

Adverse Events and Side Effects

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1. An Overview of Adverse Events and Side Effects [\[top\]](#)

Eight deaths have occurred in recent years related to RU-486 abortions: 4 in California, 1 in Canada, 2 in the United Kingdom and 1 in Sweden. In addition, a Tennessee woman died from a ruptured ectopic pregnancy after undergoing an RU-486 abortion.

On November 15, 2004, the FDA reported having received 676 "adverse event" reports concerning RU-486 abortions, including 17 ectopic pregnancies, 72 cases where blood transfusions were needed, and 7 serious infections.

In U.S. trials of RU-486/misoprostol, at least 99% of patients experienced at least one of the following:

- abdominal pain (cramping) (97%)
- nausea (67%)
- headache (32%)
- vomiting (34%)
- diarrhea (23%)
- dizziness (12%)
- fatigue (9%)
- back pain (9%)
- uterine hemorrhage (7%)
- fever (4%)
- viral infections (4%)
- vaginitis (4%)
- rigors (chills/shaking)(3%)³⁷

"More than one adverse event was reported for most patients. ... **Approximately 23% of the adverse events ... were judged to be severe.**"³⁸

The **Cytotec (misoprostol) label** contains a "Special Note for Women" which states in part: "Miscarriages caused by Cytotec may be incomplete, which could lead to dangerous bleeding, hospitalization, surgery, infertility, or maternal or fetal death."

Hospitalizations. Patients in U.S. trials were carefully screened to be in good health, yet **fourteen had to be hospitalized, eight for severe excessive bleeding.**³⁹

Emergency room visits. Another nineteen patients were treated in emergency rooms, but not admitted to the hospital.⁴⁰ Sixteen had excessive bleeding; the others were experiencing chest pain, cramping, and nausea and vomiting.⁴¹

2. Pelvic Infections [\[top\]](#)

A California teenager, Holly Patterson, died from septic shock in September of 2003 after taking RU-486. She went to the hospital several days after receiving the pills and according to the San Francisco Chronicle she was told "her pain and bleeding were normal, and she was sent home with painkillers."¹ Three days later, she returned to the hospital where she died of septic shock.

Population Council's RU-486 drug trials in Canada were suspended in 2001 following the September 1, 2001 death of a woman participating in the trials, from septic shock due to a bacterial infection.⁴² The Canadian newspaper, *National Post*, reported that she took RU-486 pills on August 23 and returned two days later for misoprostol. By August 28 she was bleeding and suffering from cramps. She was hospitalized with unspecified side effects and died September 1, from a toxic-shock type syndrome brought on by a bacterial infection identified as *Clostridium sordelli*. **The Vancouver abortion provider heading the Canadian drug trials, Dr. Ellen Wiebe, told the National Post that "The drugs caused the abortion and the infection is related to the abortion. ..."**⁴³

Studies on Infection Rates Following RU-486 Abortions

In a World Health Organization (WHO) study, 30% of women who had incomplete RU-486 abortions developed pelvic/genital tract infections because one effect of the drugs combination is to suppress immune system response. In fact, the WHO study calls for women to receive antibiotics for six weeks following an RU-486 abortion.⁴⁴

One review of RU-486/prostaglandin regimens around the world reports on a trial involving 2,000 cases.⁴⁵ "The most common problems reported at follow-up were continued pain, vaginal bleeding, and offensive discharge. Antibiotics were prescribed for 5% of the 1,322 women for presumed genital infection."⁴⁶

Four percent of the women in U.S. trials had RU-486-related fever, viral infection and vaginitis.⁴⁷ Ten cases of endometritis (inflammation of the uterine lining) also occurred.⁴⁸

3. Excessive bleeding [\[top\]](#)

Near fatalities in U.S. and China.

Iowa. An emergency room doctor, Mark Louviere, M.D., treated a woman from Waterloo, Iowa two weeks after she had taken RU-486 at the local Planned Parenthood clinic. When **she arrived at the ER, according to Dr. Louviere's testimony, she was "in obvious shock" having "lost between one-half to two-thirds of her blood volume. ...** It was my clinical opinion that she would die soon. ... Without even doing the routine preparation we normally do for surgery, **I realized that I had to take her immediately to surgery to save her life.**"⁴⁹

