Life | The Abortion Pill (Also Known as RU-486 or Mifeprex)

Overview

In September 2000, the FDA approved the abortion pill RU-486, now known as mifepristone (brand name: Mifeprex), for use as an abortifacient (abortion-inducing drug). RU-486 is FDA-approved for use through the first seven weeks of pregnancy.¹ RU-486 is different from the “morning-after pill,” also known as “emergency contraception,” which must be taken within 72 hours after intercourse to be effective.

RU-486 acts by halting the growth of the uterine lining. The preborn baby is then starved of nutrients supplied by the mother’s womb. Two days later, the woman takes an ulcer drug, misoprostol (brand name: Cytotec), which has the side effect of starting uterine contractions, in order to expel the dead baby. The FDA has not specifically approved the use of misoprostol for medication abortions, but its use for this purpose is common.

Two weeks after taking RU-486, the woman visits the doctor or clinic again, this time to make sure that the entire baby was expelled. If it has not been expelled, as is the case in about five to eight percent of women, a surgical abortion is performed.²

In September 2003, Holly Patterson, an 18-year-old from Livermore, California, went to a local Planned Parenthood office and was given abortion medication to abort her pregnancy. Four days later, she went to an emergency room, bleeding and in extreme pain. Three days after that, she returned to the hospital, once again in a great deal of pain. She died that afternoon. The coroner concluded that she died of septic shock, due to endomyometritis caused by the drug-induced abortion.³

Since Holly Patterson’s death, seven more American women have died from infection after taking RU-486.⁴ In total, evidence shows that as of March 2012, at least 21 deaths worldwide are linked to RU-486.⁵ As of 2011 the FDA had received reports that in the U.S. there were 2,207 adverse events since the drug was approved in 2000, including 14 deaths and 339 cases of bleeding severe enough to require transfusions.⁶ In Ohio alone, there were 42 failed uses of the drug reported in August 2013.⁷ Because the FDA readily admits that the adverse effects of most medications are underreported – only about one percent to 10 percent of complications are reported for any given drug – RU-486’s adverse effects are probably dramatically understated.⁸
Medical Issues

As the manufacturer of the abortion pill explains in its prescribing information: “Nearly all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction.”

Some of the problems a woman is likely to experience after taking RU-486 are the following:

- abdominal pain (cramping) (96%)
- nausea (61%)
- headache (31%)
- vomiting (26%)
- diarrhea (20%)
- dizziness (12%)
- uterine hemorrhage (5%)

In clinical trials before the drug’s approval, nearly 99 percent of women who received a medication abortion experienced one or more of the above side effects. In those trials, about one out of every 14 women using RU-486 experienced bleeding severe enough to require medical attention.

Since its approval, RU-486 has been implicated in the deaths of 14 American women:

- Two died after their respective ectopic pregnancies ruptured.
- Eight suffered from a systemic bacterial infection.
- The final four from overdose, toxic shock, or other causes.

Women who survived faced serious complications like ruptured ectopic pregnancies, systemic infections, and one heart attack after taking abortion medication.

During Canada’s test of the drug in 2001, a Canadian woman died of septic shock resulting from a clostridium infection. More recently, in 2011, a Portuguese girl died of septic shock five days after receiving a medication abortion. At least six non-U.S. women have died as a result of taking RU-486.

A study out of Finland revealed that even under the best conditions, “medical abortion had four times higher total number of adverse events than surgical abortion.”

A similar, separate study out of Australia also found that the abortion pill is more dangerous than surgical abortion.

Despite this evidence, the abortion industry continues to market this method of abortion as “easier, safer, non-invasive, and more discrete.” For a drug that is used to induce an obviously elective process, the near certainty
that a woman will suffer from a number of very unpleasant and possibly deadly side effects further counters opponents’ claims that RU-486 is a “safer alternative” to surgical abortion.

What has been touted as a way to give women “more control” and “privacy” in abortions, may have unintended psychological consequences. Women must actually self-administer the drug and cannot blame others for doing it “to” them. In addition, many women actually see the preborn child when they abort at home. For them, there is no escaping the conclusion that they have chosen to end a human life.

Abby Johnson, former director of a Planned Parenthood clinic in Bryan, Texas, describes her own experience with RU-486 as “agony.” For days, she was “too ill to get out of bed,” suffering from “excruciating” cramping, high fever, and heavy bleeding. It was two weeks before she returned to work, and eight weeks before she “felt recovered enough.”

