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Journal Analyzes Infection Responsible for Deaths of RU486 Patients

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When five young North American women died in a short period of time from the same rare infectious organism after taking RU486, it generated a firestorm of media attention. But these tragic deaths also aroused the natural scientific curiosity of the medical research community. How and why did this happen?

While trying to uncover the cause, course, and cure of a rare infectious disease is ordinarily difficult enough, it is made doubly so when researchers have to deal with politically charged issues like abortion. A recent article and editorial appearing in the journal Clinical Infectious Diseases aptly illustrates the difficulties and the dangers.

The authors of the article in the December 1, 2006, issue, Michael J. Aldape, A. E. Bryant, and Dennis L. Stevens, are all researchers with the Veterans Affairs Medical Center in Boise, Idaho. Though relatively scientific and straightforward, their presentation still shows (intentionally or not) subtle signs of the "abortion distortion" that colors their data selection and analysis.

The guest "editorial" accompanying the piece is another story. Written by Beverly Winikoff (identified by the journal as affiliated with a group called Gynuity Health Projects), it discounts legitimate concerns about the RU486's properties and minimizes its problems.

The journal claims the author has no conflict of interest, but fails to note that Winikoff has been heavily involved in the promotion of RU486. She served for 25 years as director for reproductive health and a senior medical associate for the Population Council, the group that obtained U.S. rights to RU486 and brought the abortion drug to America.

Aldape Study: Useful Infor-mation, Flawed Analysis

The three authors examined 45 cases of Clostridium sordellii infection occurring between 1927 and 2006.1

Five of these involved four women from California and another woman from Canada who died shortly after taking the abortifacient RU486. While the scientific description of the infection and its clinical progression are generally thorough and well done, there are a number of problems when it comes to their treatment of the RU486 deaths.

Aldape, Bryant, and Stevens do a good job of explaining why C. sordellii infections can be so virulent and so hard for doctors to catch. Besides being rare, "the initial symptoms are nonspecific, and frankly, misleading."

As the researchers point out, symptoms such as nausea, vomiting, and diarrhea are common, yet without the fever characteristic of other infections. Significantly, these also are expected side effects of RU486-induced abortions. As a result, both patients and clinicians see them as "typical" and thus can and do miss their potentially lethal significance.

The authors write, "[B]y the time local signs and symptoms are apparent, patients are hypotensive [low blood pressure], with evidence of organ dysfunction."

The authors also accurately characterize the danger of C. sordellii infections. "There is little, if any, information regarding the appropriate treatment for C. sordellii infection. In fact, the time between the onset of symptoms and death is often so short that little time exists to initiate empirical antimicrobial therapy."

Their presentation falters, however, when it comes to the infection's connection to RU486 and abortion.

First, they inexplicably describe RU486 (or mifepristone) as a "birth control alternative" that acts in conjunction with the prostaglandin misoprostol to stimulate "heavy vaginal secretion" and to "cause the uterine lining to slough, preventing implantation." Those who are familiar with how the two-drug abortion technique actually works can only wonder at the authors' inapt description.

RU486 is typically taken after the young embryo has implanted and has already begun to develop. RU486 shuts down the life support system, essentially starving the child to death. The prostaglandin misoprostol is taken two days later. By stimulating powerful uterine contractions, it dislodges the child, forcing the tiny corpse and the other bloody contents out of the uterus.

Second, while it is clinically helpful to look at all the known C sordellii cases to look for patterns and possible treatments, the presentation tends to obscure the significance of the unique cluster of deaths associated with RU486. It does so by placing these against a backdrop of dozens of other unrelated C. sordellii infections that occurred over a nearly 80-year period.

But were there so many deaths among a few thousand RU486 abortion patients in a five-year span? Compare that with the relatively few deaths among millions of other patients who, for example, were giving birth or having surgery, over a much longer period of time.

The implication is left that this has something more to do with pregnancy in general rather than specific dangers associated with the RU486 abortion method. But as discussed below this is likely erroneous.

Unhelpfully, Aldape and his associates continue to accept "usage" estimates put out by Danco Laboratories, RU486's U.S. distributor, which are based on sales to clinics rather than actual patient usage. This very likely inflates the number of women in the United States who have actually taken the abortifacients since 2000. This has the effect of making C. sordellii infection deaths seem rarer among RU486 patients than they actually are, minimizing the crisis.

Aldape and his colleagues twice mention a popular theory offered by pro-abortionists as a possible explanation for how the organism enters a woman's system: these infections may be due to the "intravaginal administration" of misoprostol—manual insertion of the prostaglandin into the vagina. But they do not fully explain how a substantial number of healthy women (estimates of 0.5% to 10%) have been found to carry C. sordellii in their vaginal tracts without any ill effects.

The organism is common in soil and found in many human intestinal tracts. This raises the question, unanswered in the article, of precisely what it is about the RU486 abortion process that triggers these fatal infections.

