Life Insight

Special Report

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How Many Deaths Will It Take for the FDA to Suspend Sales of RU-486?

A pattern can be discerned in the reaction of the federal Food and Drug Administration (FDA) to bad news about RU-486. See if you can spot a trend.

EVENT 1: A special issue of the *Journal of the American Medical Women's Association* (Summer 2000), seemingly intended to promote approval of the drug in the United States, was full of red flags. One study, for example, compared bleeding patterns following RU-486 and surgical abortions. Twenty per cent of women who underwent RU-486/misoprostol abortion suffered prolonged bleeding for 35 to 42 days. The FDA already knew that in the Population Council's drug trials 65 women "(7.9%) … received surgical interventions: 13 (1.6%) were… mostly for the excessive bleeding" (Mifeprex label, available at www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf). An emergency room physician from Waterloo, Iowa testified before the FDA that he had saved the life of a woman who, as a result of participating in the RU-486 drug trials, had lost 1/2 to two-thirds of her blood.

Dr. Wu Shangchun of the National Research Institute for Family Planning in Beijing, a doctor who collaborates in China's coercive population control program, warned in the same issue of JAMWA: "Some recent adverse events resulting from undiagnosed ectopic pregnancies have led providers to pay more attention to ultrasound examination" (*JAMWA*, at 197). He described "common complications" of RU-486 as including "profuse bleeding and allergy. … Allergic reactions to mifepristone [RU-486] or misoprostol were not uncommon, manifesting in facial edema, skin rash and itching, numbness of feet and hands, and even a serious case of allergic shock. The potential for such reactions is one reason to keep clients for observation" (at 198).

Due to the risks inherent in RU-486 abortion, Dr. Wu reported that it was falling into disfavor among staff members at larger hospitals: "The staffs were too busy to handle the procedure (more counseling, more visits and observation), and they also have to manage the referred cases with serious side effects and complications" (at 199).

FDA RESPONSE 1: Notwithstanding the above, in September 2000 the agency *approved* the sale of RU-486 (mifepristone) under the brand name Mifeprex! What's worse, it did so under a protocol *less* stringent than that required in France, Sweden, and even China. This despite the private, unregulated nature of healthcare and, especially, of abortion services in the United States.

Notably, the FDA did *not* require dispensing physicians to be trained in or to use ultrasound to rule out ectopic pregnancies and pinpoint gestational age. The agency did *not* require the abortions to be done in hospital outpatient clinics, nor did it require monitoring by nursing staff for at least four hours after each drug is taken. The agency did limit use of RU-486 to 49 days' gestation (49 days after the first day of the last menstrual period "LMP") and "required" that the second drug, misoprostol (intended to induce uterine contractions to expel the embryo), be taken orally at the doctor's office 2 days after administration of RU-486 (see Internet address for Mifeprex label, above). Abortion providers, however, have openly defied these restrictions, with no corrective action from the FDA. The agency blandly admits: "FDA is aware that many medical practitioners use modified regimens, which may include prescribing different doses …, dosing misoprostol on a different day, and advising the patient that the oral misoprostol tablets be inserted into the vagina. … [T]he safety and effectiveness of Mifeprex dosing regimens, other than the one approved by FDA, including use of oral misoprostol tablets intravaginally, has not been established by the FDA" ["Questions and Answers on Mifeprex (mifepristone)," available at www.fda.gov/cder/drug/infopage/mifepristone/mifepristoneqa20050719.htm].

Some abortion providers (e.g., Planned Parenthood of New York City at www.ppnyc.org/services/factsheets/mifep.htm, Capital Care Women's Center at www.capitalcarewomenscenter.com/services.php, and Camelback Family Planning at www.camelbackfamilyplanning.com/abortionpill.htm) even advertise their use of RU-486 through 63 days LMP, by which time

the rate of incomplete abortion, infection, and other complications rises sharply. In U.S. clinical trials, the failure rate for RU-486 abortions jumps to 17% at 50-56 days LMP, and to 23% at 57-63 days LMP, from 8% at 49 days or less [Spitz et al., *New England Journal of Medicine*, 338: 1241-1247 (2005)].

Deplorably, many RU-486 providers (see, e.g., those cited in prior paragraph) eliminate the follow-up visit at 48 hours, instead handing teens and young women misoprostol pills (a powerful prostaglandin) to insert vaginally at home 1-2 days later with no medical supervision. All five women from the U.S. and Canada who died from toxic shock in the week following their RU-486 abortions had been instructed to take misoprostol vaginally at home, rather than in an oral dose at the office/clinic as called for by the FDA-approved protocol.

EVENT 2: In September 2001, 38-year-old Brenda Vise of Chattanooga, Tennessee dies from a ruptured ectopic pregnancy after undergoing an RU-486 abortion.

FDA RESPONSE 2: RU-486 (Mifeprex) *not* pulled from market. No discernible action taken (hereafter "NDAT").

