February 15th, 2023

SB5 Proponent Written Only Testimony

Kari Sue Vosburgh
Sedgwick County Precinct Person

Chairwoman Gossage and Members of the Committee,

I am writing to request your support of SB5. I may be approaching this a little differently than most as I am not focusing my argument on the death of the child, but on the safety of the mother, who in some cases may be a child herself.

I didn't know any details of the chemical abortion process so I did a little research. The process requires the patient to take 2 different drugs. The first drug blocks progesterone, which causes the uterine lining to breakdown and stops the child's supply of oxygen and nutrients. The second drug is taken 24 to 48 hours later to induce contractions to expel the embryo and placenta. If the deceased embryo is not expelled infection, sepsis and potential death of the mother may occur.

In September 2000, despite known risks, the FDA approved the use of two drugs as a method of abortion under "restricted distribution requirements". This required strict protocols for use and that all serious adverse events and deaths be reported to the FDA by the manufacturer of the two drugs. The protections for women included: only trained physicians could prescribe the drugs; to determine a gestational age of under 49 days and to rule out ectopic pregnancy three in-person office visits were required. A final visit 14 days later, was necessary to confirm the abortion was complete.

In 2016 the safeguards mentioned above were severely weakened when the FDA allowed non-physicians to dispense the drugs, lowered the in-person visit to one, changed drug dosages, and changed the reporting requirements to deaths only.

In 2020, the Covid-19 pandemic was used to pressure the FDA to stop enforcing the only remaining in-person office visit. This allowed for abortions via telehealth. In December of 2021 the FDA announced it had eliminated the in-person dispensing requirement. It is predicted this would lead to even more mail-order access to abortion drugs with little or no oversight by a physician. One might wonder how is it even possible for a state to enforce telehealth and mail-order abortion regulations? How many young girls (children themselves) will unknowingly put their lives at risk by obtaining these drugs without parental consent?

Some of the risks to the mothers from chemical abortion involve death due to no physical exam requirement to rule out an ectopic pregnancy prior to starting the process. Another is an incomplete abortion due to a miscalculation of LMP (last menstrual period). This may lead to birth defects such as skull deformities and missing or deformed limbs. Failure to expel the deceased child and placenta may lead to a systemic infection and death of the mother. There is also evidence that both drugs may suppress the immune system. This could increase the chances of infection and death, especially in a health crisis and should not be allowed. Hemorrhaging is another possible outcome which may lead to death of the mother.

I encourage you to read the 3 attachments I've included, particularly the "What to Expect" attachment. I also encourage you to protect our mothers of all ages by supporting SB5.

Thank you,

Kari Sue Vosburgh

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Just the Facts: Q & A on Chemical Abortion

What is a chemical abortion?

Chemical abortion is a two-drug process intended to kill and expel a developing child from the womb in the first trimester of pregnancy.

Proponents call it "medication abortion," but that's misleading. "Medication" indicates something that is intended to manage a patient's disease or illness. The first drug—mifepristone (brand name "Mifeprex," originally called RU-486)—was not developed as a treatment or cure, but to end a child's life. Thus, "chemical abortion" is the more accurate name.

Misoprostol (brand name Cytotec) is the second drug needed to complete a chemical abortion. In 1988 Cytotec was approved by the Food and Drug Administration ("FDA") *only* for the prevention of gastric ulcers in patients at high risk of complications from long-term use of aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs). When the *unapproved,* off-label use of Cytotec for abortion and labor induction resulted in numerous reports of serious complications—including uterine rupture, fetal and even maternal deaths—both its manufacturer and the FDA explicitly warned of the dangers of giving Cytotec to pregnant women.[i]

How does a chemical abortion work?

Mifepristone can cause the death of an embryo or fetus by blocking progesterone, a hormone essential to maintaining pregnancy. This leads to the breakdown of the uterine lining and cuts off the child's supply of oxygen and nutrients. Mifepristone alone will kill 75% or more of embryos, but these deceased embryos may not be expelled. This can result in infection, sepsis, and potentially the mother's death. For this reason, the second pill—misoprostol—is taken 24 to 48 hours later to complete the abortion by inducing uterine contractions strong enough to expel the embryo and placenta.

In 2012, Drs. George Delgado and Mary Davenport pioneered the Abortion Reversal Protocol (ARP), giving high doses of progesterone in the first 72 hours after taking mifepristone and before taking misoprostol. Studies have shown a 66% success rate in saving babies' lives using the ARP.[ii]

What safety protocols did the FDA mandate to protect women's health?

