supra* note 24.

[26] David C. Reardon et al., *Deaths associated with pregnancy outcome: a record linkage study of low income women*, 95 S. Med. J. 834, 838 tbl. 3 (2002).

[27] M. Gissler et al., *Suicides after pregnancy in Finland, 1987-94: register linkage study*, 313 Brit. Med. J. 1431 (1996); E. Karalis et al., *Decreasing mortality during pregnancy and for a year after while mortality after termination of pregnancy remains*

similar results, finding a 39% increased risk of death after first-trimester abortions and a 341% increased risk of death after later abortions.[28]

All in all, analyzing the safety of abortion is complicated given the significant shortcomings in the data concerning abortion complications and maternal deaths. The most accurate data comes from records-linkage studies, and those studies undermine the bold claims about the purported safety of abortion.

II. Claims about the safety of chemical abortion are of little utility given the unreliable data about complications and adverse events.

As with claims about abortion's safety in general, the more specific claims about the safety of chemical abortion are undermined by deficient data. 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.[29] If the rate of adverse events is conservatively

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high: a population-based register study of pregnancy-associated deaths in Finland 2001-2012, 124 BJOG 1115 (2017); Mika Gissler et al., *Injury deaths, suicides and homicides associated with pregnancy, Finland 1987-2000*, 15 Eur. J. Pub. Health 459 (2005); M. Gissler et al., *Pregnancy-associated deaths in Finland 1987-1994—definition problems and benefits of record linkage*, 76 Acta Obstetricia Gyn. Scandinavica 651 (1997).

[28] David C. Reardon & Priscilla K. Coleman, *Short and long term mortality rates associated with first pregnancy outcome: Population register based study for Denmark 1980-2004*, 18 Med. Sci. Monitor 71 (2012); Priscilla K. Coleman et al., *Reproductive history patterns and long-term mortality rates: a Danish population-based record linkage study*, 23 Eur. J. Pub. Health 569 (2013).

[29] 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.

estimated at 2% (as reported by abortion advocates), then one would anticipate approximately 74,000 reported complications. Yet two analyses examining the FDA's mandated adverse event reports (AERs) from 2000 to 2019 obtained by Freedom of Information Act (FOIA) requests showed only 3,804 AERs, suggesting the FDA received reports on fewer than 5% of the estimated adverse events.[30]

Data from Planned Parenthood, which performs approximately 40% of abortions in the U.S., casts further doubt on the accuracy of the FDA's AERs. Planned Parenthood published a study reporting 1,530 significant adverse events following chemical abortion over a two-year period.[31] Planned Parenthood defined "significant adverse events" as emergency room evaluation, hospital admission, blood transfusion, intravenous antibiotics administration, ongoing pregnancy, undiagnosed ectopic pregnancy, and death. The definition did not include failed chemical abortions that require surgery. Nonetheless, the 1,530 adverse events are more than double the total number of adverse events published in the FDA's AERS database in the same two years.[32] Whether Planned Parenthood failed to report all of their

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[30] 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.

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

[32] U.S. Food & Drug Admin., *TTT# 2022-2468, NDA 020687, ANDA 091178, Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022*, https://www.fda.gov/media/164331/download; Christina A. Cirucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Serv. Rsch. Managerial Epidemiology 233339282110689 (2021); Kathi Aultman et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February*

complications to the FDA, or whether the FDA failed to provide all of its reports in response to the Freedom of Information Act (FOIA) request from which the data are derived, remains unknown.

Regardless, even data showing a higher number of adverse events, like the one from Planned Parenthood, are inaccurate. Many studies documenting low complication rates come from high-volume abortionists (like Planned Parenthood) and thus fail to reflect the quality of all abortion providers in the U.S. Many of these researchers also make the 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.[33]

This underestimation is also due in part to the many women who are treated in an emergency room following a chemical abortion but not accounted for in statistics regarding complications. The FDA's complication data show that abortion providers performed less than 40% of the surgeries required for failed chemical abortions,[34] demonstrating that many women in medical distress do not return to their abortion provider and instead have subsequent care in emergency rooms or by other providers.

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).

[33] Luu Doan Ireland et al., *Medical Compared With Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 Obstetrics Gyn. 22 (2015); Cleland, *supra* note 31; 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*").

[34] Aultman, *supra* note 32; Gary & Harrison, *supra* note 32.

