RU-486 not just a 'morning after' pill

Multiple steps, doctor's help will be required

By LAURAN NEERGAARD
Associated Press

WASHINGTON — Getting an abortion with the drug RU-486 isn't quite as simple as taking a pill.

So the Food and Drug Administration issued detailed requirements yesterday to ensure that women fully understand the process and that properly trained doctors use the drug accurately.

The abortion pill, which doctors call by its chemical name mifepristone, is only for use very early in pregnancy — 49 days from the beginning of a woman's last menstrual period; the abortion requires three doctor visits to complete.

First, a woman swallows three mifepristone pills. The drug blocks action of a hormone essential for maintaining pregnancy. Without that hormone, progesterone, the uterine lining thins so the embryo cannot remain implanted and grow.

To fully detach the embryo from the uterus and expel it, two days later a woman must swallow a second drug, misoprostol, that causes uterine contractions — miscarriagelike cramping and bleeding.

Then, she must return for a follow-up visit within two weeks to make sure the abortion is complete. While studies show mifepristone is 92 percent to 95 percent effective in causing early abortion, some women need surgical abortion to finish the job.

If the fetus survived either the mifepristone or misoprostol steps and surgical abortion is not done, a woman could have a malformed child, something that has occasionally happened overseas. If the fetus died but was not completely expelled, a woman could suffer infection or other problems, the FDA warned.

In studies where women had the necessary doctor visits, complications were rare. The FDA said 1 percent of women suffer serious bleeding that requires a surgical abortionlike procedure to stanch, and a handful needed a transfusion.

The FDA mandated that women be given a special brochure fully explaining the procedure and side effects, and that they sign a form agreeing to the necessary visits.

The FDA ruled that mifepristone can be distributed only to doctors trained to accurately diagnose duration of pregnancy and detect ectopic, or tubal, pregnancies, because those women cannot receive mifepristone.

Also, the FDA restricted mifepristone's use to doctors who can operate in case of bleeding or if a surgical abortion is needed, or to doctors who have made advance arrangements for a surgeon to be on call for such care.

Unlike with surgical abortions, mifepristone does not require anesthesia. Planned Parenthood's Dr. Paul Blumenthal, who helped test the drug, said most women take over-the-counter ibuprofen for the pain.

HOW THE ABORTION PILL WORKS

The Food and Drug Administration approved the abortion pill mifepristone, offering American women an alternative to surgical abortions. Here is an illustration of how the drug works.

The process

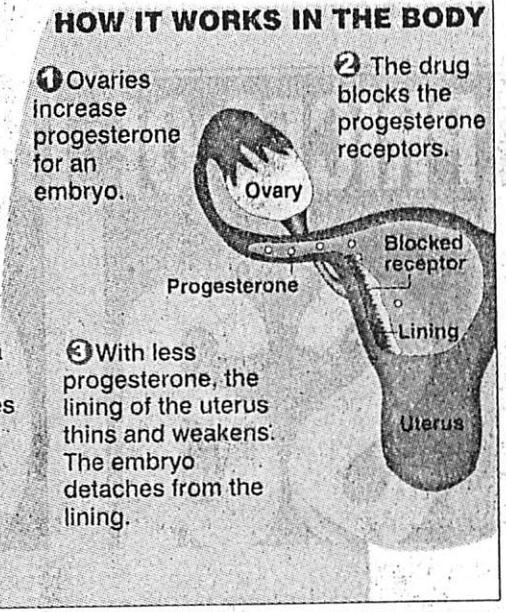
1. In a doctor's office, the patient swallows three mifepristone pills during the first seven weeks of pregnancy.

2. The drug causes the embryo to detach from the uterus lining.

3. Two days later, the patient returns to the doctor's office to take a second drug, misoprostol, that causes contractions needed to expel the embryo.

4. Within two weeks, a third appointment is required to confirm the abortion is complete.

HOW IT WORKS IN THE BODY



Sources: National Abortion Federation; Food and Drug Administration; Journal of American Medical Women's Association

ASSOCIATED PRESS

Abortion pill decision fuels controversy

Some applaud act while others vow to continue fight

By LAURAN NEERGAARD
Associated Press

WASHINGTON — Defenders of abortion yesterday hailed the FDA's decision to approve the abortion pill RU-486, but antiabortion groups vowed to continue fighting.

The pill, known chemically as mifepristone and by the brand name Mifeprex, will be available to doctors within a month.

"At long last, science trumps antiabortion politics and medical McCarthyism," said Eleanor Smeal of the Feminist Majority Foundation.

Mifepristone may "turn the tide against anti-choice intimidation," because doctors who don't offer surgical abortion can use the pill in private offices instead of protester-targeted clinics, added Planned Parenthood president Gloria Feldt.

