MIFEPRISTONE SAFETY & EFFICACY

9 Quick Facts about the Abortion Pill

Drug-induced abortions are painful and bloody.
These pills work by shutting down the child's life support system, initiating bleeding, and then stimulating powerful, painful contractions to expel the child and other contents from the uterus. Pain and bleeding are unavoidable parts of the process.[8]

Women lose more blood from a chemical than a surgical abortion.[9]
Chemical abortions take longer to complete than surgical ones.
Not counting recovery time, surgical abortions may take maybe 10 minutes to complete, so that a woman can be in and out of a clinic in a couple of hours[10]. Chemical abortions involve multiple drugs taken over a number of days and may take days or weeks to be fully completed.[11]

"Medication" abortions have a significant failure rate.
The FDA warns these drugs fail to deliver a complete abortion 2-7% of the time[12].

The risk of failure and complications increases with gestational age.
The FDA originally limited use of mifepristone to women no more than 49 days after their last menstrual period (LMP) because of reduced efficacy and increased complications after that point.[13] Years of field experience have confirmed this.[14]

Women see their aborted children's bodies.
Identification of the embryo or fetus is one of the ways a woman is able to confirm the abortion pill has done its job, but it can also prove traumatic when women report seeing their child's eyes, fists, or other body parts.[15]

There have been at least 28 deaths and thousands of injuries among American mifepristone patients.
The FDA reports that more than two dozen mifepristone patients in the U.S. have died after taking mifepristone and that thousands of others have suffered from complications such as hemorrhages, infections, and the rupture of previously undiscovered ectopic pregnancies, many requiring hospitalization and surgery.[16]

The warning signs of ectopic pregnancy are disturbingly similar to chemical abortion side effects.
Because women having drug-induced abortions normally face considerable abdominal pain and bleeding, patients and even doctors who have not seen an ultrasound have missed these anger signs of a rupturing ectopic pregnancy.[17]

Several mifepristone users came down with serious bacterial infections.
A number of women taking mifepristone died after contracting *Clostridium sordellii*, an anaerobic bacteria that thrives in oxygen-poor environments where there may be an open wound.[18]

Bleeding can lead to life-threatening hemorrhage.
Every woman going through a chemical abortion does a considerable amount of bleeding, but when this bleeding is heavy and does not stop, she can be in serious danger if she does not get surgical treatment.[19]

Detailed Notes & Citations

8. FDA Mifepristone Label (see note 1) on page 7 says: Abdominal pain/cramping is expected in all medical abortion patients and its incidence is not reported in clinical studies. Treatment with MIFEPREX and misoprostol is designed to induce uterine bleeding and cramping to cause termination of an intrauterine pregnancy. Uterine bleeding and cramping are expected consequences of the action of MIFEPREX and misoprostol as used in the treatment procedure. Most women can expect bleeding more heavily than they do during a heavy menstrual period. Daniel Grossman, *et al.*, in "Experiences with pain of early medical abortion: qualitative results from Nepal, South Africa, and Vietnam," *BMC Women's Health*, Vol, 19, No. 1 (October 15, 2019) notes on page 2 that "Pain is often cited by women as one of the worst aspects of the MA [medical abortion] experience."

9. *Ob.Gyn. News* (1989), No. 24, p. 1, noted that the average blood loss from mifepristone abortion was reported to be 70ml, nearly four times the blood loss from a standard vacuum curettage abortion.

10. Planned Parenthood, "In-Clinic Abortion," says "In-clinic abortions are also much faster than the abortion pill: most in-clinic abortions only take about 5-10 minutes, while a medication abortion may take up to 24 hours to complete" www.plannedparenthood.org/learn/abortion/in-clinic-abortion-procedures, accessed 1/22/22.

11. The FDA's "Medication Guide" for Mifepristone (part of the Mifepristone Label, note 1) advises women that "medication abortion" is a two-drug, multi-step process where the prostaglandin misoprostol is taken 24 to 48 hours after the first drug, mifepristone. Though cramps and bleeding may ensue within 2-24 hours after taking the misoprostol, the FDA says on page 19 of the guide that "Bleeding or spotting can be expected for an average of 9 to 16 days and may last up to 30 days."

12. The FDA's "Medication Guide" for Mifepristone (part of the Mifepristone Label, note 1) says on page 17 that "About 2 to 7 out of 100 women taking Mifeprex will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding." Even proponents trumpeting newer protocols admit high failure rates. UCSF Health's "Aspiration Versus Medication Abortion," at ucsfhealth.org/education/aspiration-versus-medication-abortion (accessed 5/10/23) says 3-5% require surgery or an "additional aspiration procedure due to ongoing pregnancy, prolonged or excessive bleeding, or preference."

13. "Table 4" of the FDA's 01/2023 Label for Mifepristone (see note 1) notes that efficacy diminishes each week after 49 days LMP.