Thus, abortion providers are likely unaware of these complications. And even if abortion providers are aware of complications, most of them do not maintain hospital admitting privileges and thus would be unable to care for hospitalized women.[35] The result of all of this is that a woman needing care from a different provider is likely to have her complications go unreported.

An additional defect in claims about chemical abortion's safety is that, for certain populations, complications are completely unstudied, not just understudied. Mifepristone, the first drug used in a chemical abortion, is a synthetic steroid that blocks progesterone receptors in the uterus of the woman or girl who consumes it. Although the FDA is required to test medications that are used in children and adolescents, the agency ignored its own rules in its approval of mifepristone, performing no studies focused on girls under the age of 18. Even today, more than two decades after the FDA approved the drug for abortion, no studies specific to the pediatric population have been performed. What is the effect of using an endocrine disruptor that blocks progesterone in a developing adolescent? Could this impair sexual development or lead to impaired fertility later in life? Does it work differently in an adolescent than an adult woman? No one knows, since the FDA has failed in its duty to answer (or even attempt to answer) these questions.

Although much is unknown about the number of complications following chemical abortion and what specific complications affect adolescents, we do know that

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

the drugs can have devastating and dangerous consequences. And, as discussed next, these consequences merit a more rigorous review.

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

To fairly assess the risks from chemical abortions, it is important to recognize at the outset that even the "normal" side effects of chemical abortion are serious. After taking chemical abortion drugs, the average woman bleeds for nine to sixteen days, and 8% of women will bleed longer than a month. The side effects of cramping, vaginal bleeding, hemorrhage, nausea, weakness, fever, chills, vomiting, headache, diarrhea, and dizziness occur in most women.[36]

Beyond these "normal" side effects, prevailing practices fail to account for known risk factors and thus endanger women. The American College of Obstetricians and Gynecologists (ACOG) lists the following situations where chemical abortion may be dangerous: hemoglobin < 9.5 g/dL, severe liver, renal, or respiratory disease, uncontrolled hypertension, or cardiovascular disease.[37] 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.[38] The extreme

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[36] 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.

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

[38] Ingrid Skop, *The "No-Test Medication Abortion" Protocol: Experimenting with Women's Health*, Charlotte Lozier Inst. (July 30, 2020), https://lozierinstitute.org/the-no-test-medication-abortion-protocol-experimenting-with-womens-health/. *See also*

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.

On top of these known side effects and risk factors, research suggests that mifepristone itself may cause additional complications of hemorrhage, infection, and mental health issues through direct pharmacologic effects. Mifepristone impairs the ability of the spiral arterioles in the uterus to contract, predisposing women to excessive blood loss.[39] The drug also blocks glucocorticoid receptors, which may contribute to an impaired inflammatory response, increasing the risk of infection and sepsis.[40] In addition, mifepristone releases inflammatory cytokines, which have been identified as contributing to depression. In a rat model, the group of pregnant rats given mifepristone had significantly decreased body weight, food intake, locomotor-related activity, and sucrose consumption, which are all animal proxies for depression and anxiety.[41]

U.S. Food & Drug Admin., *Approved Risk Evaluation and Mitigation Strategies (REMS), Mifepristone, REMS Materials*, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.

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

[40] 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).

[41] 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. And international systematic reviews and records-linkage studies in countries with more robust recordkeeping demonstrate high failure rates for chemical abortion. For example, a systematic review of 45,000 abortions documented that almost 5% of chemical abortions failed, requiring surgery, and 1% of chemical abortions failed to kill the fetus.[42] 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.[43]

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 incidents related to chemical abortion from 2002 to 2015 (the period when chemical abortions were penetrating the Medicaid population).[44] By 2015,

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[42] 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).

[43] Mentula, *supra* note 42.

[44] Studnicki, *Cohort Study*, *supra* note 10. In response to Plaintiffs' motion for preliminary injunction, the FDA criticizes this study by stating that "[t]here are many reasons why patients seek ER care." Defs.' Opp'n to Pls.' Mot. for Prel. Inj. at 36, Doc. No. 28. The FDA ignores that (1) these ER visits occurred within 30 days of the chemical abortion, making it highly unlikely that the visit was unrelated to the abortion, and (2) the steep increase in the number of women seeking ER care

more than 35% of women who had a chemical abortion had an ER visit for some reason within 30 days. This trajectory is cause for alarm, especially as chemical abortion becomes more prevalent and easier to access.