Despite the known risks of mifepristone and misoprostol, in September 2000 the FDA inexplicably approved their use as a method of abortion[iii] under "restricted distribution requirements," meaning that Danco Labs—which owns the rights to manufacture, market, and distribute Mifeprex—would adhere to strict protocols for use and report all serious adverse events and deaths to the FDA.

Among the "*safeguards to protect women"* were the following[iv]: only trained physicians could prescribe the drugs; three in-person office visits were required so that doctors could determine a gestational age of under 49 days LMP (calculated as the days passed since the first day of the last menstrual period) and also rule out ectopic pregnancy. Crucially, they were *not required* to use transvaginal ultrasound. A final visit, 14 days later, was deemed necessary to confirm a completed abortion. If incomplete, a second dose of misoprostol could be given to expel the deceased embryo and placental tissue to avert serious infection, sepsis, and maternal death (if not already too late). In 2011, the FDA incorporated the original safeguards in a Risk Evaluation and Mitigation Strategy[v] (REMS).

The safeguards related to Mifeprex/mifepristone in the REMS were severely weakened in 2016, however, when the FDA permitted non-physicians to dispense the drugs, eliminated the second and third office visits, changed drug dosages, and eliminated the requirement on providers to "report any hospitalization, transfusion or other serious event to Danco Laboratories."[vi] Only deaths were to be reported to Danco.

In 2020, abortion proponents seized upon the COVID-19 pandemic to sue[vii] for the right to dispense chemical abortion drugs without even the initial office visit with a trained provider. A federal judge initially agreed, but the U.S. Supreme Court ruled on January 12, 2021 that the FDA, pending appeal, could enforce the REMS designed to protect women undergoing chemical abortion.[viii] But the FDA bowed to pressure from the abortion lobby and declined to enforce the REMS, ushering in at-home abortions via telehealth and mail.

Why is the abortion lobby pushing so hard to eliminate the REMS and encourage in-home mail order abortions?

The abortion industry is in trouble. The annual number of U.S. abortions has steadily declined from a high of over 1.6 million in 1990 to fewer than 863,000 in 2017.[ix] The abortion rate in 2017 was 13.5 per 1,000 women, the lowest ever recorded.[x] Fewer providers in many parts of the country, lower pregnancy rates (especially among teens), the provision of ultrasounds in pregnancy care centers, new state efforts to restrict abortion and protect pregnant women can all mean lower revenues for the industry and contribute to its efforts to promote risky at-home abortions. Sadly, on December 16, 2021 the FDA announced that it eliminated the "in-person dispensing requirement" for chemical abortions, which will significantly increase mail-order access to abortion drugs with little or no oversight by a physician. With this action, we'll never know the full extent of harm to the women whom the FDA is supposed to protect.

Updated October 2022

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[i] FDA-approved Cytotec label as of 2018, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019268s051lbl.pdf and FDA, Questions and Answers on Mifeprex | FDA, accessed November 8, 2021.

[ii] Charlotte Lozier institute, "Abortion Pill Reversal: A Record of Safety and Efficacy," September 24, 2021. https://lozierinstitute.org/abortion-pill-reversal-a-record-of-safety-and-efficacy . Accessed November 8, 2021.

[iii] Center for Drug Evaluation and Research. Approval Letter for Mifeprex NDA 20-687. February 18, 2000. Food and Drug Administration, p. 5. Accessed November 8, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687approvable00.pdf.

[iv] Kathi A. Aultman et al., "Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019," *Issues in Law & Medicine* 36:1 (2021), p. 6.

[v] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2011. 1-11. Reference ID:2957855. Published June 8, 2011. Accessed November 8, 2021. Mifeprex REMS (fda.gov).

[vi] Aultman et al., pp 6-7, citing NDA 20-687 MIFEPRIX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2016. p. 6. Reference ID: 3909592. Published March 29, 2016. Accessed November 8, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf.

[vii] https://www.courthousenews.com/wp-content/uploads/2020/07/093111166803.pdf.

[viii] *Food and Drug Administration, et al. v. American College of Obstetricians and Gynecologists, et al*. SCOTUS. 20a34_3f14. https://www.supremecourt.gov/opinions/20pdf/20a34_3f14.pdf. Accessed November 8, 2021.

[ix] https://en.wikipedia.org/wiki/Abortion_statistics_in_the_United_States#/media/File:U.S._abortions_and_abortion_ratios,_1973-2017,_Guttmacher_Institute.png. Accessed November 8, 2021.

[x] https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017.