The authors also mention, but do not provide citation for, the possibility that "Mifepristone/misoprostol may facilitate colonization of uterine tissue, trigger toxin expression, or induce hypotension and systemic shock by dysregulating the host's immune response." In fact RU486's possible role in suppressing the immune system has been written about. Moreover, at least two presenters, Brown University molecular pharmacologist Ralph Miech and NIH researcher Esther Sternberg, discussed this at the May 2006 conference on Clostridium sponsored by the Centers for Disease Control and Prevention (CDC), which Aldape's co-author, Stevens, attended.

Winikoff: Live with Uncertainty

While Aldape's study looks at Clostridium sordellii infections in general, Beverly Winikoff confines her remarks to the implications of the study for chemical/RU486 abortions.

Admitting "we have few answers to offer" about the cause of or possible cure for such infections, Winikoff quickly begins to list and dismiss any theories that would imply fundamental problems with RU486 or the mifepristone/misoprostol drug process.

Concerns that the pills, manufactured in China, might have become tainted in the manufacturing process, Winikoff argues, were eliminated by testing of samples. While the unusual geographical clustering—with four of the five deaths in California—might be accounted for by some local mutation of the pathogen, Winikoff points out that this would not necessarily explain the particular relation to chemical abortions.

As noted above, the idea that RU486 might suppress the immune system was seriously advanced by two distinguished, published scientific experts who spoke at the CDC's Clostridium conference. Winikoff casually dismisses this as a "fairly elaborate" hypothesis based on animal studies that has yet to be observed in humans. She says that "there are several larger-picture facts that seem to speak against the importance of this theory."

Winikoff says that "no such infections have been recorded" in experimental long-term use for chronic diseases, such as meningoma, fibroids, and ovarian cancers. While true, she fails to note two important considerations.

First, the circumstances are dissimilar. Unlike RU486 abortion, these do not present the opportunity of an open, bleeding wound, in which anaerobic bacteria like C. sordellii thrive. Second, there is no real comparison because use in these non-abortion circumstances is extremely limited.

Winikoff argues further that there have been no reports of C. sordellii toxic shock in Europe, where the drug has been in use (at least in France) since 1988. There are actually reports of at least one French woman, two British women, and one Swedish teen who died after taking the drug, though these were not attributed to C. sordellii.

But these deaths were only discovered after government ministers requested information from the national health service or family members came forward with their stories to the media. This raises serious questions about how open or complete European safety data is on the drug.

As noted above, proponents consistently exaggerate the use of RU486, thus diluting the significance of the risks that have shown up. National abortion figures for 2002 (complied by the CDC after RU486 had been on the market for over a year) show only 36,297 chemical abortions (called "medical" abortions) for the whole year. While the actual number is certainly higher, given that seven states were missing from the CDC totals, this number is still a far cry

from the 100,000 to 125,000 annual RU486 abortions that would be expected if figures reported by the abortion industry were accurate.

Winikoff's calculation of the infection rate also depends on there being some confidence that all these infections and deaths have been reported. Yet as Aldape and his colleagues point out, these infections are not always recognized as such. It is conceivable that additional deaths may have been incorrectly attributed to other causes.

While certain of these deaths—the Canadian woman in September 2001, teen Holly Patterson in September 2003—were publicized relatively quickly, the deaths and details of the other three California RU486 patients only became known gradually. There is also some thought that the concentration of reports in California may be due to greater awareness and better reporting rather than any concentrated West Coast epidemic.

Finally, Winikoff also discusses the popular notion, pushed by many abortion proponents, that women may have introduced this bacteria into their reproductive systems when vaginally administering misoprostol, the prostaglandin (see NRL News, May 2006). She says that explanation has a number of problems.

While the FDA protocol directs that the prostaglandin be taken orally, Winikoff states that nearly all clinics followed an alternate protocol (pushed by the abortion industry) that called for vaginal self-administration of the misoprostol at home. Winikoff thinks there should have been many more C. sordellii infections and deaths.

The lack of any C. sordellii reports from the United Kingdom, Sweden, and South Africa, where Winikoff says vaginal use of the misoprostol is standard, raises additional doubts about whether the method of administering the prostaglandin is the problem.

In the end, Winikoff has no answer for the sudden cluster of C. sordellii deaths among RU486 abortion patients. She notes that in 2006 Planned Parenthood, the nation's biggest abortion chain and one of RU486's biggest promoters, decided to stop using misoprostol vaginally in favor of buccal (oral) administration.

Winikoff says that a "large natural experiment" is now underway that may provide some indication of which hypothesis is more likely. "We will have to wait," she writes, "many months or years, but eventually we may see whether this change in practice is accompanied by any measurable change in the rate of these tragic deaths."

She adds, "In the meantime, we will have to live with our uncertainties and avoid the mistakes so easily caused by acting on assumptions and guesses rather than facts." In other words, leave the drug alone, and don't be bothered by these statistically insignificant (though "tragic") deaths.

The problem is that if RU486 is not pulled from the market, many more women may not be able to "live" with the uncertainty. It certainly won't save the lives of unborn children. And clouding the issue simply means more lives put at risk.

Note

1. M.J. Aldape, A.E. Bryant, and D.L. Stevens, "Clostridium sordellii Infection: Epidemiology, Clinical Findings, and Current Perspectives on Diagnosis and Treatment," Clinical Infectious Diseases 43, no. 11 (December 1, 2006): 1436–46.