China. "Press reports from Henan province and Chengdu relate cases where women narrowly escaped death when excessive bleeding occurred after taking RU-486 without a physician's supervision,"⁵⁰ according to the U.S. Embassy in Beijing. Some Chinese women had been able to obtain the drug from pharmacies or on the black market. Recently China banned all pharmaceutical sales of RU-486 in order "to guarantee patients' safety and protect their health."⁵¹

Severity of bleeding. Due to excessive bleeding, 25 women in the U.S. trials had to be hospitalized or treated in emergency rooms, 56 required surgery and 22 received

intravenous fluids.⁵² [[More](#)]

Four patients in U.S. trials received blood transfusions; three of them had to be hospitalized.⁵³ One hundred forty-six patients (about 7%) were given uterotonic medications to help stop excessive bleeding.⁵⁴

Up to 8% of patients had a decrease of more than 20% in hemoglobin or hematocrit levels.⁵⁵

Duration of bleeding. Nine percent of women in U.S. trials bled for over 30 days, and one percent of women were still bleeding 60 days after taking RU-486.⁵⁶

In a Columbia University study, 20% of women bled or spotted for five to six weeks.⁵⁷

Two women describe bleeding. Two patients in Des Moines, Iowa RU-486 trials told a *TIME* magazine journalist that their bleeding was "like turning a jug of water upside down" and "like a faucet was turned on. There was a steady stream of blood. I passed a golf ball size blood clot that scared me."⁵⁸

4. Allergic reactions [[top](#)]

The FDA warns that mifepristone (RU-486) and misoprostol should not be given to women with known allergies to either drug,⁵⁹ but it doesn't explain how a woman would know she's allergic to either of these drugs before taking them.

"The common complications of medical [i.e., RU-486/ prostaglandin] abortion are profuse bleeding and allergy. ...

Allergic reactions were not uncommon, manifesting in facial edema [swelling], skin rash and itching, numbness of feet and hands, and even a serious case of allergic shock. The potential for such reactions is one reason to keep clients for observation.⁶⁰

5. Cardiopulmonary problems [[top](#)]

After taking misoprostol, up to 1.4% of patients in U.S. trials had hypotension and up to 1.7% of patients had hypertension. A decrease in heart rate of more than 20% occurred in up to 21.3% of patients after taking misoprostol. An increase in heart rate of more than 20% after misoprostol occurred in up to 14.1% of patients.⁶¹

Prostaglandins used with RU-486 for abortion have caused life-threatening cardiovascular complications, including 3 myocardial infarctions (1 fatal) and 3 cases of severe hypotension.⁶²

6. Emotional and psychological reactions [[top](#)]

The former chairman of Roussel-Uclaf (the French company which developed RU-486), Edouard Sakiz told the French newspaper *Le Monde*:
"As abortifacient procedures go, RU-486 is not at all easy to use. ... True, no anaesthetic is required. But a woman who wants to end her pregnancy has to 'live' with her abortion for at least a week using this technique. It's an appalling psychological ordeal."⁶³

Catherine Euvrard, formerly a spokeswoman for Roussel-Uclaf who now holds the same job for the new French manufacturer of RU-486, Exelgyn, has said: *"When [women] take a pill,*

they have the feeling they are truly responsible for the abortion. ... [There can be more] psychological pain."⁶⁴

"During this critical two-week period [between 49 and 63 days] the tiny embryo in an amorphous sac begins to look very much like a baby, with a discernible head and limbs. ... Nurse Frenpzel remembers a day ... when she ... saw six surgical dishes with six embryos in them by the sink. 'It was upsetting,' she said. 'It was like looking at a little row of people. The women too were shocked when they looked at what they had expelled.'"⁶⁵

"You have to be very confident to choose this method. It may be physically more natural, but psychologically it hits you much harder. You preside over the killing of a baby, completely unblinking. For women who are confused or vulnerable, and of course, so many are in this position, it is really terrible."⁶⁶

One woman in U.S. trials was hospitalized for depression after attempting suicide.⁶⁷

¹ Russell, Sabin. "Taker of abortion pill died due to infection." *San Francisco Chronicle* 1 Nov. 2003, sec. A:19.

³⁷ Medical Officer's Review, *supra* note 8, at 11-12.

³⁸ *Id.* at 11.

³⁹ Medical Officer's Review, *supra* note 8, at 13.

⁴⁰ Medical Officer's Review, *supra* note 8, at 13.