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Major Risks and Complications of Chemical Abortion for Women

Chemical abortion is a two-drug process intended to kill and expel a developing child from the womb in the first trimester of pregnancy. Proponents call it "medication abortion," but that's misleading. "Medication" indicates something that is intended to manage a patient's disease or illness, but chemical abortions end the life of an unborn child and can be dangerous to the health and lives of pregnant mothers, as well. Here is why.

Ectopic Pregnancy: An ectopic (tubal) pregnancy is when an embryo implants somewhere other than in the mother's uterus (often in the fallopian tube). If an embryo remains in the fallopian tube, its growth leads to a rupture of the tube and possibly maternal death. An estimated 2% of reported pregnancies are ectopic, but tracking is inadequate, so the number could be higher.[i] In 2011 to 2013, "ruptured ectopic pregnancy accounted for 2.7% of all pregnancy-related deaths and was the leading cause of hemorrhage-related mortality."[ii]

It is medically imperative for ectopic pregnancy to be ruled out by ultrasound examination before a woman undergoes a chemical abortion. Otherwise, the severe pain and bleeding associated with chemical abortion would mask the similar symptoms of ectopic pregnancy. And since chemical abortion does not lead to the death of an embryo in the case of ectopic pregnancy, the embryo would continue growing, and the ectopic pregnancy would remain undetected until the fallopian tube ruptured, potentially taking the mother's life, as well as her child's.

Incomplete abortion: As a pregnancy continues, the effectiveness of the chemical abortion regimen decreases, and the possibility of incomplete abortion increases. One outcome of incomplete abortion is ongoing pregnancy, which has been linked to birth defects, such as missing and deformed limbs and skull deformities.[iii] Another possible outcome of incomplete abortion is failure to expel all or part of the deceased child and placenta, leading to systemic infection and, potentially, maternal death.

The FDA initially approved the chemical abortion regimen only up to the gestational age of 49 days LMP (calculated by counting from the first day of the last menstrual period) because effectiveness drops sharply with each passing week. In the U.S. clinical trial, the regimen was effective for 92 percent of patients with pregnancies up to 49 days' gestation, 83 percent effective in pregnancies between 50-56 days, and 77 percent effective in pregnancies between 57-63 days' gestation.[iv]

Analyzing the U.S. chemical abortion trial, I. Spitz et al. reported that the decreasing effectiveness of chemical abortion was seen most dramatically in the increased rate of ongoing pregnancies between gestational age groups. In the under-49 days' gestation group, one percent of pregnancies continued despite being subjected to the chemical abortion regimen; in the 57-63 days group, nine percent of pregnancies continued.[v]

A U.S. study by J. Jensen et al. compared serious adverse events among women in the U.S. clinical trial for chemical abortion to women later undergoing surgical abortion at the same clinic. Subsequent surgical intervention was required for 18.3 percent of the chemical abortion patients versus 4.7 percent of surgical patients.[vi] Among chemical abortion patients needing subsequent surgery, 15.6 percent were for incomplete abortion in which there was a failure to expel the deceased child and/or placenta and 28.1 percent for ongoing pregnancy.[vii]

A woman's abortion pill provider needs to know the gestational age of the fetus to assess the likelihood of incomplete abortion and the resulting associated risk to the mother. It is important to the mother's health to not rely upon an estimation of the first day of her last period, which is prone to human error. While direct

observation with a basic ultrasound may suffice in the earliest weeks, transvaginal ultrasound is essential in assessing gestational age in later weeks when her risk is greatly increased.

Infection: An article in the *New England Journal of Medicine* warned: "Medical studies estimate that RU-486 results in ten times the fatalities to women, from infection alone, than surgical abortion in early pregnancy – and that was calculated before the most recent deaths."[viii] A journal article titled "Post Abortion Infections"[ix] warned that "because medical termination may be incomplete in between 3% and 23% of patients, retained tissue and subsequent infection may go unrecognized in those lost to follow-up." Additionally, there is evidence that both drugs used in chemical abortion can suppress a woman's immune system.[x]

Many maternal fatalities have been linked to *Clostridium sordellii*, a bacterium that lives in the gut flora of approximately 10% of women.[xi] Normally, a woman's immune system can keep this toxic bacterium in check. It can grow rapidly and fatally, however, when contractions dislodge the cervical mucus plug protecting the uterus and child, and the bacterium can then feed off decaying tissues.[xii]

Hemorrhaging: Severe blood loss can result in death. Examining what little data the FDA's adverse event system contained, K. Aultman et al. found that "of the 3056 women who took both [pills], 1572 (51.44%) hemorrhaged. … It was unclear whether 84 patients took misoprostol or not. Fifty-four (64.29%) of them hemorrhaged."[xiii]

