

Abortion pill gets approval of FDA

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The early-abortion pill, RU-486, was approved for use yesterday by the **Food and Drug Administration**, a milestone victory for abortion-rights advocates who fought for more than a decade to bring the drug to the United States.

Proponents said the drug will make abortion a more private matter for thousands of women each year because it can be taken in the home, away from family planning clinics and hospitals. There are 1.5 million abortions performed in this country each year.

They said it will also make abortion more accessible to women who live far from family planning centers and other clinics that offer surgical abortions.

The drug, according to the FDA ruling, may be taken within the first seven weeks of pregnancy. It blocks a hormone necessary for the continuation of a pregnancy, and it must be followed two days later by another drug that expels the egg from the uterus.

"For those who choose to have an early termination of their pregnancy, this is a reasonable medical alternative," said FDA Commissioner Jane Henney.

In its decision, the agency said the drug can be dispensed only by doctors who have been trained to advise women about its use and possible complications.

Also, doctors must be qualified to operate - or have a referral system - in the event the pill does not complete its job or the patient develops serious complications. They must also know how to date a pregnancy and diagnose a tubal pregnancy.

The drug will not be sold in pharmacies or be legally available over the Internet, the FDA said. It is expected to become available in a month. Its price has not been announced.

Abortion-rights groups have argued for the drug's approval since 1988, when it was made available in France. The drug, formally known as mifepristone, is legal in a dozen countries, most of them in Western Europe.

"This is definitely one of the most significant advances in women's reproductive health in decades," said Nancy Lineman, executive director of the Maryland chapter of the National Abortion and Reproductive Rights Action

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"Instead of having women going to clinics where they are often victims of harassment by anti-choice protesters, it will make it a more personal decision in a much more private setting."

Abortion opponents denounced the decision.

"The Clinton-Gore administration, which claimed it wanted to make abortion rare, has embraced an abortion pill that will result in more abortions and new risks to women," said Laura Echevarria, a spokeswoman for the National Right to Life Committee.

Surveys in Europe have found that the number of abortions did not rise after the drug was introduced, said Dr. Paul Blumenthal, associate professor of obstetrics and gynecology at the Johns Hopkins School of Medicine.

Even so, he said, the drug enables a broader array of doctors - including family physicians and internists - to offer abortions to their patients.

The pill also offers an incentive for women to have abortions early in their pregnancies.

A clinical trial, conducted in medical practices across the United States, found the drug was 93 percent to 98 percent effective in terminating pregnancies.

In most cases, patients experience cramping, nausea and bleeding. There were no deaths in the clinical trial, and in far fewer than 1 percent of cases did women bleed so heavily that they required transfusions.

"Our national experience has been that this is very safe," said Blumenthal, who helped to oversee the trial at the [Johns Hopkins Bayview Medical Center](#).

Blumenthal is also medical director of Planned Parenthood of Maryland.

The pill blocks a hormone, progesterone, that is necessary for maintaining a pregnancy in a healthy state. Without the hormone, the egg withers and dies.

Women taking mifepristone take three pills, a 600-milligram dose, all at once. Two days later, they take misoprostol, that causes the embryo to be expelled.

Patients are advised to return to their doctors two weeks later to make sure the abortion was successful.

While predicting that many women will choose the drug, Blumenthal said others will undoubtedly prefer the surgical abortion because it is more immediate.

"The upside of the surgical abortion is that you come in, are seen by a physician, and you leave the office within an hour knowing you've completed the procedure," he said.

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er U.S. rights to the nonprofit Population Council
DA approval. Rights to manufacture the drug in the

United States were licensed to Danco, a private company.

Although the FDA declared the drug safe and effective in 1996, it took four more years for Danco to meet federal manufacturing and labeling requirements.

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