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APR 24 10:25

FDA Dockets Management  
Branch (HFA-305)  
5630 Fishers Lane  
Rockville, MD 20852

APR. 15, 2000

**Re: DOCKET #99P-4613**

Dear Sir or Madam:

A petition has been filed with the Food and Drug Administration in Washington, DC to ban the use of genetically engineered Bovine Growth Hormone on dairy cows. I am writing to urge you to act on **Docket #99P-4613** to prevent the use of unhealthy and inhumane BGH on dairies.

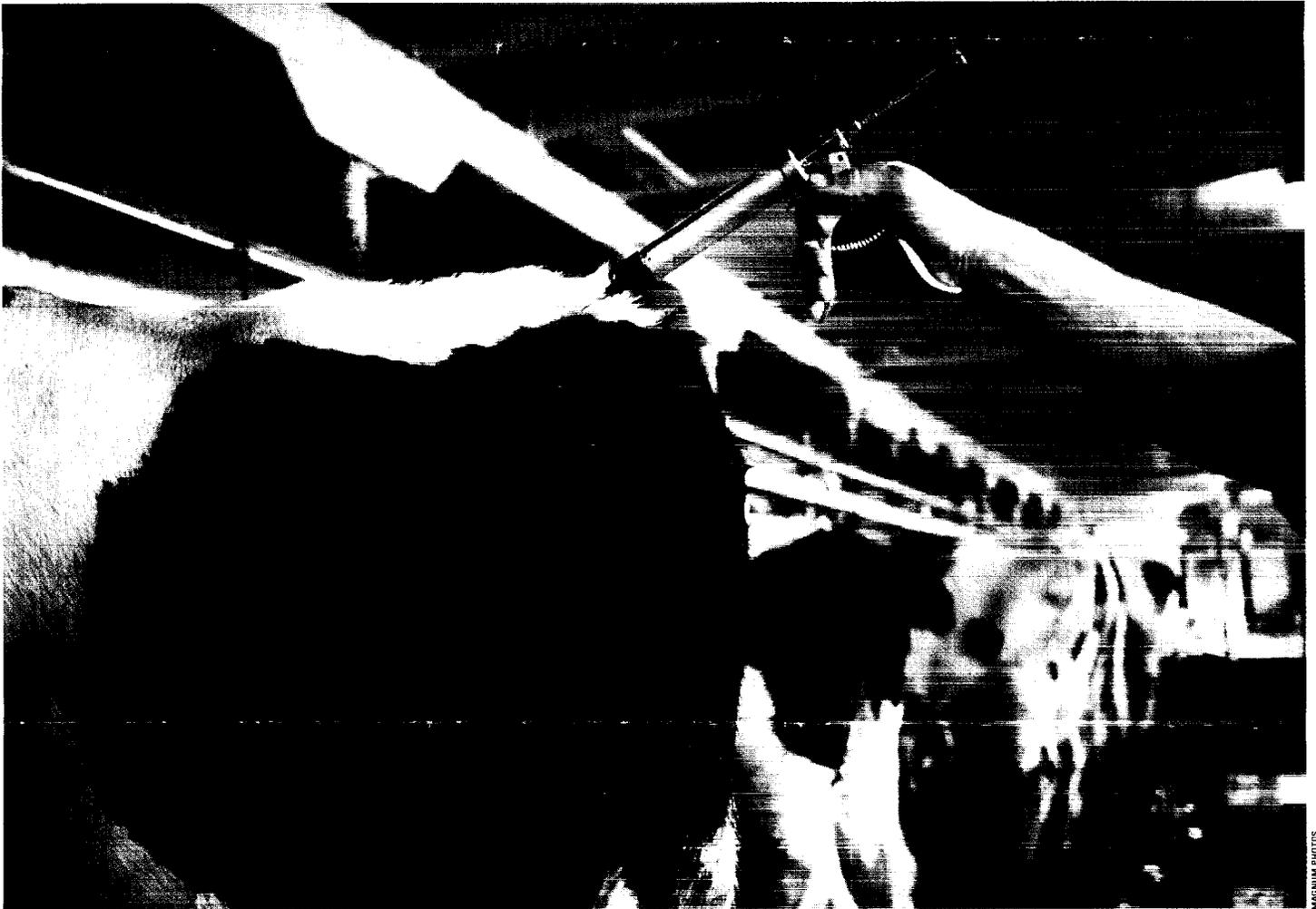
Sincerely,

*AnnMarie L. Miller*

AnnMarie L. Miller

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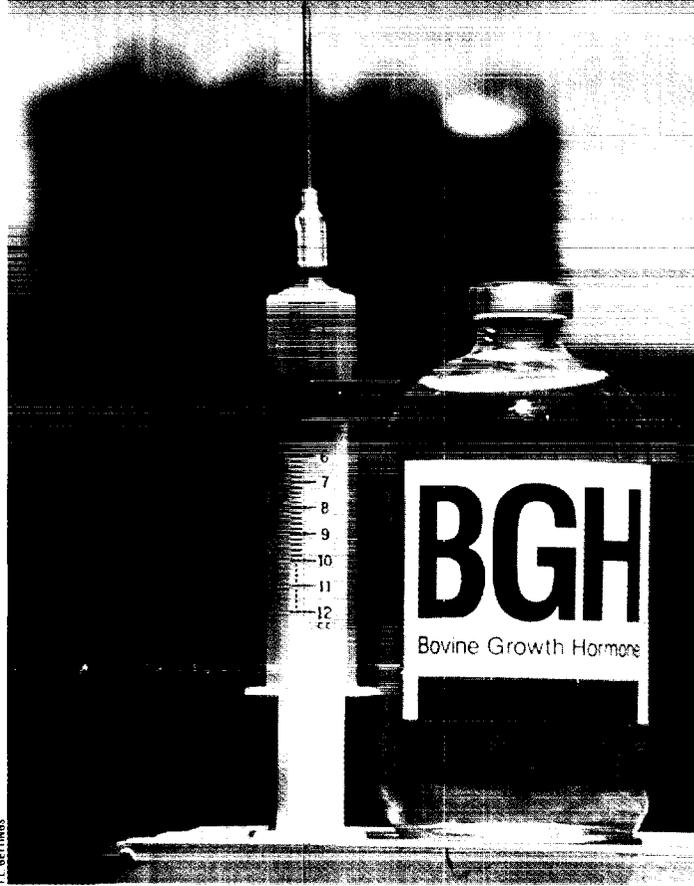
# **B**ovine **G**rowth **H**ormone

## Turning Cows Into Biotech Milk Machines

Milk and dairy products produced in the United States – *unless otherwise labeled* – now come from cows routinely injected with a genetically engineered hormone called recombinant Bovine Growth Hormone (BGH).

This is the story of BGH – its effect on cows, consumers, and farmers, as well as the efforts of agribusiness drug companies to get genetically engineered hormones into our nation's dairy cows.

# What is BGH?



T. GETTINGS

## BGH-Milk – It Does *No Body* Good

**B**GH-milk contains higher levels of a human growth promotant known as Insulin-like Growth Factor One, or IGF-1. This hormone, which is identical in cows and people, is a suspected carcinogen. Dr. Samuel S. Epstein, an internationally-renowned toxicologist, warns that “all women from conception to death will now be exposed to an additional breast cancer risk due to milk from cows treated with recombinant bovine growth hormone.”

Cancer is but one potential risk of consuming BGH-induced milk. Other risks result from the health problems that artificial BGH causes in cows.

The FDA admits that BGH injections increase sickness and drug use in dairy cows. Consumers Union, publisher of *Consumer Reports* magazine, reports that “because of increased udder infections, it is more likely that milk from treated cows will be of lower quality – containing more pus and bacteria – than milk from untreated cows.”

