

## GOT HORMONES – THE CONTROVERSIAL MILK DRUG THAT REFUSES TO DIE

By Jeffrey Smith  
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"Effective December 1, 2004, as a current customer, you will have access to an increased supply of POSILAC." [1] This news from Monsanto to its customers was disappointing for those around the world who understood its consequences. Back in January, the company announced that they would reduce their supply of the drug by 50%, after FDA inspectors discovered unacceptable levels of contamination. Many people hoped that Posilac would quietly disappear altogether. "If Monsanto gives this stuff up, it would be a godsend to both cows and people," [2] said Rick North who heads up the campaign by Oregon Physicians for Social Responsibility to fight the drug. But on October 8, 2004, Monsanto announced it would be increasing its supply back up to "at least 70%."

Posilac is a genetically engineered drug that increases milk production in cows by 10–15%. It is also known as recombinant bovine growth hormone, rbGH, Bovine Somatotropin, BST, and "Crack for Cows." Its controversial history has left fifteen years of frustrated whistleblowers strewn in its wake.

Early casualties were scientists at the Food and Drug Administration (FDA) during the drug's evaluation. Chemist Joseph Settepani, in charge of quality control for the approval process of veterinary drugs at the Center for Veterinary Medicine (CVM), testified at a public hearing about threats to human safety. Soon after, he was reprimanded, threatened, stripped of responsibilities, and relocated to a trailer at an experimental farm. In later testimony before a congressional subcommittee, Settepani said, "Dissent [at CVM] is not tolerated if it could seriously threaten industry profits." [3]

Division director Alexander Apostolou wrote in an affidavit, "Sound scientific procedures for evaluating human food safety of veterinary drugs have been disregarded. I have faced continuous pressure from my CVM superiors to reach scientific conclusions favorable to the drug industry. . . In my time at CVM I have witnessed drug manufacturer sponsors improperly influence the agency's scientific analysis, decision-making, and fundamental mission. " [4] Apostolou was forced out after he began to express his concerns.

FDA Veterinarian Richard Burroughs said that agency officials "suppressed and manipulated data to cover up their own ignorance and incompetence." [5] He also described how industry researchers would often drop sick cows from studies, to make the drug appear safer. Burroughs had ordered more tests than the industry wanted and was told by superiors he was slowing down the approval. He was fired and his tests canceled.

The remaining whistle-blowers in the FDA had to write an anonymous letter to Congress, complaining of fraud and conflict of interest in the agency. They described one FDA scientist who arbitrarily increased the allowable levels of antibiotics in milk 100-fold. This was necessary before approving rbGH. Since the

drug increases the chance of udder infections, farmers inject cows with more antibiotics. This leads to a higher risk of antibiotic resistant diseases in cows and humans. According to the letter, Margaret Miller authorized the increased levels. She had formerly conducted research on rbGH while with Monsanto and then moved into the FDA department that evaluated her own research.

Dr. Samuel Epstein, Professor at the University Of Illinois School Of Public Health, cited numerous potential or theoretical health dangers from rbGH, including "hormonal and allergic effects. . . premature growth and breast stimulation in infants," and possibly cancer in adults.[6] Epstein also received an anonymous box of stolen files from the FDA. Documents revealed that in order to show that rbGH injections did not interfere with fertility, industry researchers allegedly added cows to the study that were pregnant prior to injection. Also, blood hormone levels skyrocketed by as much as a thousand-fold after injections.[7]

Monsanto tried to silence Epstein. Their public relations firm created a group called the Dairy Coalition, which included university researchers whose work was funded by Monsanto, and selected "third party" experts and organizations. Representatives of the Dairy Coalition pressured editors of the USA Today, Boston Globe, New York Times and others, to limit coverage of Epstein.

### Hormones in Your Milk

Several claims made by FDA scientists in defense of rbGH have not held up under scrutiny. For example, they said that bovine growth hormone does not increase substantially in milk from treated cows. The study they cited, however, shows a 26% increase in the hormone. Furthermore, researchers injected cows with only a 10.6 mg daily dose of rbGH compared to the normal 500 mg bi-weekly dose used by farmers. In fact, they didn't even use Monsanto's rbGH, but rather another version that was never approved. They then pasteurized the milk 120 times longer than normal in an apparent attempt to show that the hormone was destroyed during the process. They only destroyed 19% of the hormone. They then spiked the milk with powdered hormone—146 times the naturally occurring levels—heated that 120 times longer than normal, and were then able to destroy 90% of the hormone. [8]FDA scientists reported that 90% of the hormone was destroyed during pasteurization.[9]

The hormone most critics are concerned about, however, is insulin-like growth factor 1 (IGF-1). Natural milk contains IGF-1. Milk drinkers increase their levels of IGF 1.[10] Studies suggest that pre-menopausal women below 50 year old with high levels of IGF-1 are seven times more likely to develop breast cancer.[11] Men are four times more likely to develop prostate cancer.[12] IGF-1 is also implicated in lung and colon cancer. Milk from cows treated with rbGH has significantly higher levels of IGF-1.[13] (No comprehensive study has evaluated a direct link between rbGH and human cancer.)

