FDA Okays RU486 After Years Of Controversy Essay, Research Paper

NEW YORK, Sep 28 (Reuters Health) – After 4 years of controversy and negotiation, the US Food and Drug Administration (FDA) on Thursday approved the abortion drug mifepristone, more commonly known as RU-486. The approval comes with some, but not all, of the prescribing restrictions originally discussed as conditions for getting the drug onto the market.

Mifepristone, which will be sold under the trade name Mifeprex, will be available to doctors within about 4 weeks, according to Danco Laboratories, the New York City-based pharmaceutical company that will distribute and market the drug.

The procedure for obtaining mifepristone is more burdensome than for other drugs, but the FDA’s requirements surrounding the abortion drug are far less restrictive than they might have been.

As recently as June, it appeared that prescribing of the drug might have been limited to doctors who were trained to perform surgical abortions, had facilities to monitor patients using ultrasound, and were located within an hour of emergency facilities.

Dr. Carole Joffe, a professor at the University of California-Davis who studies abortion policy in the US, called the fact that the FDA will allow doctors who do not currently perform surgical abortion to prescribe Mifeprex ‘a tremendous victory.’

‘The major premise of this drug is to increase access (to abortion services), because in the United States we are in a serious crisis of access,’ she told Reuters Health. ‘If the tiny pool of present abortion providers could not be increased, the approval would have been a much more limited gain.’

The FDA’s major restriction on Mifeprex is that the drug will not be available through pharmacies, even with a prescription. Instead, it will be distributed directly to doctors’ offices or clinics, and doctors will need to sign a statement certifying that they have met certain requirements before they may place an order.

A Danco spokesperson stressed that information about which doctors have ordered the drug ‘will never be made available to the public.’

In a recent poll by the Kaiser Family Foundation, 9% of family practice physicians said that they would be very likely to prescribe mifepristone and 22% said that they would be somewhat likely to offer the drug. Only 5% of family physicians currently perform surgical abortions.

Joffe stressed that the amount of additional access to abortion services resulting from the approval of mifepristone will not be clear for several years.

‘Each state has its own laws governing abortion provision, and we haven’t had big-time medical abortion in this country before,’ she said. Legal requirements that vary from state to state, such as 24-hour waiting periods, parental notification and reporting of procedures ‘will ultimately all need to be worked out’ as mifepristone begins to change the way abortions are performed, she said.

Mifepristone, which is taken orally, is approved for use for up to 7 weeks after the beginning of a woman’s last menstrual period and can be prescribed as soon as pregnancy is confirmed. The drug works by blocking the hormone progesterone; without the hormone, the lining of the uterus breaks down and bleeding begins.

Obtaining a medical abortion using Mifeprex requires three visits to the doctor. In the first visit, a woman receives counseling and information, signs a consent form and takes three tablets of Mifeprex.

Two days later, she takes two tablets of misoprostol, a contraction-inducing drug that is currently sold by Searle for the prevention of ulcers. Misoprostol will be distributed separately from Mifeprex and is not sold by Danco.

A follow-up visit, generally scheduled for about 12 days after the misoprostol dose, confirms that the pregnancy has effectively been terminated.

The combination of mifepristone and misoprostol is 92% to 95% effective at ending pregnancy, according to Danco. Bleeding and cramping ‘are a normal part of the process,’ and some bleeding or spotting often continues for over 2 weeks, the company said. Side effects include nausea, headache, vomiting and diarrhea.

‘Physicians when ordering need to be able to assess gestational age of the pregnancy, and diagnose ectopic (tubal) pregnancies,’ Danco spokesperson Heather O’Neil told Reuters Health. ‘And, in the few cases where Mifeprex doesn’t work to end the pregnancy, physicians need to either provide surgical procedures themselves or refer the patient to someone who does.’

Mifepristone, which is widely used in Europe, has been winding its way through the US approval process since 1996. The final approval from the FDA follows an ‘approvable’ letter issued to the Population Council in February.

Right-to-life groups expressed anger and disappointment over the agency’s action. In a prepared statement, Judie Brown, president of the American Life League, called mifepristone ‘a chemical assault weapon aimed at the tiniest babies’ and called on Congress to hold hearings on the FDA’s ‘raw, inhumane decision.’

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