Milk from BGH-injected cows is more likely to contain dangerous residues of the more than 80 different drugs, many of them antibiotics, used to treat sick cows. From infancy to adulthood, people are dosed with antibiotic residues that contaminate baby formula, milk, cheese, and other dairy products.

The FDA and the dairy industry claim that they test raw milk for drug contamination. But this testing is wholly inadequate. They only look for a few of the scores of drugs actually administered to dairy cows.

Furthermore, the FDA allows drug-contaminated milk to be sold as long as the residues are at a ‘safe’ level. These so-called ‘safe’ levels have been shown to cause increases in drug resistant strains of virulent diseases.

This alarms medical experts, such as Dr. Stuart Levy of Tufts University. Dr. Levy warns of the growing human health crisis posed by “antibiotic resistance.” As disease organisms are exposed to the antibiotics used on dairy cows and other farm animals, they become increasingly resistant to drug treatment.

Well over ten thousand people die in the U.S. each year due to antibiotic resistant strains of bacteria. And the number of deaths is rising annually.

# Loss of Family Farms

Although many feel that they may be forced to use it, most dairy farmers are opposed to BGH.

The most persistent economic problem faced by the dairy industry today is *overproduction*. Every year farmers are driven out of business because milk production far outreaches demand. The increase in milk production promised by BGH's promoters would have devastating consequences.

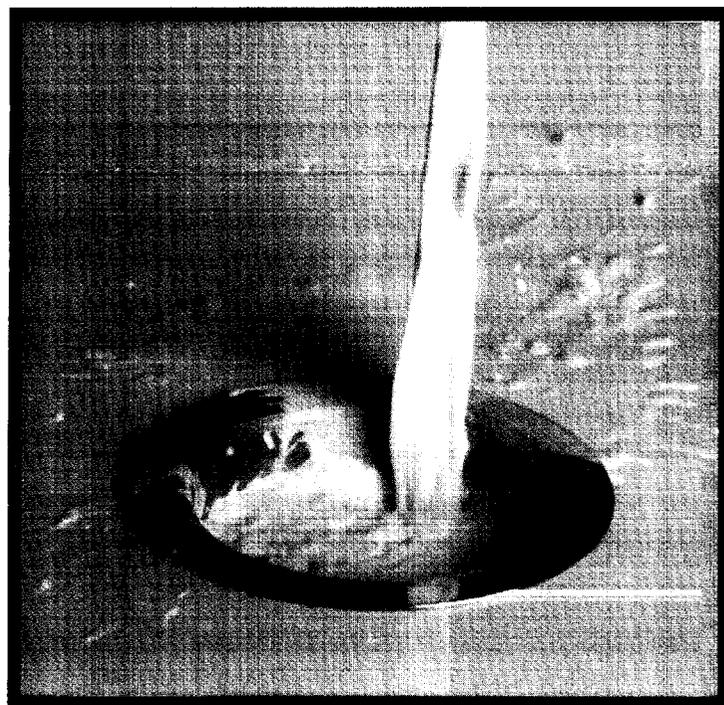
According to studies at the U.S. Office of Technology Assessment and Cornell University, widespread use of BGH would drive as many as 30% of American dairy farmers out of business. Those on the losing end would primarily be small-scale family dairy farms. These are farms which are much more inclined than corporate agribusiness to use humane, sustainable, and environmentally-sound farming practices.

The problem of overproduction is so great that in 1985 the government paid over 14,000 dairy farmers to kill their cows and get out of the dairy business. Under this misguided program, 1.62 million cows were either slaughtered or exported for the purpose of reducing milk surpluses.

Unlike most other commodities, the overproduction of milk does not mean lower prices for consumers. In fact, overproduction results in economic loss for all taxpayers. This is because milk prices are artificially propped up by the government. The government sets a minimum price and then agrees to buy all of the milk products that cannot be sold. This controversial program has cost taxpayers as much as \$2.6 billion a year.