This potential link between rbGH and cancer was one of the many controversial topics to be covered in a four-part investigative news series at a Tampa-based Fox TV station. But four days before the series was to air, Fox received a threatening letter from Monsanto's attorney. They pulled the show. The station man-

ager reviewed it, approved the content, and scheduled it for the following week. A second letter arrived from Monsanto's attorney, this time threatening "dire consequences for Fox News." [14]

The show was postponed indefinitely. Jane Akre and Steve Wilson, the award winning investigative reporters who had created the report for Fox, say that they were offered hush money to leave the station and never speak about the story again. They declined. So Fox's corporate attorney led them in a series of re-writes, attempting to soften the language and apparently appease Monsanto. Six months and 83 rewrites later, the reporters were ultimately fired for refusing to write in the script that the milk from treated cows was the same as normal milk. The reporters argued that that Monsanto's own research showed a difference, such as the increased IGF-1 levels, and even the FDA scientists had acknowledged this.

The reporters sued. Akre was awarded \$425,000 by a jury that agreed that Fox "acted intentionally and deliberately to falsify or distort the plaintiffs' news reporting on BGH," [15] and that Akre's threat to blow the whistle was the reason she was fired. But an appeals court overturned the verdict on the grounds that the whistle-blower's statute only protects people who threaten to report a violation of a law, rule, or regulation. Distorting TV news, evidently, is not technically illegal. Akre and Wilson now have to pay a combined \$196,500 to cover some of Fox's legal costs. This is on top of the \$200,000 - \$300,000 they already spent on their case.

Attacks on rbGH whistleblowers are not limited to the US. In 1998, six Canadian government scientists testified before the Senate that they were being pressured by superiors to approve rbGH, even though they believed it was unsafe for the public. Their detailed critique of the FDA's evaluation of the drug showed how the US approval process was flawed and superficial. They also testified that documents were stolen from a locked file cabinet in a government office, and that Monsanto offered them a bribe of \$1-2 million to approve the drug without further tests. (A Monsanto representative went on national Canadian television claiming that the scientists had obviously misunderstood an offer for research money.) The Canadian scientists later described how their superiors retaliated against them for testifying. They were passed over for promotions, given impossible tasks or no assignments at all, one was suspended without pay. Three of the whistleblowers, who also spoke out on such controversial topics as mad cow disease, were ultimately fired on July 14, 2004.

Most industrialized nations have banned rbGH. Within the US, many school systems have also banned it and several dairies refuse to use it. Oakhurst Dairy of Portland, Maine, for example, requires its suppliers to sign a notarized affidavit every six months. The Oakhurst label stated, "Our Farmers' Pledge: No Artificial Growth Hormones." But on July 3, 2003, Monsanto sued the dairy over their labels. Oakhurst eventually settled with Monsanto, agreeing to include a sentence on their cartons saying that according to the FDA no significant difference has been shown between milk derived from rbGH-treated and non-rbGH-treated cows. The statement is not true. FDA scientists had acknowledged the increase of IGF-1 in milk from treated cows. Nonetheless, the misleading sentence had

been written years earlier by the FDA's deputy commissioner of policy, Michael Taylor. Prior to becoming an FDA official, Taylor was Monsanto's outside attorney. He later worked at the USDA on biotech issues, and later became vice president of Monsanto.

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#### Footnotes

- 1 POSILAC® SUPPLY UPDATE October 8, 2004
- 2 Emailed correspondence
- 3 Craig Canine, "Hear No Evil: In its determination to become a model corporate citizen, is the FDA ignoring potential dangers in the nation's food supply?" *Eating Well*, July/August 1991
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- 5 Craig Canine, "Hear No Evil: In its determination to become a model corporate citizen, is the FDA ignoring potential dangers in the nation's food supply?" *Eating Well*, July/August 1991
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- 13 C. G. Prosser and others, "Increased secretion of insulin-like growth factor-1 into milk of cows treated with recombinantly derived bovine growth hormone," *Journal of Dairy Science*, vol. 56, 1989, pp. 17-26; and Peter Montague "Milk, rbGH, and Cancer," *Rachel's Environment and Health News*, no. 593, April 9, 1998
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Jeffrey M. Smith has been involved with genetically modified (GM) foods for nearly a decade. He worked for non-profit and political groups on the issue and in 1998, ran for U.S. Congress to raise public awareness of the health and environmental impacts. To protect children—who are most at risk from the potential

health effects of GM foods—Smith proposed legislation to remove the foods from school meals. He also proposed legislation to help protect farmers from cross-pollination by GM crops. Later, he was vice president of marketing for a GMO detection laboratory.

Smith has lectured widely, spoken at conferences, and has been quoted in articles around the world. Prior to working in this field, he was a writer, educator, and public speaker for non-profit groups, advancing the causes of health, environment, and personal development. This book *Seeds of Deception*, researched and written after he left the industry, combines Smith's passion for these causes with his extensive knowledge of the risks and cover-ups behind genetically modified foods.

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