Frequency of Adverse Events: Records-linkage documented evidence[xiv] in the United States points to the frequency of injuries to women undergoing chemical versus surgical abortion. Seventeen states maintain records of state Medicaid reimbursements for abortions and subsequent emergency room ("ER") treatment within 30 days of the abortion.[xv] Based on this data, in 2015, the rate of ER visits per 1,000 women who underwent a chemical abortion in the past 30 days was an astonishing 354.8.[xvi]

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[i] K. Aultman et al., "Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019," at 21. Accessed Nov. 20, 2021.
[ii] Ibid., citing ACOG Practice Bulletin No. 193: Tubal Ectopic Pregnancy, Obstet Gynecol: March 2018; 131(3): e91-e103. Accessed Nov. 21, 2021.
[iii] Irving Spitz et al., "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," *New England Journal of Medicine* 338 (April 30, 1998): 1241-47.
[iv] AAPLOG 2002 Citizen Petition to the FDA, 29. Accessed Nov. 20, 2021.
[v] Irving Spitz et al., "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," *New England Journal of Medicine* 338 (April 30, 1998): 1241-47.
[vi] J. Jensen et al., "Outcomes of Suction Curettage and Mifepristone Abortion in the United States: A Prospective Comparison Study," *Contraception* 59 (1999): 153-159.
[vii] Ibid.
[viii] Michael F. Greene, MD and J.L. Ecker, MD, "Abortion, Health, and the Law," *New England Journal of Medicine* 350;2, 184-186, Jan.8, 2004); *Life Insight*, March-April 2006. Accessed Nov. 20, 2021.
[ix] ix A.K. Kreutner et al., "Postabortion Infections," Contemporary Ob/Gyn 1 (2001) at 37-42 is quoted in AAPLOG 2002 Citizen Petition to the FDA, at 68 (note 300). Accessed Dec. 14, 2021.
[x] Aultman et al., note 1, at 6.
[xi] "How Many Deaths Will It Take for the FDA to Suspend Sales of RU-486? Accessed Nov. 20, 2021.
[xii] Ibid.
[xiii] Aultman et al., note 1, at 13.
[xiv] Records-linkage studies are particularly credible because of the large amount of data available and the ability to cross-reference and filter it. Where single-payer healthcare exists (in which the government is the entity paying providers), governments maintain databases of all healthcare records of all individuals. The records of names, diagnoses, and treatments are coded, but these comprehensive registries can easily be searched to identify and link information from multiple sources to one person.
[xv] J. Studnicki et al., "A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions 1999-2015," *Health Services Research and Managerial Epidemiology* 8 (2021): 1-11. Accessed Nov. 20, 2021.
[xvi] Id., at 1.

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What to Expect from the FDA's Permanent Approval of "Telehealth" Abortions

Chemical abortion is a two-drug process intended to kill and expel a developing child from the womb in the first trimester of pregnancy. Proponents call it "medication abortion," but that's misleading. "Medication" indicates something that is intended to manage a patient's disease or illness, but chemical abortions end the life of an unborn child and can be dangerous to the health and lives of pregnant mothers, as well. Now that the FDA has tragically decided to eliminate the important safety protocol of in-person dispensing, which is needed to protect women's health, here is what we can expect:

1. As long as the federal Food and Drug Administration (FDA) withholds information about the true risks of chemical abortion and the frequency of serious adverse events[i]—thereby allowing chemical abortion to be promoted as a safe and private alternative to surgical abortion ("like a miscarriage")—its use will continue to grow.

2. Major risks and complications[ii] to women's health may rise sharply due to the lack of even minimally adequate screening. It is essential to verify gestational age to determine the risk to the mother of using chemical abortion, which increases as the baby develops. It is also critical to rule out ectopic pregnancy (which is possible only by an ultrasound exam) and to rule out other conditions that increase the risks of maternal injury and death. Such medical determinations may require bloodwork. In her analysis of a "no test protocol" (meaning no in-person ultrasound and blood testing) proposed by abortion advocacy groups[iii], Ingrid Skop, M.D. a Fellow of the American College of Obstetrics and Gynecology, notes: "[I]t is a frequent occurrence for a woman to underestimate gestational age by a month or more. One study found almost 15% of Atlanta women were in error by more than two weeks when calculating gestational age based on LMP" (the number of days since the first day of the last menstrual period)." An October 2021 study in England[iv] calculated that over 10,000 women who were undergoing a chemical abortion via "pills-by-post" sought emergency medical assistance for complications.