BGH would undoubtedly benefit a few large-scale dairy factories which, with BGH increasing their yields, could gain an advantage over other farms. But that advantage would only be temporary. In order to compete, other dairies would soon be forced to adopt the same technology. In short, BGH would trigger a pharmaceutical arms race, requiring milk producers to use more and more hormones, antibiotics, and other drugs.

Many dairy farmers know that administering BGH will actually harm cows and make their work harder. Once BGH is on the market, however, they will be virtually forced to use it. According to Vermont dairy farmer Robert Baird, "None of us are excited about pushing our cows any harder. But if we're forced to, we will use BGH to stay in business."



**DOWN THE DRAIN**  
The dairy industry **already** produces enormous quantities of excess milk. Overproduction has cost taxpayers over \$18 billion since 1980.

DECLINE  
OF U.S.  
DAIRY  
FARMS

1,100,000  
1,000,000  
900,000  
800,000  
700,000  
600,000  
500,000  
400,000  
300,000  
200,000

1964 '69 '74 '78 '82 '87



SOURCE: CENSUS OF AGRICULTURE

As U.S. milk production has increased, the number of family farms able to survive has dwindled. With large dairy factories now dominating the industry, food safety and animal welfare problems have become widespread.

# Dairy Politics

Despite opposition from many farmers, some dairy industry organizations are promoting BGH and have employed highly questionable means to achieve their goals.

The National Dairy Board, which is closely aligned with corporate agribusiness, has conducted a survey regarding consumer reaction to the introduction of BGH in milk. Not surprisingly, consumers expressed alarm at the idea of genetically engineered hormones ending up in their children's milk.

The Dairy Board has set out to counteract this negative response. In 1990 it paid \$1.1 million to a public relations firm to boost BGH's image – even though most dairy farmers oppose BGH and would be harmed by its use.

In January 1990, an organization representing small-scale farmers sponsored a public forum on BGH. The Dairy Board's P.R. firm hired people to attend the forum and pose as "average citizens" who just happened to be in favor of BGH. They attempted to give the news media and dairy farmers in attendance the false impression that the public actually supported the use of BGH.

# Animal Suffering

Though little has been done to measure BGH's effects upon human health, pharmaceutical companies have sponsored tests to measure the impact of hormone injections on cows. Even these tests – clearly biased in favor of BGH – indicate the dangers of its use.

Routine injection of BGH into a cow increases her level of stress. A cow may not metabolize food quickly enough to compensate for the extra milk the hormone forces her to produce. This can throw her into what can be termed low-level shock. The cow remains in this condition for as long as the hormone is administered.

Cows injected with BGH may not be allowed to graze in pastures. Instead, they

would be confined in small areas where their diet and movement would be tightly controlled. Rather than grazing on grass, BGH-treated cows must consume a highly-concentrated diet to keep up with increased production. This, in turn, can lead to higher rates of metabolic disease.

Industry tests also indicate that BGH may cause enlargement of internal organs, declines in the rate of pregnancy, increased intolerance to heat, and a dramatic increase in the amount of blood pumped through the animal's heart.

Through reproductive technologies, the quantities of milk produced by cows has already increased dramatically. In extreme cases, cows must wear bra-like

harnesses to support their engorged udders.

As a cow is made to produce greater quantities of milk, she is increasingly prone to mastitis – a painful infection of the udder. Tests have shown a dramatic increase in the incidence of mastitis in cows receiving BGH injections.

In 1930 the average cow produced 12 pounds of milk a day. By 1988 the average had risen to 39 pounds. If, as proponents claim, BGH increases production by 20%, that volume could rise to 49 pounds a day per cow. This would lead to a corresponding increase in veterinary problems associated with intensive milk production.



*Painful afflictions of the legs and udder and other problems associated with intensive dairy production would increase with the use of BGH.*

# Drug Abuse Goes Industry Wide

There is another set of human health concerns that arises indirectly from the use of BGH. Because hormone-treated cows are pushed to the limits of endurance, their immune systems are weakened. Producers respond by administering more antibiotics and other drugs to keep the over-stressed animals alive.