Given all of the complications discussed above, it is unsurprising that the most reliable data available show that chemical abortion is more dangerous than surgical abortion. 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.[45] Another study showed that women who had chemical abortions faced complications four times as often as women who had surgical abortion.[46]

When it comes to ER visits, chemical abortion is also more dangerous than surgical abortion. ER visits properly coded as abortion related are twice as high for chemical abortions as for surgical abortions.[47] And abortion complications that are miscoded as miscarriages are nearly four times as high for chemical abortions as for

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following a chemical abortion over the 16-year period of the study is by itself concerning.

[45] Niinimäki, *supra* note 42.

[46] *Id.*

[47] Studnicki, *Cohort Study*, *supra* note 10.

surgical abortions.[48] Miscoded women in the ER following a chemical abortion who are subsequently admitted to the hospital are also more than twice as likely to be admitted for surgical removal of "retained products of conception" (86.4% for miscoded chemical abortion versus 34.2% for miscoded surgical abortion).

In sum, chemical abortions present significant safety concerns—even greater than for surgical abortions. And the studies that herald the safety of chemical abortion ignore these concerns.

IV. The FDA's continual relaxation of safety requirements is not supported by reliable evidence and endangers women.

Given the deficiencies in the studies the FDA has relied on to claim these drugs are safe, and the alarming findings in the studies described above that the FDA has ignored, the history of the FDA's regulation of chemical abortion drugs is troubling. And the way the FDA has continued to strip the few safeguards that did exist further increases the risks of chemical abortion drugs.

A. The FDA's loosening of restrictions for chemical abortion drugs is scientifically unsupported.

The FDA initially approved mifepristone, along with misoprostol, in 2000 for use up to 49 days' gestational age. The drugs required strict supervision under FDA's Subpart H restrictions, which govern the use of potentially dangerous drugs. These restrictions eventually became the Risk Evaluation and Mitigation Strategy (REMS) for chemical abortion drugs. The prescriber had to be a physician who became registered only after specific training. The drugs could be dispensed only in certain

[48] *Id.*

medical settings, and abortion providers had to inform patients of the risk of serious side effects. The restrictions also required abortion providers to have the ability to assess the duration of pregnancy accurately, diagnose ectopic pregnancy, and intervene surgically if needed or have an arrangement with a provider who could perform surgical intervention.[49]

Over time, the FDA, without compelling data to support its actions, has methodically removed these safeguards to the detriment of women. In 2016, the FDA extended use of chemical abortion drugs until 70 days' gestational age, despite very few studies supporting such a change and the documented higher failure rates in later gestational ages.[50] The FDA also 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.[51]

In December 2021, the FDA permanently removed the requirement that a pregnant woman see a physician in person before and after obtaining the chemical

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[49] U.S. Food & Drug Admin., *NDA 20-687, Mifeprex (mifepristone) Tablets, 200 mg, Risk Evaluation Mitigation Strategy (REMS)* (June 9, 2011), available at https://www.fda.gov/media/164648/download.

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

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

abortion drugs. Under the new rules, a woman can obtain mifepristone without in-person examination, sonogram, or laboratory analysis, and physicians can prescribe the drugs via telemedicine.[52] The drugs can also now be sent to a pregnant woman in the mail rather than obtained in person in a medical setting.

The FDA justified the 2021 changes with studies that purportedly found similar outcomes after comparing telemedicine abortions to in-person abortions. 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) 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 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.[53]

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

[53] Chong, *Home Use Study, supra* note 33; 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*

In January 2023, the FDA made additional unsupported changes that permit mifepristone distribution through retail pharmacies.[54] These recommendations contradict the results of a 2019 survey of abortion providers, which found that one-third of the providers had seen complications as a result of "self-managed" abortion, and only half felt that it was safe.[55]

Simply put, the FDA's increasingly lax treatment of chemical abortion is unscientific, unsettling, and dangerous to women.

B. The FDA's relaxed rules pose dangers to women.

Both the 2016 and 2021 changes to chemical abortion restrictions will likely increase the risks of the myriad complications detailed above. Indeed, by themselves, the 2016 changes, allowing women to use abortion drugs through 10 weeks' gestation and removing the requirement for abortion providers to report non-fatal, serious complications, increase safety risks. One study showed that extending chemical abortion to 10 weeks results in far higher failure rates in the higher gestational ages

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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).