3. Women in rural communities could have easy access to the pills by telehealth and mail order but be unable to access emergency care when experiencing a life-threatening complication.[v]

4. More minors will be able to more easily obtain the pills without parental knowledge or consent, in violation of state parental involvement laws.

5. The lack of medical oversight would presumably increase the possibility of maternal health risk. For example, women face increased risk from the procedure the longer the baby develops.[vi] With mail-order medical termination of pregnancy (MTP) kits, there is no guarantee women will take the pills prior to the gestational "cut-off" date, 70 days LMP (which is already risky). One study found a failure rate of 14.9% when the gestational age was 57-63 days LMP with oral misoprostol.[vii]

6. Without in-person counseling in the privacy of a doctor's office, it is even more difficult to assess whether coercion is bearing on the woman's decision. Additionally, there is no certainty that the woman who obtains the pills is the person who will take them. Four men have been prosecuted

for attempting to or succeeding in killing their unborn child by slipping abortion pills into their girlfriends' drinks or food.[viii]

7. On April 12, 2021, the FDA reversed its ban on mail order sales of chemical abortion pills,[ix] ostensibly as a response to the Covid pandemic and only for its duration. It thus eliminated any pretense of a doctor-patient relationship and the ancient medical maxim, "First, do no harm." Websites trafficking in chemical abortion pills have proliferated.

8. "Medical termination of pregnancy" (MTP) kits can be found on hundreds of websites.[x] Some pills have been found to vary widely from the stated dosages recommended by the FDA.[xi]

9. The ability to purchase abortion pills in bulk will further enable sex traffickers to continue in the abuse and enslavement of girls and young women.[xii]

10. More women will experience the emotional toll of seeing their deceased child, an experience providers of surgical abortion strive to avoid.

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[i] The FDA claimed it had "conducted a full literature search prior to its decision" to suspend the adverse event reporting (AER) requirements with respect to chemical abortions (except mortalities). A 2021 peer-reviewed study of adverse events obtained through the Freedom of Information Act, however, "found a variety of serious and life-threatening conditions that were reported to the FDA and withheld from public knowledge." CLI Fact Sheet: An Abundance of Neglect: FDA's Suspension of Medical Management of Abortion Pills. (Undated). Accessed Nov. 22, 2021.

[ii] C.f. "Major Risks and Complications of Chemical Abortion for Women," United States Conference of Catholic Bishops, December 2021.

[iii] I. Skop, "The 'No-Test Medication Abortion' Protocol: Experimenting with Women's Health," July 30, 2020. Accessed Nov. 22, 2021.

[iv] Kevin Duffy, "FOI Investigation into Medical Abortion Treatment Failure," Percuity Ltd. (October 27, 2021). foi-ma-treatment-failure-211027.pdf (wordpress.com) Accessed December 8, 2021.

[v] https://www.ruralhealthinfo.org/topics/emergency-medical-services. Accessed December 8, 2021.

[vi] E. Raymond E., et al. (2013). "First trimester medical abortion with mifepristone 200 mg and misoprostol." *Contraception*, 87(1), 26-37. Accessed December 8, 2021.

[vii] One study "found a statistically significant difference in success rates by gestational age. For gestational age up to 5 weeks the success rate was 100%. Up to 6 weeks, the success rate was 86%, and when the gestational age was higher than 6 weeks (7–9 weeks) the success rate was 78%." https://www.fertstert.org/action/showPdf?pii=S0015-0282%2808%2900896-0. Accessed December 8, 2021. See also, https://journals.lww.com/greenjournal/Abstract/2008/12000/Two_Distinct_Oral_Routes_of_Misoprostol_in.18.aspx . Accessed December 8, 2021. Failure can involve ongoing pregnancy (with likelihood of deformities from misoprostol) or retained products of conception leading to infection and death if not treated by surgical abortion.

[viii] H. Howard, "Medical and Social Risks Associated with Unmitigated Distribution of Mifepristone: A Primer," Oct. 1, 2020. Accessed Nov. 22, 2021.

[ix] C. Freiburger, "Citing Covid-19, Biden FDA Approves Dispensing Abortion Pills Through Mail," LifeSite News, April 13, 2021. Accessed Nov. 22, 2021.

[x] C. Kerestes et al., "Googling Abortion Pills: The Ease of Buying Misoprostol and Mifepristone Online for Home Use," Obstetrics & Gynecology: May 2019. Vol. 133. Accessed December 8, 2021.

[xi] Ibid.

[xii] Fact Sheet: Online Sales of Mifeprex and Misoprostol for Self-Abortion - Charlotte Lozier Institute, April 23, 2018. Accessed Nov. 22, 2021.