

Two more women die after taking abortion pill

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Unclear whether deaths related to unapproved use of RU-486

WASHINGTON (AP) -- Two more women have died after using the so-called "abortion pill" RU-486, regulators said Friday in a warning that brought renewed calls for pulling the drug combination from the market.

The organization that provided the drugs to the two women said it would start following the approved instructions for their use.

The Food and Drug Administration warned doctors to watch for a rare but deadly infection previously implicated in four deaths of women who had taken RU-486. The drug combination, also called Mifeprex or mifepristone, has not been proved to be the cause in any of those cases.

Nor has the FDA confirmed the cause of the latest two deaths. However, in one of them, the woman's symptoms appeared to resemble those in a cluster of four cases in California where the women died from an infection of the bloodstream, or sepsis. Those women did not follow FDA-approved instructions for a drug-induced abortion, which requires swallowing three tablets of one drug, followed two days later by two pills of another drug.

In the four California cases, the second course of pills was administered vaginally, an "off-label" use that studies have shown to be effective and that has been recommended by a majority of the nation's abortion clinics. That use does not have federal approval, though studies have indicated it produces fewer side effects than the oral regimen.

It was not immediately known if the two new deaths followed vaginal administering of the second course of pills, an FDA spokeswoman said. She declined to be identified, saying she was not authorized to speak publicly about the issue.

RU-486 is sold by Danco Laboratories and is approved to terminate pregnancy up to 49 days after the beginning of the latest menstrual cycle. It blocks a hormone required to sustain a pregnancy. The second medicine, misoprostol, induces contractions, terminating the pregnancy.

Danco said it was reviewing information about the cases as it becomes available.

Two Senate abortion foes, Republicans Jim DeMint of South Carolina and Tom Coburn of Oklahoma, urged passage of legislation that would suspend sales of RU-486 until the Government Accountability Office reviews how the FDA approved it.

"RU-486 is a deadly drug that is killing pregnant women," DeMint said. "This drug should never have been approved, and it must be suspended immediately."

Monty Patterson, a California man whose 18-year-old daughter, Holly, died in 2003 after taking RU-486, also said the drugs should be pulled from the market. The Senate bill is informally called "Holly's Law."

"The bottom line is that this is not about the abortion debate. This is about the safety, health and welfare of women," Patterson said.

Meanwhile, Planned Parenthood Federation of America Inc. said it would stop recommending vaginal insertion of the second course of pills. Four of the women who died, including the latest two, received the pills at Planned Parenthood-affiliated clinics, said Dr. Vanessa Cullins, the organization's vice president for medical affairs. Planned Parenthood estimates RU-486 has been used 560,000 times in the U.S. since it was approved in 2000.

The FDA previously has said the abortion pill remains safe enough to stay on the market. The rate of sepsis is about one in 100,000 uses, comparable to infection risks with surgical abortions and childbirth.

At least seven U.S. women have died after taking the drugs since 2000. The other U.S. death associated with Mifeprex occurred in 2001 in a woman who had a ruptured ectopic, or tubal, pregnancy. The drugs are not to be used in those cases, in which the fertilized egg implants outside the uterus.