[54] Am. Coll. Obstetricians & Gyns. (ACOG), *Updated Mifepristone REMS Requirements, Practice Advisory* (Jan. 2023), https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/01/updated-mifepristone-rems-requirements.

[55] Courtney A. Kerestes et al., *Abortion providers' experiences and views on self-managed medication abortion: an exploratory study*, 100 Contraception 160 (2019).

due to the increased amount of pregnancy tissue (a larger developing fetus) that must be expelled from the uterus.[56] Another study, a systematic review of 33,000 chemical abortions, documented less than 2% failures under seven weeks' gestation. But this number more than tripled (to 7%) by 10 weeks' gestation.[57]

The FDA's rule that prescribers report only deaths exacerbates the problem. 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.

The 2021 changes raise even more concerns. Permitting chemical abortion through telemedicine multiplies risks for women by removing necessary safeguards before, during, and after taking the drugs that will end and then expel, through tremendous pain and blood, the life growing inside of the mother. Specifically, 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.

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[56] Winikoff, *Extending Services, supra* note 50.

[57] Chen, *supra* note 42.

1. Ultrasounds

Ultrasounds are critical to appropriate abortion counseling and care. They ensure accurate information regarding the pregnancy, detect complications, and provide women with the tools to make a truly informed decision regarding their pregnancy.

First, without an in-person consultation, women are unlikely to obtain an ultrasound or physical examination to confirm the gestational age of their child. This is important because underestimation of gestational age will lead to far higher failure rates, resulting in additional complications and medical or surgical interventions.[58] Abortion advocates often assume that a woman will be able to determine her gestational age based on her last menstrual period, but that is an unreasonable assumption.[59] Women frequently miscalculate their fetus's gestational age.[60] 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. Further,

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[58] Mentula, *supra* note 42; Chen, *supra* note 42; Winikoff, *Extending Services, supra* note 50; Raymond, *supra* note 42.

[59] 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.

[60] 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).

increasing obesity rates have led to a higher incidence of polycystic ovarian syndrome, which causes irregular ovulation and menstruation.[61] 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.

Second, ultrasounds are the most accurate way to diagnose ectopic pregnancy. ACOG's website lists many common risk factors for ectopic pregnancies: previous pelvic or abdominal surgery, sexually transmitted infections, pelvic inflammatory disease, endometriosis, cigarette smoking, age older than 35 years, history of infertility, and use of artificial reproductive technology. Yet the website also states that half of women with ectopic pregnancies do not have any of these risk factors, so ectopic pregnancy cannot be ruled out merely by taking a history via telemedicine.[62] The gold standard for diagnosis of ectopic pregnancy is ultrasound.[63]

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

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[61] 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.

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

[63] 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).

to grow, possibly to the point of tubal rupture, which can lead to catastrophic bleeding and death.[64] Studies have documented that a woman is 30% more likely to die from a ruptured ectopic pregnancy while seeking abortion if the condition remains undiagnosed because she 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.[65]

Undiagnosed ectopic pregnancy leads to many other complications. One study examined 452 women with pregnancies of unknown location, 31 of whom were eventually diagnosed with ectopic pregnancies. The researchers documented four ruptured ectopic pregnancies, four hospitalizations, and eight major surgeries, clearly unacceptable outcomes for women who are already being cared for in a medical setting.[66]

The study also showed that women who received chemical abortion pills outside a medical setting (despite the inability to document pregnancy location and rule out ectopic pregnancy) had a failure rate of 14.6%, which is far higher than the 3–7% generally reported in the chemical abortion literature.[67] This same study

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[64] 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).

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

[66] Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 Obstetrics Gyn. 771, 775 (2022).

[67] *Id.*; Chen, *supra* note 42.

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.[68]

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."[69] And, while ectopic implantations occur in only 2% of pregnancies, they account for many maternal deaths. Despite the danger of undiagnosed ectopic pregnancy, the FDA allows, and abortion advocates recommend, chemical abortion even when the pregnancy location cannot be documented by ultrasound.

Third, ultrasounds also detect other crucial information, such as fetal well-being. Determination of fetal life and health should be documented prior to abortion. 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 abortion. Selling an abortion, when in fact the pregnancy has miscarried, will cause many women to undergo an unnecessary procedure, as well as carry the unnecessary guilt of ending a life. Failure to make this critical diagnosis may be the reason that

[68] Goldberg, *supra* note 66 at 776.