But anti-abortion groups, which fought mifepristone by threatening U.S. drug companies with boycotts, said they would not give up.

"We will not tolerate the FDA's decision to approve the destruction of innocent human persons through chemical abortion," said Judie Brown of the American Life League.

"Never before has the FDA approved a drug intended to kill people," said Rep. Tom Coburn, R-Okla., who promised legislation calling for severe limits on which doctors could administer mifepristone.

Margie Montgomery, executive director of Kentucky Right to Life, said, "I'm disappointed, but we knew it was coming. We really hoped they would delay it while they did a little more studying about the health effects.

"The FDA joined the abortion trade as far as we're concerned."

She said she doesn't expect abortions to increase significantly because using the pill is not as simple as some portray it.

"They make it sound real easy, just a little pill you put in your mouth. It's not that; a woman has to come back three times. Two out of every 100 are hospitalized with excess bleeding. The make it sound like a morning-after pill. It isn't."

"The FDA joined the abortion trade as far as we're concerned."

Margie Montgomery, Kentucky Right to Life

However, Ted Clingner, executive director of Planned Parenthood of Louisville, had a different opinion on the decision. "It's good news," he said. "The approval of mifepristone is as big an event as approval of birth control pills 40 years ago. It will enable a woman in the privacy of her own doctor's office to decide whether to continue her pregnancy.

"It should make the decision easier for women. In Kentucky right now, the only place a woman can go is Lexington or Louisville. If you live in Western or Eastern Kentucky, you have to go a long way. That makes it especially difficult on the poor."

He also said not having to run the gantlet of protesters or having to go to an abortion clinic "has the potential to make a tremendous impact on women going in for abortions. It's private, and there is no registry. How much it does will have to be seen over a period of time, but I don't think it will cause a significant increase in abortion."

Another person, The Rev. Vaughn Walker, senior pastor of First Gethsename Baptist Church in Louisville, said: "I'm not a radical anti-abortion advocate but I believe all life is sacred. Theologically and ethically, I have problems with killing a child. I believe abortion is murder."

Beth Wilson, reproductive freedom project director for the ACLU of Kentucky, said, "It's an important victory for women, a victory we hope will ultimately increase the availability of medical services both here in Kentucky and across the country.

"We hope there will be more physicians throughout the state who will be willing to offer medical abortions. I'm hopeful, but how much it increases remains to be seen. I think it's giving us an opportunity to reverse the trend in decline of physicians (offering abortions) and to protect the right to choose. The right to choose can be legal forever, but if there's no access to physicians, it doesn't really matter."

"It's an important victory for women. . . ."

Beth Wilson, reproductive freedom project director, ACLU of Kentucky

However, Bob Cetrulo, president of the Northern Kentucky Right-to-life Committee, said, "The clear thrust of the abortion industry is to get out from under the onus of bloody surgical procedures inherent in that. This is a new mechanism to practice their barbarity."

On the campaign trail, George W. Bush called the FDA's decision "wrong," but stopped short of saying he would try to overturn it if elected. "I fear that making this abortion pill widespread will make abortions more and more common," he said. "As president, I will work to build a culture that respects life."

Vice President Al Gore praised the pill's availability. "Today's decision is not about politics, but the health and safety of American women and a woman's fundamental right to choose," he said.

President Clinton said the FDA's four-year study of the drug shows the decision was "purely one of science and medicine." He said the FDA "bent over backward to do a lot of serious inquiries. . . ."

Staff writer Butch John contributed to this story.

PATH OF FDA APPROVAL FOR THE ABORTION PILL

Source: AP wire reports

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Surgery likely to remain most popular form of abortion

Associated Press

Don't expect overwhelming demand for the abortion pill RU-486, despite years of anticipation, say doctors and women's health advocates.

They say surgical abortion will remain the predominant method of terminating a pregnancy because it can be done in a day rather than the two to three days for RU-486. Also, some doctors won't prescribe the pill, and women may hesitate to take it once they learn about the pain and discomfort.

"Most people think you take the pill and the pregnancy is gone, and nothing else is involved," said Dr. Deborah Oyer, a family doctor with Aurora Medical Services in Seattle who was involved in the clinical trials of RU-486. "Women who have gone through a spontaneous miscarriage know it does not feel good."

The pill-induced abortion can be painful, causing bleeding and nausea for days. Heavy bleeding is a potentially serious but rare side effect.

Oyer said she expects only about 10 percent of the 1.3 million annual abortions in the United States to be done with the pill, which will become available for American women in about a month.

Danco Laboratories, a small, privately owned New York company that was formed in the late 1990s for the sole purpose of introducing the abortion pill, will sell RU-486 in the United States under the brand name Mifeprex.