EVENT 3: In September 2001, a Canadian woman dies of toxic shock following an RU-486 abortion during the Canadian drug trials; bacterium identified as *Clostridium sordellii*.

FDA RESPONSE 3: RU-486 *not* pulled from market. NDAT.

EVENT 4: A 21-year old woman, with no family history of heart problems, has a heart attack after undergoing an RU-486 abortion; more non-fatal adverse events such as undetected ectopic pregnancies and serious, systemic bacterial infections are reported.

FDA RESPONSE 4: April 19, 2002, RU-486 *not* pulled from the market, but Danco (U.S. distributor of RU-486) is required to send out a "Dear Health Care Provider" letter advising of the possibility of more such events and fatalities.

EVENT 5: In June 2002, one of the two RU-486-related fatalities in the United Kingdom is reported to the FDA.

FDA RESPONSE 5: RU-486 *not* pulled from market. NDAT.

EVENT 6: On August 20, 2002, the American Assn. of Pro-Life Obstetricians and Gynecologists, the Christian Medical Assn., and Concerned Women for America file a Citizens' Petition with the FDA asking the agency to revoke approval of RU-486 pending review of the flawed approval process and citing proven health risks. By law, the agency must respond to the petition within 6 months.

FDA RESPONSE 6: RU-486 *not* pulled from market. Only response from FDA in 3½ years has been a notification that the agency is "studying" the petition.

EVENT 7: On September 17, 2003, 18-year-old Holly Patterson of Livermore, California dies from toxic shock; bacterium identified as *C. sordellii*. (See Event 3.)

FDA RESPONSE 7: RU-486 *not* pulled from market. NDAT.

EVENT 8: On December 29, 2003, 21-year-old Californian Vivian Tran dies of toxic shock following an RU-486 abortion; bacterium identified as *C. sordellii*. (See Events 3 and 7.)

FDA RESPONSE 8: RU-486 *not* pulled from market. NDAT.

EVENT 9: On January 14, 2004, 22-year-old Chanelle Bryant of Pasadena, California dies of toxic shock following an RU-486 abortion; bacterium identified as *C. sordellii*. (See Events 3, 7, and 8.)

FDA RESPONSE 9: RU-486 *not* pulled from market. NDAT.

EVENT 10: In March 2004, 16-year-old Rebecca Tell Berg of Sweden bleeds to death following an RU-486 abortion.

FDA RESPONSE 10: November 15, 2004, RU-486 *not* pulled from market, but FDA amends "black box" warning label for RU-486 to discuss recent fatalities and adverse events involving bacterial infections, heavy bleeding, and ectopic pregnancies.

EVENT 11: On May 24, 2005, Oriane Shevin, a 34-year-old lawyer and mother of two from Sherman Oaks, California, dies of toxic shock after taking RU-486; bacterium identified as *C. sordellii*. (See events 3, 7, 8, and 9.)

FDA RESPONSE 11: July 19, 2005, RU-486 *not* pulled from market, but FDA requires Danco to modify its labeling to advise that all four women from California and the unnamed Canadian woman died of massive bacterial infections. On November 15, 2005, FDA publishes a Public Health Advisory and

"Question and Answer" on RU-486 updating information on the deaths from *C. sordellii*.

Eleven life-threatening or fatal events, eleven neglectful responses.

Over 660 "adverse event" reports were recorded by the FDA describing "problems" which arose in the course of RU-486 abortions, over the four years ending October 2004.

These adverse event reports only start to tell the whole story of this dangerous drug. Physicians are not required to report adverse events to the FDA; only drug makers are. Dr. L. Clifford McDonald, an epidemiologist with the Centers for Disease Control ("CDC") speculates there may be more women who have died whose deaths have not been reported. "'It may be that we've found all there are. We don't know. … Until we've tried to draw the circle around the true number of cases, we can't get a sense of what the risk involved is'" (quoted in M. La Ganga, "Abortion Pill Investigated in Four California Deaths," *Los Angeles Times*, Aug.15, 2005).

Given the laxity of abortion providers in following the FDA's cut-off of 49 days LMP, it is important to remember that the failure rate for RU-486 more than doubles at 56 days and is almost 3 times higher at 63 days LMP (see Spitz et al, cited above). "Failure" means a continuing pregnancy or a dead embryo that is unexpelled or only partially expelled. Such circumstances present grave risks of infection, excessive bleeding, loss of fertility, and death.

Named after the California teen who died from toxic shock, "Holly's Law," the RU-486 Suspension and Review Act, was jointly introduced in both houses of Congress in 2003 and again in 2005. In the House, Rep. Roscoe Bartlett (R-MD) introduced the House bill (H.R. 1079) on March 3, 2005. It has 77 co-sponsors and was referred to the Subcommittee on Health of the House Energy and Commerce Committee. The same day, Sen. Jim DeMint (R-SC) introduced the companion bill (S. 511). The measure has 11 co-sponsors and was referred to the Committee on Health, Education, Labor, and Pensions. Three and a half months later, on July 20, 2005, the FDA's failure to take decisive action prompted several lawmakers, including Sens. Jim DeMint (R-SC), Sam Brownback (R-KS), and David Vitter (R-LA), and Congresswoman Melissa Hart (R-PA), to again urge Congress to take RU-486 off the market and force a thorough review of its safety by the Comptroller General. For additional information on the legislative history, see http://www.nchla.org/issues.asp?ID=15 (National Committee for a Human Life Amendment).