[69] ACOG, *Practice Bulletin No. 193*, *supra* note 64.

only 1% of Planned Parenthood's pregnancy services are miscarriage management, while 96% are elective abortions.[70]

Further, some women seek abortion because they are concerned that actions they have taken earlier in pregnancy, such as drinking or smoking, may have caused some damage to the fetus.[71] Seeing normal development in their fetus may give them reassurance and confidence to continue the pregnancy.

Finally, 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.[72]

The many risks of not having an ultrasound, or even the possibility of an ultrasound, are unacceptable.

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.[73] Nevertheless, because abortion is a medical procedure, it is subject to the doctrine of

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[70] Planned Parenthood Fed'n Am., *2020-2021 Annual Report* (Sept. 6, 2022), https://tinyurl.com/2u96rk6e.

[71] Sarah C.M. Roberts et al., *Alcohol, Tobacco and Drug Use as Reasons for Abortion*, 47 Alcohol & Alcoholism 640 (2012), https://doi.org/10.1093/alcalc/ags095.

[72] ACOG, *Practice Bulletin No. 175*, *supra* note 63.

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

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. And, to ensure that consent is sufficiently informed, the American Medical Association's guidelines on informed consent state that a patient should be given information about the diagnosis, the nature and purpose of recommended interventions, and the burdens, risks, and expected benefits of all options, including forgoing treatment.[74]

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 truth 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. This implicit claim is unsupported by the data and misleading to women.

Moreover, counseling women about additional risks might compel them to choose a surgical abortion instead, or perhaps if they were thoroughly counseled about all potential risks of abortion, they might choose to continue their pregnancies. A remote abortion provider likely will not counsel a woman on options other than abortion. Even in-person abortion provision seems deficient in this vital element of informed consent. Planned Parenthood's annual report documents that 97% of their

[74] 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.

pregnancy outcome services are abortion,[75] demonstrating the clear inadequacy of options counseling by many abortionists.

Moreover, intentionally ending a preborn human life is a momentous decision—one that should not be rushed or made without adequate knowledge of the meaning and risks of the action. It is essential to provide time following abortion counseling for a woman to consider the consequences of her action, which she may regret for a lifetime. Post-abortion regret is common, as evidenced by the proliferation of counseling programs for suffering women in churches and pregnancy resource centers.[76] Some women retrospectively report that they underwent abortions without adequate time to consider their actions or without true informed consent.[77] The availability of telemedicine abortion turns a blind eye to the gravity

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[75] "Pregnancy outcome services" refers to abortions, miscarriage care, adoption referrals, and prenatal services. Planned Parenthood Fed'n Am., *2020-2021 Annual Report* 27 (Sept. 6, 2022), https://tinyurl.com/2u96rk6e.

[76] Priscilla K. Coleman, *Post-Abortion Mental Health Research: Distilling Quality Evidence from a Politicized Professional Literature*, 22 J. Am. Phys. & Surgeons 38 (2017); Priscilla K. Coleman et al., *Induced abortion and anxiety, mood, and substance abuse disorders: isolating the effects of abortion in the national comorbidity survey,* 43 J. Psych. Rsch. 770 (2009); Priscilla K. Coleman, *Induced Abortion and Increased Risk of Substance Abuse: A Review of the Evidence*, 1 Current Women's Health Revs. 21 (2005).

[77] Katherine A. Rafferty & Tessa Longbons, *#AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*, 36 Health Commc'n 1485 (2020), DOI: 10.1080/10410236.2020.1770507. Also, a 2005 governmental task force in South Dakota held a series of investigative hearings on the informed consent process at Planned Parenthood, noting, "The record reflects that women are pressured into making the decision quickly. And once they arrive the day of the scheduled abortion, the process moves ahead without time to reflect." *See Report of the South Dakota Task Force to Study Abortion* 39–40 (Dec. 2005), https://tinyurl.com/5dp6r53r.

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.

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 conclusively prove 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. There is not a 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.

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.[78] The FDA should have continued to monitor events abroad because, shortly after relaxing restrictions,

[78] Chong, *Telemedicine Abortion, supra* note 53; 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).

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 heard from individuals and groups who raised the concern about remote abortion providers' decreased ability to identify domestic abuse and coercion.[79] 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."[80] This concern seemed to be validated when a BBC poll 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.[81]

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."[82]

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[79] 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.

