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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.

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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.