**Legal Requirements**

The FDA, in its approval of RU-486 and in subsequent revisions to that approval, required special distribution rules for the Mifeprex abortion medication. The manufacturer’s information for physicians explains: “Mifeprex [RU-486] will be supplied only to licensed physicians who sign and return a Prescriber’s Agreement … Mifeprex is a prescription drug, although it will not be available to the public through licensed pharmacies.”

The label also specifies that Mifeprex should only be prescribed “by physicians who have read and understood the prescribing information.”

The FDA also placed restrictions on administration of RU-486. In addition to only approving administration through the first seven weeks of pregnancy, the abortion pill must be provided by or under the supervision of a physician who:

- Can accurately assess how far along the pregnancy is.
- Can diagnose ectopic pregnancies.
- Has the ability to provide a surgical abortion if a complication arises or has made arrangements for someone else to provide that care.
- Can assure patient access to blood transfusions and resuscitation services.
- Has read the prescribing information.
- Must notify the manufacturer of hospitalization, transfusion, or other “serious event.”

In 2010, Planned Parenthood began using “telemedicine” to dispense RU-486 to women seeking medication abortions in Iowa. Using a camera and a microphone to “chat” via computer, the physician is hundreds of miles away while he watches the woman take her first dose of mifepristone. This practice is grossly out of line with the FDA protocols and manufacturer’s instructions for medication abortion and places women at risk with no on-site provider capable of managing complications. Physician oversight in a licensed and
regulated clinic setting is imperative to ensure minimal complications and risks to the mother. Currently, 12 states prohibit telemedicine abortions. In most states, Planned Parenthood openly dispenses the abortion pill without following the FDA protocol. Despite the pill only being approved for use through the first seven weeks of pregnancy, Planned Parenthood prescribes it through nine weeks of pregnancy, does not require a follow-up visit, and uses non-doctors to prescribe the abortion pill where state law allows.

**Arizona Law**

Arizona, along with North Dakota, Ohio, Oklahoma, and Texas, has passed a law requiring the FDA protocol to be followed when administering the abortion pill, but Ohio is the only state with its law currently in force. Arizona’s requirement that the FDA protocol be followed is pending rulemaking by Arizona Department of Health Services. Arizona law also requires any clinic that dispenses abortion medication to be licensed and meet basic health and safety standards. Among those safety standards are the following:

- Staff the clinic with qualified personnel.
- Keep accurate health records.
- Keep the building clean and free of trash, bugs, and rats.
- Document and implement procedures for sterilizing equipment.

The clinic regulations require that a physician is involved in caring for patients both before and after an abortion, including a medication abortion. Arizona law also prohibits non-doctors such as nurse practitioners and physician assistants from prescribing abortion medication and prohibits the use of “telemedicine” to administer abortion medication.

**Talking Points**

- **Medication abortions are not a safer alternative to surgical abortions.** Nearly every woman who takes the abortion pill will experience some of the pills’ very serious side effects.
- **At least 14 women have died from taking the abortion pill in America.**
- **The abortion pill is not the same as so-called “morning-after pills.”** The main differences are that the “morning-after pill” can only be taken up to 72 hours after intercourse, is available over the counter, and doesn’t always act as an abortifacient. However, the abortion pill **always** takes the life of a preborn child.
The abortion industry has tried to sell RU-486 as a safer alternative to surgical abortion, but responsible medical practitioners know better. In the name of increasing access to abortion, abortion advocates have put the health and safety of women at risk by distributing RU-486 outside of the regulations specified by the FDA and dispensed it via webcam, also known as telemedicine abortion.
19 Planned Parenthood’s website notes that they send women home to complete the medication abortion (see The Abortion Pill (Medication Abortion), Planned Parenthood, www.plannedparenthood.org/health-topics/abortion/abortion-pill-medication-abortion-4354.asp (last visited Oct. 2, 2013)).
21 Mifeprex (mifepristone) Prescribing Information, supra note 8.
22 Id.
23 Id.; Mifeprex Medication Guide, supra note 1.
25 Id.
29 Arizona’s requirement that the FDA protocol be followed is pending rulemaking by Arizona Department of Health Services; Ohio’s requirement was ruled constitutional by the Sixth Circuit Court of Appeals (see Planned Parenthood v. DeWine, No. 11-4062 (6th Cir. 2012)); North Dakota and Oklahoma’s requirements are currently enjoined by court order; Texas’ requirement is scheduled to go into effect later in 2013.
30 Ariz. Rev. Stat. §§ 36-449.02 and 36-449.03.
32 See, e.g., id. at R9-10-1508(A)(2).