In late 1993, the U.S. Food and Drug Administration (FDA) gave permission for Monsanto corporation to market rBGH, a genetically-engineered hormone that is injected into dairy cows to make them produce more milk.[1] In 1990, FDA had declared rBGH (recombinant bovine growth hormone), "safe for human consumption."[2]

Now the scientific validity of FDA's 1993 safety decision is being challenged by Canadian government scientists. Consumer's Union (publisher of CONSUMER REPORTS magazine) and other U.S. consumer groups have called for a Congressional investigation into FDA's 1993 decision to approve rBGH.[3]

Today tens of thousands of U.S. dairy cows are injected with rBGH each week, and virtually the entire U.S. citizenry is exposed to milk from rBGH-treated cows through milk, cream, cheese, yogurt, frozen yogurt, buttermilk, cream cheese, ice cream, iced milk, and baked goods. No other country besides the U.S. has approved rBGH for use within its borders, though Monsanto has sought approval in Australia, New Zealand, the European Union and Canada.

In 1990, in SCIENCE magazine, FDA published a justification for its conclusion that milk from rBGH-treated cows was "safe for human consumption."[2] Such a public justification of a pending FDA decision is highly unusual, perhaps indicating the politically charged nature of FDA's decision to allow Monsanto to treat many of the nation's milk cows with a genetically-engineered hormone.

FDA's 1990 SCIENCE article offered seven tables of data to support its conclusion that rBGH is safe. The first two tables of data were taken from an unpublished Monsanto study of rats fed rBGH in high doses for 90 days.[4] In SCIENCE, FDA said the 90-day rat feeding study showed that rBGH "is not orally active in rats"[2,pg.875] and concluded that, "No oral activity was found when rBGH was administered to rats at exaggerated doses."[2,pg.883]

However, a recently-released Canadian government report indicates that the findings of Monsanto's 90-day rat feeding study were misreported by FDA in SCIENCE in 1990.[5] The Canadian report says that 20% to 30% of the rats fed rBGH in high doses developed primary antibody responses to rBGH, indicating that rBGH was absorbed into their blood. An antibody response is evidence that the immune system has detected, and responded to, a substance entering the body. Furthermore, cysts reportedly developed on the thyroids of the male rats and some increased infiltration of the prostate gland occurred. Despite these results, FDA reported in SCIENCE that there were "no...clinical findings" in the Monsanto rat study.[2,pg.878] The Canadian government report concludes flately that "the 3-month rat study did show a physiological response."[5,pg.29]

One FDA official told the Associated Press this month that FDA never examined the raw data from Monsanto's rat feeding study but based its 1993 safety conclusion only on a summary of the study provided by Monsanto. John Scheid, of FDA's Center for Veterinary Medicine, told AP reporter Frederick Bever, "We do not have the data from that study."[6] Scheid said FDA had relied on a summary of the study provided by Monsanto. For the past two years, FDA officials have refused to return phone calls from Reuters seeking comment. Drawing conclusions from a summary of a scientific study would be equivalent to describing the contents of a book by reading an author's summary of the book, instead of reading the book itself.

Furthermore, relying on a summary of a study, rather than on detailed data from the study, would violate FDA's published procedures. In its 1990 SCIENCE article, FDA said that "FDA requires the pharmaceutical companies to submit all studies they conducted on their products" and said, "The companies also submit the raw data from all safety studies that will form the basis of the approval of the product..."[2,pg.876] Furthermore, FDA explained that, "If the initial toxicity study demonstrates that the protein [such as rBGH] is indeed orally active, additional testing may be required."[2,pg.876] Thus if FDA had known in 1990 that Monsanto's rat feeding study had indicated that rBGH was orally active in rats, additional testing could have been required before a decision was made to approve or disapprove the genetically-engineered drug.

Monsanto's application to market rBGH in Canada has reportedly created political pressures on government scientists there to sidestep normal safety protocols.

** Canadian government scientists say that the Canadian government has failed to require follow-up studies that seem to be called for by the findings of the Monsanto rat-feeding study. In their report released earlier this month, they say, "The usually required long-term toxicology studies to ascertain human safety were not conducted. Hence, such possibilities and potential as sterility, infertility, birth defects, cancer, and immunological derangements were not addressed."[6]

** The scientists who wrote the report testified before an inquiry board earlier this month that they have been pressured by higher-ups to alter the content of their report, which has now been published on the Internet at www.nfu.ca/infu/Gapsreport.html.

The purpose of the Canadian report was to identify data gaps, and procedural gaps, in the handling of Monsanto's application to market rBGH in Canada.

** Two of the report's authors, and four other Canadian government scientists, testified that they have been threatened with transfers to other jobs where "they would never be heard of again" if they did not speed up approval of Monsanto's rBGH product in Canada, despite the absence of long-term data showing the product is safe for humans. Monsanto's application to market rBGH in Canada has been pending since 1990. According to the TORONTO STAR, "The scientists contend managers in Health Canada [the Canadian equivalent of FDA] are more concerned about pleasing the companies that submit the drug applications and are paying for their approval than they are about protecting health."[7] The Canadian scientists have been forbidden to speak to the press about their concerns, but they testified last month before a government board of inquiry.