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

[81] 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/us/knowledge-centre/poll/reproductive-coercion-poll-bbc-radio-4-8-march-2022/.

[82] David C. Reardon & Tessa Longbons, *Whose Choice? Pressure to Abort Linked to Worsening of Subsequent Mental Health,* Charlotte Lozier Inst. (Feb. 7, 2023),

Telemedicine abortion also raises serious concerns about coercion 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.[83] Making abortion pills available via telehealth allows traffickers to limit trafficking victims' access to healthcare professionals, removing this crucial protection for victims.

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.[84] And more than half of the survivors who responded "indicated that one or more of their abortions was at least partly forced upon them."[85] Because 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

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https://lozierinstitute.org/whose-choice-pressure-to-abort-linked-to-worsening-of-subsequent-mental-health/.

[83] 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.

[84] *Id.* at 73.

[85] *Id.*

women to obtain prescriptions so that the traffickers can stockpile abortion pills and coerce other women into taking the pills against their will.

4. Mailing Pills

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 obtaining abortion pills from international distributors found that the pills took on average two weeks to arrive, some misoprostol pills contained only 15% of the advertised amount of misoprostol, the packages often arrived damaged, and none of the packages contained instructions.[86]

Another smaller study of 40 women in India examined the feasibility of providing chemical abortion pills over the counter and found that 27% of the women consumed the pills past the recommended gestational age cutoff, with 17% of the women consuming the pills more than three weeks past the cutoff. This resulted in

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

excessive hemorrhage in 77% of the women, surgical evacuation in 68%, severe anemia requiring transfusion in 12%, and hemodynamic shock in 5%.[87]

Even if some oversight exists for obtaining the pills within the U.S., the FDA's regulation signals to women everywhere that abortion pills via mail are safe and thus it is likely that more women will try to obtain the pills from alternate and unsafe sources.

5. 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 is 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."[88]

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[87] K. Nivedita & Fatima Shanthini, *Is It Safe to Provide Abortion Pills over the Counter? A Study on Outcome Following Self-Medication with Abortion Pills*, 9 J. Clinical & Diagnostic Rsch. QC01 (2015).

[88] ACOG, *Practice Bulletin No. 225, supra* note 37.

In addition, fetal survival continues in 1–3% of women consuming the medical abortion pills.[89] Prompt diagnosis that the medical abortion did not work will allow these women to obtain a surgical abortion earlier (and more safely) than if there is no follow-up and the diagnosis is made belatedly. Plus, providers prescribing abortion pills should have the ability to treat this frequent complication rather than leaving women to rush to the emergency room. It is patient abandonment to force these women to obtain this care from our 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.[90] Without a physician-patient relationship, a woman experiencing these common complications after chemical abortion finds herself abandoned and at high risk for adverse outcomes.[91]

Even if a complication arises that exceeds a particular abortion provider's expertise, such as sepsis from Clostridium sordellii,[92] all physicians can obtain a consultation from another physician, such as an infectious disease specialist or intensive care specialist, when these rare events occur. A woman should not be left to find an appropriate doctor on her own.

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[89] Raymond, *supra* note 42; Winikoff, *Extending Services, supra* note 50.

[90] 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.

[91] 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).

[92] Fischer, *supra* note 40; Miech, *supra* note 40.

6. Harms to physicians

Finally, telemedicine chemical abortion harms 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. Like other physicians, obstetricians work for the wellbeing of their patients. An obstetrician occupies a unique space, however, because the obstetrician has two patients: the mother and the unborn child, who each have unique, and sometimes conflicting, needs.

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."[93] Obstetricians exercise "reasonable medical judgment" to provide the best care possible, even if reducing the risk for one patient may increase the risk for the other. Rejection of elective abortion is not only consistent with the two-patient paradigm, it is also the fulfillment of the physician's oath that he or she will not intentionally harm a patient.

Abortion advocates, however, follow a "one-patient paradigm," whereby they seem willing to consider only the interests of the mother. 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

[93] 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).

