US Food and Drug Administration approves RU-486 abortion pill

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After more than a decade, the US Food and Drug Administration (FDA) approved the use of Mifeprex, also known as mifepristone or RU-486 on September 28.

Used in combination with a prostaglandin such as misoprostol, Mifeprex induces abortion by blocking receptors of the progesterone hormone essential for establishing and maintaining pregnancy. Since it was first approved in France in 1988, it has been used safely and effectively in early pregnancy by more than 600,000 women in Europe, with a reported 99 percent success rate.

Under FDA guidelines, from next month women pregnant for less than 49 days from the beginning of their last menstrual period will be able to opt for a medical termination. This involves three visits to a doctor and two sets of drugs. On the first visit, a woman will be prescribed 600 milligrams of Mifeprex, which softens the uterus and loosens its connection with the embryo. On the second visit two days later, the woman will be prescribed misoprostol, which triggers the contractions that expel the embryo. Women must return for a follow-up visit approximately 14 days after taking the first course to determine whether the pregnancy has been terminated.

Training in the use of RU-486 is being offered in half-day sessions by doctors working with the National Abortion Federation, an organisation of abortion providers. So far, 1,800 doctors, nurses and counsellors have attended, including about 300 from clinics or medical practices that do not currently offer surgical abortions. Only those physicians will be allowed to prescribe the drug who are able to determine accurately the period of gestation, detect an abnormal pregnancy and be able to perform a surgical abortion or refer the patient to another doctor for such surgery if the drug-induced abortion is incomplete.

In explaining the decision to finally approve RU-486, FDA Commissioner Jane E. Henney said it was the result of “careful evaluation of the scientific evidence related to the safe and effective use of this drug.” The regime has not caused any fatalities and has been shown to be free from the risk of uterine perforation and complications caused by anaesthesia in surgical interventions. The most common side effects are abdominal pain and heavy menstrual-type bleeding for a short duration.

The FDA Advisory Committee for Reproductive Health Drugs had ruled RU-486 was safe, effective and “approveable' in 1996. Part of their ruling was based on clinical trials that had been conducted the previous year on 2,121 women by the Population Council, a New York-based, non-profit organisation. The trials showed that Mifeprex was effective in terminating 92 percent of pregnancies of up to 49 days' duration. The lower success rate in these trials as compared to European studies was attributed to lack of clinical experience with the procedure in the US. The same trials also revealed that 96 percent of women on the regimen would recommend its use to others.

Mifeprex's distribution has been delayed due to a combination of political factors.

It has been held hostage by the anti-abortion lobby led by the Republican right and Christian fundamentalists and the reluctance of the Clinton administration to directly challenge them.

In 1989, RU-486 was banned from import into the US under the Republican administration of George Bush, even though it had been licensed for use in Europe. A Supreme Court ruling in July 1992 upheld the ban, despite a lower court ruling in favour of Leona Benten, who had attempted to import the drug for personal use.

Anti-abortion groups are particularly hostile to distribution of RU-486 because it offers the possibility of safe, early termination, thereby making abortion more acceptable. Opinion polls in the US have consistently shown a majority in favour of abortion rights and, the earlier the intervention, the greater the support.

More importantly, distribution of RU-486 places practical obstacles in the path of anti-abortion groups' reliance on tactics of intimidation and even terror to achieve their ends. Doctors have been murdered for carrying out terminations, clinics bombed and female patients regularly subjected to protests, sometimes violent, aimed at "shaming" and frightening them. For several years the pharmaceutical firm Roussel-Uclaf, which has sole rights over the drug, had refused to distribute it in the US on grounds that political and social conditions were "unreceptive".

With RU-486, the procedure becomes a more private affair, with a woman able to take the pill in her own home.

The camp of Republican Presidential candidate George W. Bush had taken the decision at the start of the campaign to downplay the issue of abortion in the greater interest of ousting the Democrats. Announcement of RU-486's approval made this problematic.

With abortion rights in the spotlight, Bush was anxious not to alienate his right-wing base whilst, on the other hand, not wanting to take a position that would hurt him at the polls. In a signal to his traditional supporters that he would do whatever he could get away with, Bush said he would, if elected, order a review of RU-486's safety, but he refused to state directly that he would move to block its distribution.

In light of the record of terrorist attacks by anti-abortion fanatics, the FDA, in an unprecedented decision, chose not to publish the names of experts who had reviewed RU-486 for the agency and have refused to publish the name or location of the company that will manufacture it in the US.

Several prominent anti-abortion individuals and groups responded to the FDA's decision with language bordering on hysteria. Reform Party Presidential candidate Patrick Buchanan called RU-486 "a human pesticide", while Randall O'Bannon from the National Right to Life Committee alleged that the drug will be "from the People's Republic of China—a nation that is a leading source of tainted drugs and which itself is tainted by the government's pervasive use of compulsory abortion".

One anti-abortion group said it would consider visiting private homes to "counsel" a woman about her decision if "she was a friend or relative". Other anti-abortion extremists made clear they would attempt to block the distribution of RU-486.

Troy Newman of the anti-abortion group Operation Rescue West said his organisation would call every physician and ask if he would prescribe RU-486. "Then we will treat them the exact same way we treat an abortion provider," he said. Just two days after the FDA's decision, Rev. John Earl, a Roman Catholic priest, rammed his car into a Northern Illinois abortion clinic and hacked at the building with an axe. Nobody was hurt in the incident, for which Earl was later charged.

On October 3, Republican Senator Tim Hutchinson and Representative Tom Coburn proposed legislation imposing tighter restrictions on the prescription of RU-486, the net effect of which would be to limit access largely to abortion clinics. Coburn also said he intended to present a bill requiring publication of a registry of those doctors prescribing the drug. Anti-abortionists have previously used such lists to target physicians and clinics.