

Danger of RU486 Ignored in Focus on Second Drug

By Randall K. O'Bannon, NRL-ETF Director of Education and Research

How do you convince customers that a drug that has already been associated with the deaths of at least six healthy American women is safe? How do you keep the government agency responsible for drug safety from pulling your drug off the market when it knows about these deaths and hundreds more who have suffered complications?

If you're America's abortion industry, you do what you've always done. Create a diversion, make a show of "solving" the problem, and hope that the whole thing can be papered over with happy talk.

The most recent example of blame-shifting is the six deaths associated with RU486. There is a major effort underway to pin the blame not on the artificial steroid RU486 but on misoprostol, a prostaglandin which is the second drug used in this two-drug chemical abortion technique.

This diversionary tactic attempts to remove scrutiny from the fundamental safety issues with RU486 itself, and the particular role it may have played in the septic infections which killed several of the women. Furthermore, cosmetic changes in the way the drugs are administered (the "protocol") do little to address the underlying flaw of the method. Side effects which are customary to the chemical abortion process may cause patients and doctors to miss signs of other dangerous conditions such as infections or ruptured tubal pregnancies.

A May conference scheduled by the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) is supposed to address some of the issues associated with the lethal, but usually inert, bacterium that has killed at least four American abortion pill patients. Whether the abortion industry will be forced to come clean about inherent problems with RU486, or whether it will be successful in diverting attention to the way the prostaglandin has been deployed, is yet to be seen.

Shifting Blame to Misoprostol

When stories of the deaths began to surface, the initial reaction of the abortion industry was to express sympathy and concern, promise cooperation in any investigations, and to try and talk about hundreds of thousands they claimed had used the drug safely. The more women died and the more details that came out about their experiences, the less effective this strategy was.

Danco, the U.S. distributor of RU486, tried to argue in July 2005 that "no causal connection" had been established between the drugs used in the chemical method and the women's deaths even though government investigations had found that three women* had died from the same bacterial infection, along with two more in similar circumstances.

Danco did mention something else in letters to doctors. It wrote that the prescribers who gave these women the pills had followed an alternative protocol to the one recommended by the FDA. This included having women administer the prostaglandin, misoprostol, to themselves vaginally, rather than orally. Danco reminded doctors of the FDA protocol.

The theory that misoprostol, rather than RU486, might be to blame began to be floated in the press. Philip Darney, an abortion researcher from the University of California-San Francisco often quoted by reporters, mentioned to the Los Angeles Times (8/15/05) that he suspected that vaginal self-administration of the prostaglandin was the culprit.

RU486 has “gotten all the attention because it’s been labeled the ‘abortion pill,’” Darney said. But, he said, “We think that the explanation for these unusual deaths ... may be the vaginal self-administration of misoprostol under unusual circumstances.”

After the FDA revealed the deaths of two additional RU486 patients in March 2006 (one was later determined not to be RU486-related), Planned Parenthood, the nation’s largest abortion provider and one of the organizations taking the lead in promoting RU486, announced that its clinics would no longer be recommending the vaginal self-administration of misoprostol.

Planned Parenthood did not explain why it chose to change this aspect of the protocol and not others. But its actions clearly drew attention to the prostaglandin and in particular to the mode of its administration, and away from RU486.

RU486’s Effect on the Immune System

There is reason to think the irresponsible deviations from the FDA protocol may have contributed to the danger of the method, and that vaginal self-administration of the misoprostol could be a factor in how germs were introduced into the reproductive tract. However, RU486 itself has properties which may reduce a woman’s immune system and make her body more susceptible to infections.

Serious concerns about RU486 itself are not new, nor are they confined to pro-lifers. As far back as 1991, in a book titled RU-486: Misconceptions, Myths, and Morals, a team of pro-abortion feminists passionately opposed its use.

In the book, they raised a number of issues which have proven prescient—the dangerous side effects; the basic problems of a multi-drug, multi-visit process; and the lack of any real understanding as to how RU486 and the prostaglandin act and interact.

One thing they discuss is RU486’s activity not just in blocking progesterone (a hormone essential to maintaining pregnancy) but also as an antiglucocorticoid. Glucocorticoids are natural hormones, such as cortisol, produced by the adrenal cortex.

