

## 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. 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."

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.<sup>iii</sup> 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.<sup>iv</sup>

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.<sup>v</sup>

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." A journal article titled "Post Abortion Infections" 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."

Many maternal fatalities have been linked to *Clostridium sordellii*, a bacterium that lives in the gut flora of approximately 10% of women.<sup>xi</sup> 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.<sup>xii</sup>

**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<sup>xiv</sup> 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.<sup>xv</sup> 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.<sup>xvi</sup>

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<sup>&</sup>lt;sup>i</sup> K. Aultman et al., "<u>Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019,"</u> 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.

<sup>&</sup>lt;sup>v</sup> 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 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.

<sup>&</sup>lt;sup>x</sup> 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., <u>"A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions 1999-2015</u>," *Health Services Research and Managerial Epidemiology* 8 (2021): 1-11. Accessed Nov. 20, 2021.

xvi Id., at 1.