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.[94] 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 pro-life plaintiffs in this case, is not undercut by the fact that leadership at several larger progressive medical organizations support expansive abortion. Historical examples demonstrate that large medical organizations are not the bearers of scientific or moral truth. In the early 1900s, the American Psychological Association (APA) created a Committee on Measurement, which consisted of many psychologists who supported "racial hierarchy and/or eugenics." In fact, as the APA acknowledges, "[b]etween 1892 and 1947, 31 presidents of APA acted in leadership positions in eugenics organizations[.]"[95] Then, in 1952, the APA classified homosexuality as a mental disorder. The APA did not remove homosexuality as a mental disorder until 1973.[96] And the American Medical

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[94] 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).

[95] Am. Psych. Ass'n, *Historical chronology: Examining psychology's contributions to the belief in racial hierarchy and perpetuation of inequality for people of color in U.S.* (Oct. 2021, updated Feb. 2022), https://www.apa.org/about/apa/addressing-racism/historical-chronology.

[96] Sarah Baughey-Gill, *When Gay Was Not Okay with the APA: A Historical Overview of Homosexuality and its Status as Mental Disorder*, 1 Occam's Razor (W. Wash. U.) 1, 7 (2011).

Association (AMA), for its part, opposed the creation of Medicare.[97] 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 the American College of Obstetricians and Gynecologists, one must understand the organization's two distinct roles—issuing policy and position statements and issuing clinical guidelines. ACOG policy and position statements address ideological issues outside of the organization's field of expertise. For instance, recent ACOG position statements call on "national and international leaders to act to curb greenhouse gas emissions and limit further climate destabilization."[98]

Although abortion is within ACOG's wheelhouse, ACOG releases these types of statements on abortion that are driven by political ideology, such as *Committee Opinion No. 815: Increasing Access to Abortion*, which states, "Safe, legal abortion is a necessary component of comprehensive health care."[99] Similarly, *Committee Opinion No. 385, The Limits of Conscientious Refusal in Reproductive Medicine*, claims that, when it comes to abortion, "[p]hysicians … have the duty to refer patients

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[97] 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.

[98] ACOG, *Position Statement, Addressing Climate Change* (rev. Nov. 2021), https://tinyurl.com/5ybutebf.

[99] ACOG, *Committee Opinion No. 815: Increasing Access to Abortion*, 136 Obstetrics Gyn. e107 (2020), https://tinyurl.com/svyxap3p.

… if they do not feel that they can in conscience provide the standard reproductive services that patients request."[100]

But this statement is contradicted by ACOG's Committee Opinion 390, Ethical Decision Making in Obstetrics and Gynecology, which 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."[101] It is difficult to understand why ACOG does not apply these principles to fetuses, especially considering that many OBGYNs do try to avoid harm to a fetus, which is evidenced by the fact that only 7–14% of them will perform elective abortions.[102] The chasm between ACOG's pro-abortion statements[103] and their membership's actual medical care and willingness to perform abortions undermines the weight one should attribute to ACOG's position.

In addition to the position and policy statements, ACOG provides clinical practice guidelines for members that are developed through a peer-review process that generally ensures that the recommendations are based on science.[104] But ACOG

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[100] ACOG, *Committee Opinion No. 385: The Limits of Conscientious Refusal in Reproductive Medicine*, 110 Obstetrics Gyn. 1203 (2007), https://tinyurl.com/yckv2ydv.

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

[102] Desai, *supra* note 94; Stulberg, *supra* note 94.

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

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

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,[105] 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,[106] and (in Grossman's case) who cowrote *Practice Bulletin No. 135: Second-Trimester Abortion*.[107]

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. Some of these emergency situations will force pro-life doctors into situations in which they feel complicit in an elective chemical abortion by needing to remove a baby with a beating heart as the only means to save the life of the woman or girl. This 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

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[105] 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.

[106] ACOG, *Practice Bulletin No. 225* at e71, *supra* note 37.

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

of medicine itself, which is to heal and not to electively kill human beings regardless of their location.

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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. And this disregard for scientific evidence is harming both women and physicians.

V. The claimed benefits of chemical abortion do not outweigh the substantial risks.

To counter the risks described above, the FDA points to the purported benefits of chemical abortion, including economic benefits and greater abortion access and convenience. *See, e.g.*, Defs.' Opp'n to Pls.' Mot. for Prel. Inj. at 38–40, Doc. No. 28 (Opp'n). But abortion is economically *disadvantageous*, and the excessive accessibility of chemical abortion creates additional risks, not benefits.