The most encouraging development on the RU-486 front has been the recent spate of journal articles and letters revealing its dangers.

Ralph P. Miech, M.D., Ph.D. (Associate Professor Emeritus, Department of Molecular Pharmacology, Physiology and Biotechnology, of Brown University's Medical School) has published an extremely important paper entitled "Pathophysiology of Mifepristone-Induced Septic Shock Due to *Clostridium sordellii*" in *The Annals of Pharmacotherapy* 39:1483-8 (September 2005). Mifepristone is the generic name for RU-486. In this article, 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.

RU-486 can bring about a toxic bacterial infection for the following reasons. *Clostridium sordellii* is a bacterium that is part of the normal vaginal flora of about 10% of women. The bacterium can live and grow in the absence of oxygen. It produces two principal toxins appropriately named "lethal" and "hemorrhagic." Normally the body's innate immune system can destroy the bacteria before they can multiply and secrete toxins into the bloodstream. However, RU-486 causes cervical dilation and the loss of the mucus plug which separates the uterus and cervix from the vagina during pregnancy. *C. sordellii* is then able to enter the cervix and grow rapidly off the decaying embryonic tissue. RU-486 also undermines the body's natural defenses against such infections.

RU-486 interferes with chemical regulators called cytokines which regulate activation of the innate immune system so the body is not able to respond effectively. The infection spreads rapidly, and there is no "cure" once toxins are in the bloodstream. One reason why women are especially at risk from RU-486 abortions is that *C. sordellii* does not produce symptoms typical of a bacterial infection. There may be no fever or tenderness on examination. Even in the presence of excessive blood loss, the hemoglobin levels may be normal or even elevated due to hemoconcentration so that a physician may not be alerted to the severity of hemorrhage. Pain, nausea, cramps and other symptoms of infection are the same symptoms that accompany a normal RU-486 abortion.

In November 2005, the on-line journal *Contraception* published an article by Beverly A. Lawton et al., of the Wellington (New Zealand) School of Medicine and Health Sciences: "Atypical presentation of serious pelvic inflammatory disease following mifepristone-induced medical abortion" (subscription required; abstract available at www.contraceptionjournal.org/article/PIIS0010782405 003616/abstract). The authors describe a 20-year-old patient who underwent an RU-486 abortion and subsequently visited the hospital twice due to extreme

pain and bleeding. She was given medication and tested for STDs. Two days later the results came back that she had a rare, invasive infection (*Streptococcus C*) of the genital and pelvic tract which required 8 days' hospitalization and IV antibiotics. The authors state that this case confirms "the need for enhanced vigilance for infection" following RU-486 abortions.

Contraception 72: 393-397 (2005) has subsequently published a well-footnoted letter from two Los Angeles physicians, Drs. James A. McGregor and Ozlem Equiles, explaining the "rapid lethality" that can occur from *C. sordellii* following an RU-486 abortion. Their reasoning and conclusions mirror those of Dr. Miech.

Lastly, physicians and scientists from the U.S. Centers for Disease Control and Prevention, led by Dr. Marc Fischer, have published a detailed report on the deaths from toxic shock syndrome of the four California women within a week of their RU-486 abortions (M. Fischer et al., "Fatal Toxic Shock Syndrome Associated with *Clostridium sordellii* after Medical Abortion," *New England Journal of Medicine*, 353: 2352-60 (2005)). They conclude as follows: "The side effects of misoprostol [the second drug used in RU-486 abortions] (e.g., vomiting, diarrhea, and abdominal cramping) may be similar to the initial symptoms of toxic shock syndrome associated with *C. sordellii*. To improve diagnosis and therapy, clinicians should be aware of the distinctive features of this potentially fatal entity. …"

Holly Patterson's father, Monty, believes there is no way to safely administer RU-486 and misoprostol because it is impossible for women, and even medical personnel, to tell the difference between the desired effects of the drugs and the signs of serious infection. "Women who take the drugs, he said, are told that they should expect abdominal pain and heavier bleeding than during a normal menstrual period, results that are similar to the drug's danger signs" (La Ganga article cited earlier). He asks how we can expect a teenager "to figure out if she's beyond the so-called normal side effects … to serious adverse events"? A minor would have to realize what is happening, know how to get help, and then convince ER personnel to run a battery of tests to determine if she is going through the normal misery of an RU-486 abortion or is going to be dead in two days. That's too much to ask of a teenager!

So we simply ask the question: How many more deaths will it take before the FDA suspends the sale of RU-486?

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