

Intergel Scandal: A "Dangerous Precedent" at FDA?

June 24, 2007. By Anne Borden

Washington, DC: In the wake of the *Gynecare Intergel* recall, many critics are questioning why the Food and Drug Administration (FDA) ever approved Intergel for medical use. Could it be, as some suggest, that the FDA is playing politics to its drug-company funders?

Intergel: Initially "Not Approvable"

Initially (2000) the FDA rejected Intergel as "not approvable", concluding that use of Intergel increased a woman's risk of infection. Its manufacturer, Lifecore, appealed the denial. In November 2001, the FDA approved the product in what *USA Today* called "an unprecedented about-face."



However, even upon approval, the FDA called the use of Intergel only "reasonably safe." The FDA cited a study of 281 women which found 5.6 percent of Intergel recipients suffered an infection at the surgical site, versus just 2.9 percent of women who received standard surgical treatment.

Given this data, why (or how) was Intergel approved by the FDA?

"We don't care how it got approved, we just care that it got approved," responded Lifecore President Jim Bracke back in 2001. "They'll be watching us carefully for safety and that's fine. It'll prove out."

Memo to Mr. Bracke: It didn't.

FDA Reports Fatal Results"

The FDA has more than 70 "adverse events," on record related to Intergel, including three deaths and 48 injuries. One "adverse event report" sent to the FDA reported that a patient died after Intergel was used during a hysterectomy by laparotomy. According to the report:

"...a few days later the patient developed pain and other symptoms. A bowel injury was found. The patient showed signs of sepsis and was taken to the operating room where an exploratory laparotomy was performed.... The patient expired two days later. The doctor believed gynecare intergel was responsible."

It wasn't until early January 2003 that the FDA issued a warning letter to Lifecore; this was followed by the company's voluntary recall of Intergel on March 27, 2003.

A "Dangerous Precedent"?"

We may never know exactly what information or pressures impacted the FDA's decision to switch gears and approve Intergel in 2001. But some speculate that conflicts of interest can arise at the FDA due to the way that the organization is funded. For many years, the FDA was funded by taxpayers, but today, it is partially funded by the very medical/pharmaceutical companies that it is supposed to monitor.

As Dr. John Abramson of Harvard Medical School states: "More than half of the budget of the division of the FDA that approves new drugs and oversees drug safety is being funded by the drug companies."

According to a statement by Public Citizen, a consumer advocacy group, this situation has "created an untenable conflict of interest in which the FDA is literally in hock to the industry it is supposed to be regulating. The result has been a decline in safety standards at the FDA."

Dr. Sidney Wolfe, an advisor for Public Citizen called the Intergel approval: "a very dangerous precedent."

Need for Reform"

Dr. Wolfe is not alone in his analysis of the Intergel precedent. In fact, a group of leading health experts and lawmakers have voiced their concerns about the need for FDA reform in the recent documentary [Money Talks: Profits Before Patient Safety.]

But perhaps Representative Henry A. Waxman (D-CAL) said it best. Rep. Waxman, who newly-appointed Chair of the Committee on Oversight and Government Reform, said: "Under the Bush Administration, FDA has undermined enforcement and betrayed its consumer-first legacy."

"FDA must start enforcing the law and return to a culture that places public health concerns ahead of industry profits."