** The same rat-feeding study that has raised such controversy in the U.S. has also proven controversial in Canada. A Canadian legislator, Mira Spivak, whose committee is investigating the approval process for rBGH in Canada, says Canadian health officials provided her staff with a copy of the Monsanto study in which the information about the potentially troubling effects of rBGH on rats was "blocked out."[8]

** The Canadian government report, which is critical of the rBGH review process in both Canada and the U.S., will be sent on to a panel of experts (six members from the Royal College of Physicians and Surgeons and six from the Canadian Veterinary Medical Association) for a "completely objective and arm's length review." However, the TORONTO STAR has reported that one of the physicians reviewing the report, Rejeanne Gougeon, served as a consultant to Monsanto from 1993 until May, 1998. In 1994 Gougeon published a paper recommending that the Canadian government approve rBGH. The paper was supported with a grant from a lobbying group that Monsanto helps finance, the STAR said. Gougeon told the STAR that she had never promoted rBGH, but that in the past Monsanto had paid her to give talks to consumers about genetic engineering "in a friendly context."[9]

** The Canadian government report (pg. 26) says that levels of IGF-I (insulin-like growth factor-1) are elevated in the milk produced by rBGH-treated cows. IGF-I is identical in cows and in humans and, as the name implies, it promotes growth. The
Canadian report notes that U.S. FDA acknowledges that IGF-I is increased in milk from rBGH-treated cows. The Canadian report concludes, "There is insufficient information [about IGF-I] to provide a quantitative risk assessment; therefore, many potential health concerns remain unresolved."

** The Canadian government report offered additional data which, if corroborated, could have prevented U.S. FDA from approving rBGH for injection into cows. FDA says that, before a drug can be approved for use in animals, "the company must show that the drug is effective and safe for the animal." [2, pg. 875] The Canadian government report (pg. 29) says, "Evidence from the animal safety reviews were [sic] not taken into consideration. These studies indicated numerous adverse effects in cows, including birth defects, reproductive disorders, higher incidence of mastitis (infection leading to inflammation of the udder), which may have had an impact on human health." Furthermore, the Canadian government report says (pg. 14), "There are reports on file that Monsanto pursued aggressive marketing tactics, compensated farmers whose veterinary bills escalated due to increased side effects associated with the use of rBST [rBGH], and covered up negative trial results. All the four U.S. manufacturers [Monsanto, Eli Lilly, Cyanamid and Elanco, with only Monsanto actually marketing a product] refused to disclose the lists of their research grants to U.S. universities." Without such lists, one could not inquire what effects (if any) had been revealed by animal experiments.

The Canadian government report concludes (pg. 5) that, in Canada, "Both procedural and data gaps were found which fail to properly address the human safety requirements of this drug under the Food and Drugs Act and Regulations." It is evident from the Canadian report that the U.S. approval process for this drug was equally flawed. None of the questions raised by the Canadian government scientists have been addressed by U.S. FDA.

--Peter Montague (National Writers Union, UAW Local 1981/AFL-CIO)

[1] See REHW #381, #382, #383, #384, #454, #483, #593, #598.


[4] The complete Monsanto rat feeding study has never been officially released, published, or, so far as we know, subjected to peer review. FDA has vigorously resisted all efforts by citizens, under the federal Freedom of Information Act, to obtain a copy of this study: including the raw data. For the story of one citizen's attempts to obtain a copy of the study, see Robert Cohen, MILK THE DEADLY POISON (Englewood Cliffs, N.J.: Argus Publishing, 1997), pgs. 77-96. ISBN 0-9659196-0-9. FDA has successfully argued in federal court that release of the Monsanto study "would cause substantial competitive and financial harm to the company." If John Scheid of FDA is right, FDA could not release the study because, Scheid says, FDA has never possessed a complete copy of the study.

[5] Shiv Chopra and others, RBST (NUTRILAC) "GAPS ANALYSIS" REPORT BY RBST INTERNAL REVIEW TEAM, HEALTH PROTECTION BRANCH, HEALTH CANADA (Ottawa: Health Canada, April 21, 1998). Health Canada is the Canadian equivalent of the U.S. Food and Drug Administration. This report was recently made available on the world wide web at: www.nfu.ca/gapsreport.html. [The Canadian government report is available from us for $5.00; write to Rachel's, P.O. Box 5036, Annapolis, MD 21403.] To avoid using the word "hormone" to describe rBGH, Monsanto renamed the drug recombinant bovine somatotropin, or rBST. In the U.S., Monsanto sells rBGH (or rBST) under the trade name Posilac; in Canada, they are seeking approval to sell it under the trade name Nutrilac.


Desciptor terms: milk; food safety; rbgh; rbst; monsanto; canada; genetic engineering; consumer's union; michael hansen; cattle; cows; agriculture; dairy farming; fda; whistle blowers;