14. Mary Gatter, Kelly Cleland, Deborah L. Nucatola, "Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days," *Contraception*, Vol 91, No. 4 (April 2015). Note particularly Tables 2 and 4, p. 4, ttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC4373977/pdf/nihms662931.pdf, accessed 1/22/22. See also Elizabeth G. Raymond, Beverly Winikoff, *et al.*, "First trimester medical abortion with mifepristone 200mg and misosprostol: a systematic review," *Contraception*, Vol. 87, no.1 (January 2013), pp. 26-37 showing "treatment failure" for 4.8%. Raymond, *et al.*, notes that risk of failure is higher among groups with higher percentage of patients with gestational ages of more than 8 weeks.

15. "Blood and Tears," *Newsweek*, 9/17/95. A 21-year old told Louise Levanthes, of *Health* (Jan/Feb 1995) "When I looked at it, it had two dark spots like eyes and a little skeleton not quite formed....I haven't talked about it to anyone. I feel quite empty." See also the Endowment for Human Development (EHD) website on fetal development at 8 weeks at ehd.org/science_main.php?level=i#th9, accessed 1/26/22. EHD lists a number of features that would be present and visible in the child's eighth week (10 weeks LMP). At this stage of development, the child would be more than an inch tall from the crown of the head to his or her

rump and would have a fully distinguishable head with a visible face, mouth, ears, nose, eyes as well as arms, hands, legs, and feet.

16. FDA, “Mifepristone U.S. Post-Marketing Adverse Events Summary though 6/30/2022,” Reference ID: 5075481, available at https://www.fda.gov/media/164331/download, accessed 5/10/23. Though the FDA stopped soliciting information on complications and non-lethal events in March 2016, the post-marketing report still records not only 28 deaths which include eight cases of death associated with *Clostridium sordellii*, another with *Clostridium perfringens*, two cases of ruptured ectopic pregnancy, cases of hemorrhage, overdose, etc., but also hundreds of non-lethal infections, blood loss requiring transfusions, and nearly a hundred cases of ectopic pregnancy. The FDA also notes more than a dozen deaths from other countries which involved bacterial sepsis, hemorrhage, heart attack, and other cases. Reported U.S. complication rates have been lower than those reported by European governments with nationalized medical systems and centralized health registrations which are thought to obtain more complete, accurate counts. A Finnish study from 2009 (M. Niimnimäki, *et al.*, “Immediate complications after medical compared with surgical termination of pregnancy,” *Obstetrics & Gynecology*, Vol 114, No. 4 (October 2009), pp. 1281-89) showed that 20% of chemical abortion patients experienced adverse events (largely a result of a higher rate of hemorrhage of 15.6%).

17. The FDA’s label for mifepristone (see note 1) notes at “5.4 Ectopic Pregnancy” that “Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed MIFEPREX” (p. 6).

18. Marc Fischer, *et al.*, “Fatal Toxic Shock Syndrome Associated with *Clostridium sordellii* after Medical Abortion,*” New England Journal of Medicine*, Vol. 353, No. 22 (December 1, 2005), pp 2352-60, at p. 2358. Adam L. Cohen, *et al.*, “Toxic Shock Associated With *Clostridium sordellii* and *Clostridium perfringens* After Medical and Spontaneous Abortion,” *Obstetrics & Gynecology*, Vol. 110, No. 5 (November 2007), pp. 1027-33, at p. 1031. John Hopkins Medicine, “Toxic Shock Syndrome (TSS).” Available at https://www.hopkinsmedicine.org/health/conditions-and-diseases/toxic-shock-syndrome-tss, accessed 8/4/20. Beryl Manning-Geist, Bassam H. Rimawi, “Severe Infections in Obstetrics and Gynecology: How Early Surgical Intervention Saves Lives,” *Journal of Clinical Gynecology & Obstetrics*, Vol. 5, No.1 (March 2016), pp. 1-16, at pp. 3-4. These infections are notoriously hard to recognize because they often present without fever, keeping them from being identified and treated right away. The FDA’s 01/2023 Label for Mifepristone has a “black box” warning about “SOMETIMES FATAL INFECTIONS” on p. 1 which cautions: Atypical Presentation of Infection. Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. Very rarely, deaths have been reported in patients who presented without fever, with or without hemoconcentration, and general malaise. A high index of suspicion is needed to rule out serious infection and sepsis.

19. In addition to recorded deaths and serious adverse events associated with bleeding in the FDA’s 6/30/21 Mifepristone U.S. Postmarketing Adverse Events Summary mentioned and linked in note 16 above, there are multiple warnings about the possibility of hemorrhage on the FDA’s 01/2023 label for Mifeprex (mifepristone), including a special “black box” warning stating the following: WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING...

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use... * Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed.