

Background

In the early 1980s, four chemical/pharmaceutical companies, with the help of university scientists, began researching a new technology they believed would revolutionize the dairy industry. Through genetic engineering, researchers created recombinant bovine growth hormone (rBGH) to increase milk production in dairy cows by 10 to 25 percent.

The four companies promoting the research are Monsanto, Upjohn, Eli Lilly and American Cyanamid. Only the Upjohn version of the drug is identical to the naturally occurring hormone, bovine somatotropin (BST), responsible for lactation in dairy cows. The other three drugs differ in their chemical composition.

These companies have collectively invested over \$1 billion in the research and development of rBGH. Monsanto is the only company to receive approval from the Food and Drug Administration (FDA) to sell its rBGH product, Posilac, commercially. The other three companies' products remain in the FDA pipeline awaiting approval.

The FDA Approval Process

The FDA approved Monsanto's rBGH product, Posilac, for commercial use on November 5, 1993. A 90-day moratorium on the sale of rBGH ended on February 3, 1994. Posilac went on sale the following day.

In reviewing the safety and efficacy of rBGH, the FDA decided in 1985 that the drug posed no threat to human health. Studies indicate the use of rBGH increases the presence of the protein hormone Insulin-like Growth Factor-one (IGF-1) in milk. The FDA maintains that toxicity studies show IGF-1 is inactive when ingested by rats and is rendered obsolete under conditions used to process milk into infant formula.

Scientists such as Dr. Samuel Epstein of the University of Chicago's School of Public Health claim IGF-1 "induces the malignant transformation of normal human breast epithelial cells." And in recent testimony before the Minnesota Senate Agriculture Committee, Dr. Michael Hansen of the Consumer Policy Institute stated: "IGF-1 has been associated with the growth of numerous tumors, including colon, smooth muscle and breast."

Despite no long-term studies on the human health implications, the FDA concluded that "the use of recombinant bovine growth hormone in dairy cattle presents no increased health risk to consumers."

The FDA's Center for Veterinary Medicine (CVM) concluded rBGH was safe for animals in 1993. At issue was whether the use of rBGH increased the incidence of mastitis, or udder infections, in cows treated with the drug. At hearings last spring, former CVM Director Gerald

Guest testified that rBGH does not cause or increase the severity of mastitis in treated cows. A spokesperson for Monsanto told the panel that the incidence of mastitis rises with increased milk production regardless of whether rBGH has been used.

Another researcher, Dr. Dale Bauman, who led a Monsanto-funded rBGH trial at Cornell University, claimed that the increase in mastitis in his study was not due to the use of rBGH, but to a higher presence of mastitis in the herd prior to treatment. The Cornell study concludes "animals were in good health throughout the study" and "no incidences of catastrophic health effects ... were observed." Bauman also stated in a 1987 letter on Cornell University stationery that he is a consultant for Monsanto and American Cyanamid.

A University of Vermont study, also funded by Monsanto, showed a four-fold increase in the number of cows

that had to undergo antibiotic treatment for mastitis. Researchers involved in this study claimed that such a figure is inaccurate as the herd size in this particular study was very small — only 40 cows.

The FDA concluded in its own November 1993 Freedom of Information Summary that the increased risk of clinical mastitis to cows is 79% overall and 97% for first calf, or primiparous, heifers. Reviewing the data from the above-referenced Cornell University trial, Dr. Michael Hansen concluded the incidence of mastitis was 3.5 times higher among the treated herd than the control herd. Testifying at the CVM hearings, Hansen said, "We do not see how FDA can say a drug that causes disease is safe."

Yet the FDA accepted with little question industry-funded studies such as those performed by the University of Vermont and Cornell University upon which the agency based its final approval of Monsanto's Posilac product.

The congressional watchdog General Accounting Office (GAO) also expressed concern about the mastitis issue for another reason. The GAO was concerned that the increased incidence of mastitis would lead to the use of antibiotics, which could end up as residues in the nation's milk supply. Unnecessary exposure to antibiotics can lead to a resistance to their intended effects by the bacterial or viral diseases they are supposed to fight off.

In approving rBGH, the FDA concluded that increased mastitis as the result of rBGH use did not pose a significant antibiotic residue risk to consumers. The FDA maintains that current tests detect antibiotic residues before they reach the consumer in fluid milk and dairy products. However, the FDA failed to acknowledge the conclusion of a 1992 GAO report entitled "FDA Strategy Needed to Address Animal Drug Residues in Milk." The GAO report concluded, "States are

rBGH, Monsanto and Corporate Agriculture

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generally testing milk for only the same four animal drugs as they were in 1980, while up to 82 drugs that may leave residues in milk are known to be or are suspected of being used on dairy cows."

Despite over 100 studies on rBGH, too many contradictions exist to confidently believe these issues have been adequately addressed by the FDA.

