The New York Times

After 2 More Deaths, Planned Parenthood Alters Method for Abortion Pill

By Gardiner Harris

March 18, 2006

WASHINGTON, March 17 - After receiving reports that two more women died after taking abortion pills, Planned Parenthood, the nation's largest provider of abortion and contraceptive services, announced that it would immediately change the way it gives the medicines.

The change partly resolves a long-running dispute between Planned Parenthood and the Food and Drug Administration over the safest way to provide pill-based abortions.

The F.D.A. has now received reports that six women in the United States died after taking RU-486, or Mifeprex. A seventh died in Canada. The two most recent deaths and two of the previous four underwent their procedures at Planned Parenthood clinics, a spokeswoman said.

Federal officials do not yet know the cause of the latest two deaths. The previous four resulted from systemic infections with a virulent bacteria, Clostridium sordellii. Planned Parenthood announced in a statement that one of the two recent deaths occurred within days of the victim's undergoing a pill-based abortion, while the other woman died within five weeks.

Mifeprex has been used in more than 560,000 medical abortions in the United States and more than 1.5 million in Europe. The risks of death from infection after using the pill are similar to the risks after surgical abortions or childbirth, drug agency officials said.

When Mifeprex was first approved by the agency in 2000, the standard regimen was to give the drug in a doctor's office followed two days later by an oral dose of a different drug, misoprostol, also in a doctor's office. Women expelled the fetus over the following days or

weeks in a process that mimicked a miscarriage. The procedure must begin within 49 days of conception.

Soon after Mifeprex's approval, most Planned Parenthood doctors switched to a different regimen, instructing women to insert misoprostol vaginally at home two to three days after taking Mifeprex. Studies of the new regimen showed that it was effective, and it allowed women to take lower doses of misoprostol. It also meant fewer office visits for Planned Parenthood.

But this regimen was not approved by the drug agency. It is not unusual for doctors to use drugs differently from how they are officially approved. But as reports of deaths among women undergoing the procedure trickled into the F.D.A., government officials issued stern warnings that doctors should stick to the approved regimen.

Until Friday, Planned Parenthood had rejected those warnings.

Dr. Vanessa Cullins, vice president of medical affairs for Planned Parenthood, said in an interview that effective immediately the group would ask patients to take misoprostol orally instead of vaginally. Although the F.D.A. has asked that this be done in doctors' offices, a Planned Parenthood spokeswoman said patients would still be asked to take the second drug at home.

"There is no single reason for the change" in policy by the group, Dr. Cullins said.

"We don't really know all the circumstances surrounding these women's deaths," she said.

Whether the method of drug administration has anything to do with the deaths is not known. The drug agency said it was "investigating all the circumstances associated with these cases." The agency has already added strong warnings to Mifeprex's label regarding the risks of infection.

On Friday, the agency repeated warnings that women who undergo pill-based abortions should be vigilant for signs of trouble. If they suffer from nausea, vomiting or diarrhea and weakness with or without abdominal pain more than a day after taking abortion medicines they should be given antibiotics.

Clostridium sordellii infections are rare and can be difficult to diagnose because they are not always accompanied by fever.

Since reporting drug side effects is voluntary in the United States, it is possible that more women have died and that their deaths have gone unreported because doctors, medical examiners and coroners are not obligated to forward such reports to the F.D.A. Doctors and local officials also may not associate a death with a pill-based abortion, especially if the death occurs weeks later.

The risk of infections could be lowered or eliminated if abortion patients were given antibiotics as a preventative. But antibiotic therapy has its own risks, and officials say that the risk of infection from Clostridium sordellii is so slight that it does not merit such a precaution.

The government has scheduled a scientific conference on May 11 at the Centers for Disease Control and Prevention to discuss Clostridium sordellii and a related bacteria, Clostridium difficile, that has caused outbreaks of diarrhea and colitis in hospitals and nursing homes.

Both bacteria generally live in the soil and human intestinal tracts. Both thrive in environments with limited oxygen. When these bacteria infect the bloodstream, they can produce a toxin that causes something akin to toxic shock syndrome.

Senators Jim DeMint, Republican of South Carolina, and Tom Coburn, Republican of Oklahoma, released a statement Friday calling for the withdrawal of Mifeprex. They have sponsored a bill that would force the F.D.A. to withdraw the drug.

Monty Patterson, whose 18-year-old daughter, Holly, died on Sept. 17, 2003, from a Clostridium sordellii infection after a medical abortion, has since argued that Mifeprex predisposes women to such infections by suppressing their immune systems.

"How many women have to die needlessly before this drug is removed from the market?" Mr. Patterson asked.

A version of this article appears in print on March 18, 2006, Section A, Page 10 of the National edition with the headline: After 2 More Deaths, Planned Parenthood Alters Method for Abortion Pill