

Study Shows Abortion Drug Dangers

by Carlos Briceno

PROVIDENCE, R.I. - As a professor of pharmacology for almost 40 years, Dr. Ralph Miech said it was his job to teach students how a drug works. "Once you know that, you have a big insight in terms of how to use them properly, how to prevent any of the serious side effects," said Miech, a medical doctor and an associate professor emeritus at the Department of Pharmacology, Physiology and Biotechnology at Brown University's medical school. Sometimes taking a drug can be fatal, and it was the death of Holly Patterson, a California teenager who died in September 2003 after taking RU-486 (Mifeprex) in an attempt to abort her child, that sparked Miech's curiosity and led him to research the drug. His findings, which are to be published in the September issue of *The Annals of Pharmacotherapy*, led him to state that RU-486 may cause the rapid onset of septic shock, a serious bloodstream condition that can lead to death. The Food and Drug Administration announced in mid-July that it was issuing a health advisory to inform the public that four California women have died from septic shock following abortions with RU-486, the latest one occurring in June.

Also known as Mifeprex, the drug already has the FDA's highest-level black-box label warning, indicating that it is especially dangerous. In two of the cases, the bacterium that caused the septic shock was found to be *Clostridium sordellii*. The FDA also updated its prescribing information, medication guide and patient agreement for RU-486 to convey information about *Clostridium sordellii*, a bacterium that is difficult to identify because the patient usually does not have a fever or other signs of infection. The FDA said that it is investigating the two other cases and is collaborating with the Centers for Disease Control and Prevention, state and local health departments and RU-486's manufacturer, Danco Laboratories, to determine the causes of the septic shock. The drug blocks progesterone, a key hormone needed to establish and sustain a pregnancy. When used in combination with another medicine during an early pregnancy, misoprostol, RU-486 induces abortion. During the 25 years he worked part-time in an emergency room, Miech said he saw many cases of septic shock. But most of them involved elderly patients who also had high fevers, he said. However, Holly Patterson did not have high fever, so that led him to read medical literature on RU-486.

'Re-Examine Safety'

He found something that startled him, he said. RU-486 was originally developed to lower the excessive production of glucocorticoid hormones in patients who had Cushing's syndrome, a disorder of the adrenal glands. He also found out that these glucocorticoid receptors are extremely important to the innate immune system, so he theorized that the drug impairs the body's defense system, decreasing its ability to destroy the *Clostridium sordellii* invasion, he said. "I was startled by the fact that this was in the literature, and no one had put it together or proposed it as the mechanism for the possibility of actually causing septic shock due to infection," he said. In his article, Miech said that RU-486 causes cervical dilation, which allows *Clostridium sordellii* to contaminate the uterus. With the innate immune system malfunctioning, septic shock occurs. Some women cause more damage without realizing it, the article stated because they sometimes experience severe pain during the abortion and take codeine. The interaction of RU-486 and codeine results in a prolonged effect of both drugs, resulting in an even higher decrease in the body's immune system to fight off the invasion of the bacteria, according to the article. "I think at this particular point and time the whole safety issue with regard to RU-486 has to be re-examined," he said.

A spokeswoman for Danco Laboratories did not respond to several phone calls. But the drug company did issue a press release in mid-July, saying it was modifying its labeling for RU-486 to include updated safety information. The press release added that "childbirth, menstruation and abortion, whether spontaneous, surgical or medical, all create conditions that can result in serious and sometimes fatal infection, and there is no evidence that Mifeprex and misoprostol present a special risk of infection." It went on to say, "*Clostridium sordellii* is a common soil and enteric bacterium that has presented in a very small number of obstetric and gynecologic cases, including following childbirth [vaginal delivery and caesarian section], medical abortion and in other gynecologic and non-gynecologic conditions." Several calls to several abortion providers, Planned Parenthood and NARAL Pro-Choice America, also were not returned.

James Sedlak, vice president of the American Life League and founder of Stop Planned Parenthood, was not impressed with Danco's public statements. "We all remember the disclaimers issued by the tobacco companies in the early days of people going after the tobacco companies for having addictive products and causing all kinds of

health problems," he said. "When the manufacturer of the product comes out with statements like that, it has to be taken with a grain of salt." He said American Life League's position is very clear: RU-486 should be taken off the market. "The fact that it will harm a woman is an additional reason," he said, "but the main reason is it kills human beings in the womb."

'Adverse Events'

Wendy Wright, the senior policy director for Concerned Women for America, said she was grateful for Miech's article because he explains, in logical fashion, why the deaths have occurred. "It shows that this drug was not adequately tested," she said. Wright's organization filed Freedom of Information Act requests in order to gain access to the adverse events reports, which are filed by patients or doctors and details side effects caused by drugs. She said it took months to get the reports on what adverse effects RU-486 has caused to patients, but the numbers show that about 600 adverse events were reported from 2001 until September 2004, and about 260 were reported from September 2004 until July 2005. Miech said he predicts the five deaths are only the "tip of the iceberg." He said he hopes his article creates an awareness of the dangers of RU-486. "If physicians and patients are properly informed of the manner in which [RU-486] can cause the rapid onset of septic shock," he wrote in his article, "perhaps both groups will be more sensitive to any early warning signs, which would allow earlier treatment of this otherwise potentially lethal complication."

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