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February 7, 1999

The FDA
5600 Fishers Lane
Rockville, MD 20857

Dear Sirs:

We are writing regarding Monsanto's application to the FDA to allow the use of rBGH.

The FDA's handling of this application demands investigating. There should be a recall of rBGH treatments until the FDA conducts a new and THOROUGH review of the drug. It is ludicrous to suggest that citizens of the US should continue to consume foods which contain rBGH UNTIL the drug is proven dangerous. Surely the prudent and logical thing to do is to STOP consuming any foods containing this drug until it is proven either safe or unsafe.

It is significant that no other country except the US has approved rBGH. Does this company have such a stranglehold on our government that it is willing to jeopardize the health of Americans??!

Sincerely,

Susan & Hubert van Asch van Wyck
Susan and Hubert van Asch van Wyck
35 West Morris Road
Washington, CT 06794

Enclosure

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The Monsanto Roundup Did Monsanto Fake Science?

CANADA — In 1993, the US Food and Drug Administration had to decide whether to permit farmers to inject Monsanto's recombinant bovine growth hormone (rBGH) into dairy cows to artificially increase milk production. In 1990, the FDA had ruled that rBGH was "safe for human consumption."

Today, nearly everyone in US is affected by the FDA's decision — most of us are consuming rBGH-treated milk, cheese, yogurt, buttermilk, ice cream and baked goods.

As Peter Montague writes in *Rachel's Environment and Health Weekly* [PO Box 5036, Annapolis, MD 21403, fax (410) 263-8944]: "No other country besides the US has approved rBGH for use within its borders, though Monsanto has sought approval in Australia, New Zealand, the European Union and Canada."

In its attempt to force its way into Canada's markets, Monsanto set off a chain of events that has called into question the validity of the company's science and the credibility of the FDA.

The fuse was lit when Canadian government scientists were called in to review the science behind Monsanto's rBGH research. They found that up to 30 percent of lab rats fed rBGH for 90 days absorbed the genetically engineered material into their blood, where it caused an antibody reaction. The researchers also found cysts on the thyroid glands of male rats given rBGH.

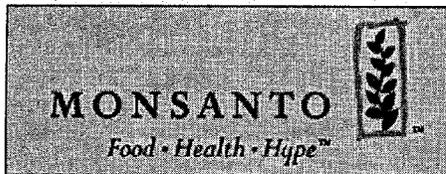
The Canadian researchers also noted elevated levels of IGF-I (an insulin-like growth factor) in the milk of rBGH-injected cows. Because IGF-I is shared by both cows and humans, the researchers cautioned that "many potential health concerns remain unresolved."

The Canadian government scientists concluded that "both procedural and data gaps were found which fail to properly address the human safety requirements of this drug under the [Canadian] Food and Drugs Act and Regulations."

The US FDA's rules require that a drug must be shown to be safe for use in animals, but the Canadian researchers found numerous studies indicating that rBGH had caused "adverse effects in cows, including birth defects, reproductive disorders, higher incidence of mastitis, which may have had an impact on human health."

How, the Canadians wondered, could the US FDA have concluded that there were "no... clinical findings" in Monsanto's original study with rats and rBGH?

The startling answer came from John



Scheid at the FDA's Center for Veterinary Medicine. The FDA never examined the raw data, Scheid told the Associated Press. "We do not have the data from that study." The FDA, Scheid stated, had relied entirely on a summary of the study provided by Monsanto.

In its 1990 ruling, the FDA stated that it "requires the pharmaceutical companies to submit all studies they conducted [and]... all the raw data from all safety studies that will form the basis of the approval of the product...." For some reason, the FDA failed to follow its own stated policy.

In its 1990 finding, the FDA declared that "if the initial toxicity study demonstrates that

The FDA took Monsanto's word that rBGH was safe for US dairies. Canadian scientists think otherwise.

[rBGH]... is indeed orally active, additional testing may be required." If the FDA had actually reviewed Monsanto's raw data they would have seen that the product was in fact, orally active.

The Canadian researchers insist that their findings require that "long-term toxicology

Cops for Crops: Monsanto Rules

US— Since the dawn of agriculture, individual farmers have selected, saved and shared seeds. No more. The Brave New World of genetic engineering is showing its totalitarian roots. In 1998, Monsanto boasted that it had "hired full-time investigators to follow up on all seed piracy leads it receives."

By September 1998, Monsanto had logged more than 475 seed piracy cases nationwide, suing family farmers whose only crime was saving and sharing Monsanto's genetically enhanced Roundup Ready soybeans and Bollgard cotton.

Scores of farmers have been forced to pay up to \$35,000 in "royalty payments." A Monsanto press release boasts that these farmers now will have to provide "full documentation confirming the disposal of [their] unlawful soybean crop" and will have to grant Monsanto's agents "full access to all of their property... for inspections... for the next five years."

studies to ascertain human safety" and address the potential risks of "sterility, infertility, birth defects, cancer and immunological derangements."

Monsanto's application has been pending in Canada since 1990 and the corporation is impatient to proceed. According to Montague, Monsanto's application "has reportedly created political pressures on government scientists there to sidestep normal safety protocols."

The Canadian report also noted that "Monsanto pursued aggressive marketing tactics, compensated farmers whose veterinary bills escalated due to increased side effects associated with the use of [rBGH], and covered up negative trial results. All four US manufacturers [Monsanto, Eli Lilly, Cyanamid and Elanco] refused to disclose the lists of their research grants to US universities." (A list of research grants could have uncovered further animal testing studies.)

Before they were silenced, the scientists told the *Toronto Star* that Health Canada (Canada's equivalent of the FDA) appeared "more concerned about pleasing the companies that submit the drug applications and are paying for their approval than they are about protecting health."

When Canadian lawmakers demanded to see copies of the Monsanto study containing the alarming side-effects of rBGH, Health Canada officials turned it over, but the critical information had all been blocked out.

In the US, Consumer's Union is calling for a congressional investigation into the FDA's 1993 decision to approve rBGH. Meanwhile, in Canada, the scientists who authored the report exposing rBGH's risks have testified that they have been threatened and were told to alter the content of their report. (The scientists have been instructed not to speak to the press, but their uncensored report is posted on the Internet at www.nfu.ca/nfu/Gapreport.html.)

Attempts by *Earth Island Journal* contributor Robert Cohen (*Milk, the Deadly Poison*) to obtain Monsanto's rat studies under the Freedom of Information Act have proven futile. FDA lawyers argue that releasing the study "would cause substantial competitive and financial harm to [Monsanto]." Montague, however, believes that the reason the FDA has resisted handing over the report is because the FDA "never possessed a complete copy of the study." — GS

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