Consumers Hate It, Farmers Don't Want It and the Cows Get Sick Thinking About It

This became the phrase that characterized the reaction of farmers, consumers and public interest groups around the nation on February 4, 1994.

In reaction to approval of rBGH, coalitions of diverse interests began forming around the nation in an attempt to get rBGH off the market. The main reasons for rejecting the drug include:

- **The FDA has not adequately studied the impacts of this product on human health.**

The FDA's conclusion that rBGH will have no adverse effects on humans was based on tests on human dwarves in the 1950s and a Monsanto test on rats in the 1980s.

- **Monsanto admits in its own packaging that rBGH can increase mastitis, thereby creating the potential for increased use of antibiotics, which could end up in the milk supply.**

Other problems highlighted in the Posilac packaging include: "reduced pregnancy rates;" "an increased risk for clinical mastitis;" "increased frequency of medication;" "increased body temperature unrelated to illness;" "increase in digestive disorders;" "increased numbers of enlarged hocks and lesions," and the possibility of injection site reactions "that remain permanent but are not associated with animal health problems."

- **A Minnesota farmer who participated in an American Cyanamid trial over two lactation periods said his herd experienced breeding problems; multiple births; deficient body condition; 100% failure to conceive after the second lactation; a 19% death rate; and a 15% "down cow" rate.**

Cyanamid refused to pick up the data from this trial and Dr. Brian Crooker, a University of Minnesota researcher, attributed "the farmer's results" to poor management. The farmer is a graduate of Penn State's College of Agriculture and a multiple winner of Holstein Breeder Association awards. To this day, the farmer remains under a Cyanamid "gag order."

- **Dairy farmers are already suffering from an overloaded milk market and depressed dairy prices.**

With the approval of rBGH, production is up 8% in California; 8% in Texas; 10% in Idaho; 29% in New Mexico; and 20% in Arizona. In addition, the National Cheese Exchange fell 20% in recent weeks. A monthly survey of the Cheese Exchange prices sets the so-called Minnesota-Wisconsin (M-W) price for fluid milk, which is used as a benchmark price for other regions of the country. Thus, the price paid to farmers for their milk is also down 20%.

If prices continue to drop, more already-vulnerable family dairy farmers will be forced out of business. The Dairy Debate estimates that 40,000 dairies, or 30% of the nation's dairy industry, will be forced out of business if widespread adoption of rBGH occurs. Some estimates are that for every seven farms that fail, one rural business fails as well. The advent of rBGH represents "the probable acceleration of restructuring and concentration of production within the dairy industry."

Corporate Agriculture: The Monsanto Case

Prior to the approval of rBGH, the St. Louis-based Monsanto company earned the bulk of its income from two products — NutraSweet and Roundup.

NutraSweet is an artificial sweetener used in a number of products ranging from carbonated sodas to chewing gum. The European patent on NutraSweet recently expired, leaving part of Monsanto's revenue stream vulnerable.

Roundup, one of the most popular herbicides on the market today, is packaged in a variety of forms to suit anyone from the farmer who works with hundreds of acres to the backyard gardening enthusiast. The patent on this product is set to expire before the turn of the century.

As a result of expiring patents, **Monsanto is looking to other products of biotechnology to provide its future revenue sources.** Products like Posilac are Monsanto's saviors. Its multi-million dollar investment in the development of rBGH is going to have to pay off if the company is to survive. **The company is using threats of legal action to keep rBGH from being a commercial failure.** Monsanto is suing Swiss Valley Farms of Davenport, IA and the Pure Milk and Ice Cream Company of Waco, TX for what it calls "false and misleading" labeling practices in an effort to stop companies from "defaming" its rBGH product.

Farmers and Consumers Respond

Meanwhile, farmers are struggling to reclaim agricultural production before it is entirely co-opted by the interests of companies like Monsanto. One strategy used by the National Farmers Union is a **boycott of Monsanto products.** NFU is asking farmers not to purchase Monsanto products for this year's growing season. In addition, they are asking consumers to avoid using Roundup in their gardens and to end their use of products containing NutraSweet.

In addition to the boycott, farmers are also uniting with consumers around the issue of rBGH and food safety. **Minnesota Safe Food Link** is one such organization which seeks to educate consumers and farmers about the mutual concerns of food safety and fair family farm policies.

Minnesota Safe Food Link is pursuing a variety of other avenues to educate the public about rBGH. Among the group's activities are:

- The passage of school board resolutions and city labeling ordinances;
- Organized pressure on processors and grocers to provide and label rBGH-free milk; and
- State legislative initiatives for voluntary labeling of milk derived from cows not treated with rBGH.

This unification of farmers and consumers around the mutual interests of food safety and fair farm policies is integral to stopping corporate agriculture from controlling our food production system from the field to the table.

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