A. Chemical abortion is not economically beneficial.

The FDA argues that if chemical abortion became unavailable, the result would be "increased health care costs due to increased health care utilization; increased taxes due to increased reliance on public assistance and social safety net programs; and general exposure to poverty, which is pervasive, hard to escape, and often persists from one generation to the next." Lindo Decl. ¶ 22 (Doc. 28-2). These arguments are flawed.

First, the actual evidence shows that the unavailability of chemical abortion is unlikely to put any strain on the healthcare system. There will likely be no strain on abortion providers, as the number of providers per abortion has significantly increased over the past few decades and remains much higher than pre-*Dobbs* or even pre-*Casey* levels.[108] Thus, there are now more providers per abortion than there were before chemical abortion was available. What is more, given the increased medical risks of chemical abortion over surgical abortion, removing chemical abortions may put *less* of a strain on the healthcare system overall.

Second, although the birth of a child may result in public assistance and safety net costs, the eventual economic (and tax) contribution of that child will quickly exceed those costs. For example, if a child who is not aborted grows up and works full time, she could expect to earn a median wage of $1,070 per week or $55,640 per year.[109] Assuming a tax burden of 25%, this would provide the government with $13,910 per year.

Third, it is also important to consider the economic effect of parenting. The presence of a child may lead to an increased sense of responsibility, thus increasing economic productivity.[110]

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

[109] U.S. Bureau Lab. & Stats., *TED: The Economics Daily, Median weekly earnings $971 for women, $1,164 for men, in third quarter 2022* (Nov. 2, 2022), https://tinyurl.com/3kxm37jm.

[110] Rebecca Glauber, *Trends in the Motherhood Wage Penalty and Fatherhood Wage Premium for Low, Middle, and High Earners*, 55 Demography 1663 (2018),

B. Convenient abortion access is a risk, not a benefit.

The FDA also argues that telemedicine chemical abortion benefits women by providing them easier access to abortion. Opp'n at 38; Lindo Decl. ¶ 13. But this easy access is not only *not* beneficial for reasons explained above, it also comes at a great cost.

For example, studies show that, in response to abortion restrictions, couples reduce promiscuity and use more effective contraception.[111] Thus, the number of unwanted births remains relatively stable, but other costly events (economic and emotional) are avoided.

Moreover, as detailed above, the availability of telemedicine abortions increases the risk of domestic abuse and coercion, particularly for victims of sex trafficking. *See supra* at 31–34. The FDA assumes that factors such as domestic violence lead to higher rates of abortion while ignoring that telemedicine chemical abortion can *itself* lead to more domestic violence.

Finally, the fact that telemedicine chemical abortion is easier to access than surgical abortion is not a benefit. *See* Opp'n at 38. The most reliable data show that surgical abortion—for all its risks—is still safer than chemical abortion. *See supra* at Section III. And the further a woman lives from the abortion provider, the greater

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https://read.dukeupress.edu/demography/article/55/5/1663/167918/Trends-in-the-Motherhood-Wage-Penalty-and.

[111] Jonathan Klick & Thomas Stratmann, *The effect of abortion legalization on sexual behavior: evidence from sexually transmitted diseases*, 32 J. Legal Stud. 407 (2003); https://www.journals.uchicago.edu/doi/10.1086/377049; Phillip B. Levine, *Sex and Consequences: Abortion, Public Policy, and the Economics of Fertility* 107–132 (Princeton Univ. Press 2004).

her risk if she suffers complications from chemical abortion. Women with limited access to emergency care would be far better served by a surgical abortion that is completed at the clinic and has a lower rate of complications. Thus, remote location is an argument *against* chemical abortion, not a reason to encourage it.

CONCLUSION

The FDA has made an unjustifiable and unreasonable risk-benefit assessment regarding chemical abortion. The end result is over-the-counter abortion provision dissociated from the medical system entirely, except, of course, for the emergency room physicians who will be called upon to care for the myriad complications. And women are left to navigate this mess alone. For these reasons, and those laid out above, *amicus* respectfully urges this Court to grant Plaintiffs' motion for preliminary injunction.

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**Pro hac vice* application forthcoming

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CERTIFICATE OF SERVICE

On February 13, 2023, I filed the foregoing document with the clerk of court for the United States District Court, Northern District of Texas. I hereby certify that I have served the document on all counsel and/or pro se parties of record by a manner authorized by Federal Rule of Civil Procedure 5(b)(2) (ECF System).

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