

Deaths After Abortion Pill To Be Studied by Officials

By GARDINER HARRIS

WASHINGTON, Nov. 22 — Federal drug regulators have discovered that all four women in this country who died after taking an abortion pill suffered from a rare and highly lethal bacterial infection, a finding that is leading to new scrutiny of the drug's safety.

Since all four deaths occurred in California, an unusual clustering, the Food and Drug Administration quietly tested to see if abortion pills distributed in California were somehow contaminated. They were not.

Stumped, officials from the F.D.A. and the federal Centers for Disease Control and Prevention have decided to convene a scientific meeting early next year to discuss this medical mystery, according to two drug agency officials who spoke on the condition of anonymity because of the sensitivity of the topic.

Among other issues, the experts hope to explore whether the abortion pill, called Mifeprex or RU-486, somehow makes patients vulnerable to an infection with *Clostridium sordellii*, the lethal bacteria. If so, they will explore how such an infection "could be more easily diagnosed and even prevented," one official said.

Monty Patterson, whose daughter Holly died on Sept. 17, 2003, less than a month after her 18th birthday, said he believed that Mifeprex inhibits the immune system, making women more vulnerable to bacteria.

Mr. Patterson's campaign against Mifeprex helped persuade the family of at least one other woman who died to have tissue samples tested for the presence of the rare bacteria, he said.

"I believe this drug should be taken off the market," Mr. Patterson said.

For now, there is no indication that the F.D.A. is considering restricting access to the drug. Indeed, it has advised doctors against giving antibiotics as a precaution to prevent the rare infections since antibiotic therapy carries its own risks.

Mifeprex has been used in more than 500,000 medical abortions in the United States since its approval in September 2000. The risks of death from infection after using the pill are similar to the risks after surgical abortion or childbirth, said Dr. Steven Galson, director of the F.D.A.'s center for drugs.

Warnings about the drug's possible link with *Clostridium sordellii* were placed on Mifeprex's label in July, and the drug agency without announcement updated this information on its Web site on Nov. 4 after it discovered that all of the deaths involved the lethal bacteria.

"I think everyone would like to know what exactly is going on regarding these rare and really serious *Clostridium sordellii* infections that we have seen happen in California," said Dr. Cynthia Summers, a spokeswoman for Danco Laboratories, maker of Mifeprex. "I don't have an answer for you, and because of that I don't have any running theories."

Information about the *Clostridium sordellii* infections has emerged slowly because the drug agency largely relies on voluntary reports by doctors, patients and others to identify drug problems and side effects.

Ms. Patterson died seven days after taking Mifeprex. She lived in Livermore, Calif.

On Dec. 29, 2003, Vivian Tran, 22, of Costa Mesa, Calif., died six days after taking Mifeprex.

On Jan. 14, 2004, Chanelle Bryant, 22, of Pasadena, Calif., died six days after taking Mifeprex. And on May 24, 2005, Oriane Shevin, 34, of Los Angeles died five days after taking Mifeprex.

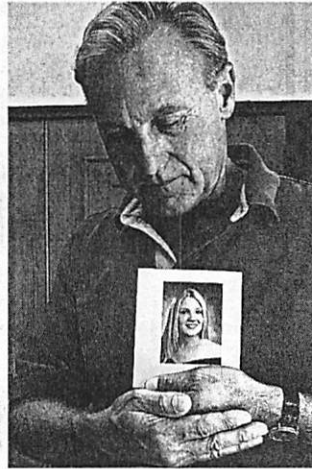
In each case, *Clostridium sordellii* infected the women's uteruses, flourished and then entered their bloodstreams. The bacterium can cause nausea, vomiting, diarrhea and

weakness but may not induce fever, so victims often fail to realize how sick they are until it is too late and succumb to toxic shock. Antibiotics are often ineffective once an infection has flourished because even in death, the bacteria release toxins.

The families of Ms. Patterson, Ms. Tran and Ms. Bryant have all filed suit against Danco, claiming the company failed to warn patients of the drug's dangers.

A woman who died in Canada after taking Mifeprex during clinical testing in 2001 also suffered from a *Clostridium sordellii* infection. No similar deaths have been reported in Europe, where Mifeprex is widely used. But in the United States, most physicians give Mifeprex and an accompanying drug, misoprostol, in a regimen that involves inserting misoprostol vaginally.

Federal drug regulators have not approved this regimen, but it is not unusual for doctors to use drugs differently from how they are officially approved. Studies indicate that this



Carl Macor/San Francisco Chronicle, via Associated Press

Monty Patterson with a photograph of his daughter Holly, who died after taking an abortion pill.

regimen is effective, requires a lower dose of misoprostol, and allows women to undergo the most emotional and painful part of the procedure at home. What is unknown is whether it may somehow contribute to bacterial infections.

Any hint that Mifeprex may cause problems usually leads to a firestorm of criticism directed at the F.D.A., and the meeting scheduled for next year is bound to incite controversy. A 1996 federal advisory committee that recommended the drug's approval met under intense security in a windowless building surrounded by federal marshals.

Wendy Wright, executive vice president of Concerned Women for America, a conservative group, said that the latest news about deaths involving Mifeprex proved that the drug was unsafe. Ms. Wright also speculated that more women were dying after using the drug but that their deaths were going unreported.

"I'm pleased that the F.D.A. is taking a serious look at this," she said, "and hope that they will no longer allow this drug to be available to cause the deaths of more women."

Dr. Scott J. Spear, chairman of the national medical committee of the Planned Parenthood Federation of America, the nation's largest provider of abortions, said there was no evidence that the vaginal administration of misoprostol increased the risks of bacterial infections.

"They're all in California, so is this a local issue?" Dr. Spear said. "I think it's dangerous to speculate in the absence of good data."

Mifeprex is sold through physicians, who dispense the drug directly to patients. Physicians are required to give their patients a medication guide that lists the drug's risks.