At appropriate levels, they regulate metabolism, control body temperature, help the body fight inflammation, and boost the immune system.

While discussion on RU486’s immunosuppressive properties in the 1991 book was limited, biologist Renate Klein, one of the book’s original authors, wrote in a December 2005 opinion piece that the antiglucocorticoid effect of RU486 “weakens a woman’s immune system, making it impossible for her to fight bacteria, and leads to septic shock and rapid death” (www.onlineopinion.com.au, posted 12/23/05).

In September 2005, retired Brown University professor of molecular pharmacology Ralph Miech outlined the possible mechanisms involved in RU486’s suppression of the immune system in the *Annals of Pharmacotherapy*. As explained in the December 2005 edition of *Life Insights*, “Dr. Miech describes two ways RU-486 may interfere with the innate immune system, contributing to the development of an infection and disrupting the innate immune system’s ability to fight the infection successfully.”

Clostridium sordellii: More about the Bacteria That Killed Abortion Pill Patients

As Klein and her co-authors pointed out in 1991, there are things about both drugs, acting together or separately on a pregnant woman’s body, that raise safety questions. But to understand why it seems unlikely that the vaginal administration of the misoprostol could be the factor behind these deadly infections, one simply needs to understand a bit more about the *Clostridium sordellii* bacteria.

Clostridium sordellii is actually a quite common bacterium, found in soil and often in the human intestinal tract. Actual infections with *Clostridium sordellii*, however, are quite rare, occurring only when the bacteria gets into the bloodstream and begins to wreak havoc.

Promoters of the abortion pill want people to believe that this organism finds its way into a woman's body when she inserts the misoprostol pills into her vagina and bleeds from her abortion. While in theory this may be one possible way the bacteria enters a woman's system, other facts argue this is an inadequate explanation.

If these bacteria were rarely encountered in a woman's womb, such an explanation might make some sense. But *Clostridium sordellii* has been found in about 10% of women's vaginal flora, yet infections like these are extremely rare.

Bleeding is a normal part of a woman's reproductive cycle, and bleeding and even some limited surgery are not unusual parts of ordinary births. Thus that factor alone would not appear to explain the sudden spike in *Clostridium sordellii* infections and deaths that arrived with the onset of the abortion pill.

The bacteria is there, the bleeding is there, but what unique factor is it that enables the germ to become deadly in this particular population taking the abortion pill? The most obvious answer is that something in the process hinders the body's normal ability to fight infection. And the most likely culprit is RU486 itself, which is known to inhibit the immune system.

If Miech and Klein are right, going back to the oral administration of misoprostol will not solve the problem. As long as the bacterium is around, and women's immune systems are compromised, women taking RU486 will continue to die.

Why the Abortion Industry Wants to Blame Misoprostol

The reason supporters of the abortion pill want to pin blame for the deaths on the vaginal administration of misoprostol rather than RU486 at the upcoming FDA conference on clostridium infections is simple. If that method of administering the prostaglandin is implicated, they can claim that they've already addressed the problem by switching back to oral administration of that drug. Problem solved, everyone can return safely to the clinics for their abortion pills.

The industry can then try to credit itself for being responsible and catching and solving the problem before the government had to step in, all the while validating the wisdom of the FDA and its original protocol.

If RU486 is found to be somehow responsible for these deaths, a much different scenario unfolds. The clinics end up with an unpredictable, unsafe product on their hands and the reputation of the industry takes yet another hit.

Bureaucrats at the FDA will have to grant that the agency didn't do a very good job when it looked at the abortion pill and the process during the Clinton years and admit that the drug never should have been approved in the first place.

If the FDA doesn't yield to good sense and pull the drug from sale, it may yet damage the marketability of RU486 with additional ominous warnings and a further beefed-up protocol. Doctors will be more reluctant to prescribe it, and women will be less likely to take it. Women who do take it will be risking their lives.

Opposition to any suggestions at the FDA's clostridium conference that RU486 may be unsafe and may be to blame in any of these women's deaths will be loud and fierce. But only if the abortion pill is pulled from the market will women—and their unborn children—be safe.

* This was referring to a woman in Canada who died in 2001 and two women from California who died in 2003. In November 2005, the FDA determined that two additional California patients had died from the same infectious agent.