⁴¹ *Ibid.*

⁴² S. Schmidt, "Woman's death sparks abortion pill debate," *National Post*, Sept. 17, 2001, at A13; R.K. O'Bannon, "Woman Dies in Canadian RU486 Trials," available at http://www.kcrtl.org/National_News/RU_486/Woman_dies_in_ru486.htm ; C. McGovern, "Woman Dies in Canadian Abortion-Pill Testing," available at <http://www.ru486.org/wiebe2001.html>.

⁴³ S. Schmidt, *supra* note 34.

⁴⁴ World Health Organization, "Pregnancy Termination with Mifepristone and Gemeprost: A Multicenter Comparison Between Repeated Doses and a Single Dose of Mifepristone," *Fertility and Sterility*, 56:1, 1990, at 40.

⁴⁵ P.W. Ashok *et al.*, "An Effective Regimen for Early Medical Abortion: A Report of 2000 Consecutive Cases," *Human Reproduction*, 1998; 13:2962-2965.

⁴⁶ H. von Hertzen, "Research on Regimens for Early Medical Abortion," *Journal of the American Medical Women's Assn.*, Supplement 2000, 133, at 136.

⁴⁷ Medical Officer's Review, *supra* note 8, at 12.

⁴⁸ I. Spitz *et al.*, *supra* note 2, at 1244.

⁴⁹ FDA Reproductive Health Drugs Advisory Committee, Hearing Transcript, July 19, 1996, at 224).

⁵⁰ U.S. Embassy Beijing, "Family Planning in China: RU-486, Abortion and Population Trends," November 2000.<http://www.usembassy-china.org.cn/english/sandt/ru486.html>.

⁵¹ On October 22, 2001, Cybercast News Service reported that China has "banned all pharmaceutical sales of abortion pill RU-486, citing safety concerns about the drug. 'In order to guarantee patients' safety and protect their health, it is decided that no matter whether patients have a doctor's prescription or not, retail drug stores are forbidden to sell mifepristone (RU-486) tablets,' read a notice from China's state drug administration reported in international news agencies" (Christine

Hall, "China Bans Abortion Pill," CNSNEWS.COM, October 22, 2001).

⁵² "Excessive bleeding necessitated blood transfusions in four women, and accounted for 25 to 27 hospitalizations (including emergency room visits), 56 of 59 surgical interventions, and 22 of 49 administrations of intravenous fluId. Hospitalizations, surgical interventions and intravenous-fluid administration were reported for 2 percent of the women in the (I Spitz *et al.*, *supra* note 2, at 1243).

⁵³ Medical Officer's Review, *supra* note 8, at 13.

⁵⁴ *Ibid.*

⁵⁵ Medical Officer's Review, *supra* note 8, at 14.

⁵⁶ I. Spitz, *et al.*, *supra* note 2.

⁵⁷ A. Davis *et al.*, "Bleeding Patterns After Early Abortion with Mifepristone and Misoprostol or Manual Vacuum Aspiration," *Journal of the American Medical Women's Assn.*, Supplement 2000, 141, at 143.

⁵⁸ Sachs, "Abortion Pills on Trial," *TIME*, Dec. 5, 1994, at 45.

⁵⁹ Mifeprex label, *supra* note 14.

⁶⁰ Wu, *supra* note 20, at 198.

⁶¹ Medical Officer's Review, *supra* note 8, at 14-15.

⁶² A. Ulmann, *et al.*, "Medical Termination of Early Pregnancy with Mifepristone (RU 486) Followed by a Prostaglandin Analogue," 71 *Acta Obst. Gyn. Scand.* 278 (1992); Anonymous, "A Death Associated with Mifepristone/Sulprostone," 337 *Lancet* 969 (1991); See also, Institute of Medicine, *Clinical Applications of Mifepristone (RU 486) and Other Antiprogestins 27* (1993), reporting one patient death during the first trial of RU 486 with oral misoprostol.

⁶³ Interview, "Drug firm defends marketing strategy on abortion pill," *Guardian Weekly* (U.K.), August 19, 1989, at 16.

⁶⁴ F. Vrazo, "In Europe, 'Abortion Pill' Has Not Met Expectations," *Philadelphia Inquirer*, August 25, 1996, at A01.

⁶⁵ Louise Levathes, *Hippocrates*, February 1995, at 45.

⁶⁶ "One Woman's Experience," *London Evening Standard*, December 4, 1993.

⁶⁷ Lisa Rarick, M.D., of the FDA's Reviewing Division, testimony before the Reproductive Health Drugs Advisory Committee, Hearing Transcript FDA, July 19, 1996, at 134.