The FDA has been notoriously lax in dealing with the misuse of drugs in the

dairy industry. It is estimated that there are more than 80 different drugs currently used by milk producers. Several of these drugs are passed on to people through milk, as well as through meat from slaughtered dairy cows and calves.

Many people have had debilitating allergic reactions to these antibiotics. In addition, one of the drugs routinely found in milk is sulfamethazine. Promoted by

the drug industry as "safe and effective," sulfamethazine is now known to be carcinogenic.

Health officials also warn that the overuse of antibiotics promotes the development of antibiotic resistant strains of bacteria such as salmonella. The widespread use of BGH would only exacerbate these and other food safety problems associated with intensive dairy farming.

# FDA Suppresses Information

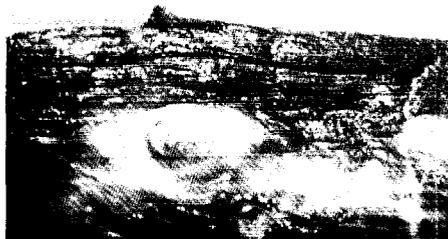
The controversy surrounding BGH has renewed public concern about the integrity of the FDA. The very agency which should be protecting the nation's food supply has actively worked with the drug companies to suppress information about BGH that would put the hormone in a negative light. The FDA violated its own internal policies in helping the pharmaceutical industry reap the profits of genetic engineering.

Dr. Richard Burroughs was a staff veterinarian and senior scientist at the FDA overseeing the analysis of industry-sponsored tests on BGH. He raised a number of questions about the safety of BGH and about the approval process his agency was using. Dr. Burroughs reported that:

- Cows treated with BGH have higher than normal levels of reproductive problems.
- Their udders show an increased tendency to become infected.
- The FDA did not assign reviewers with the expertise needed to evaluate the data.
- Adequate human health studies of the effects of BGH had not been conducted.

Dr. Burroughs was fired on November 3, 1989. "I was told that I was slowing down the approval process. It used to be that we had a *review* process at the FDA. Now we have an *approval* process. I don't think the FDA is doing good, honest reviews. They've become an extension of the drug industry."

The firing of Dr. Burroughs sent a powerful message to others working within the FDA who might have raised similar concerns.



*These cow necropsy photos show the painful tissue damage that can be caused by BGH injections.*

# Boycott Hormone-Milk

Public opinion surveys reveal that 90% of shoppers want BGH-induced milk to be clearly labeled. That's because most people want to avoid dairy products from hormone-treated cows.

The FDA, however, refuses to require that milk and dairy products from BGH-injected cows be labeled. The reason is obvious: the FDA wants to avoid consumer rejection of this dangerous drug.

The FDA's refusal to label BGH-induced milk undermines the public's right to know how food is produced and how farm animals are treated.

The economic and political forces behind BGH even want to prevent the labeling of milk that is free of synthetic hormones. Monsanto, the first company to sell BGH, has gone so far as to sue dairies that label their milk as being free of the artificial hormone.

The Humane Farming Association is urging a boycott of all BGH-induced milk and dairy products. If you buy dairy products, please purchase only those labeled as free of synthetic BGH.

If you can't find labeled dairy products, you can ask the managers of stores and dairy companies to provide you with a written statement of their BGH policy. Their policy should clearly state that the products they sell come from dairies that have agreed not to use BGH. Read carefully any policy on BGH because some companies have misled the public on this issue.

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# Bad Medicine

HFA has warned for years that the use of synthetic BGH would harm cows. This, of course, was vehemently denied by BGH manufacturers. Now, HFA has been proved correct. Below are excerpts from the official government warning that by law must accompany Monsanto's BGH:

"Use of [BGH] is associated with increased frequency of use of medication in cows.... Use of [BGH] in cows in which injection site swellings repeatedly open and drain should be discontinued.

"The number of cows affected with clinical mastitis and the number of cases per cow may increase.... Use of [BGH] has been associated with increases in cystic ovaries and disorders of the uterus.... Cows may have...increased twinning rates. Also, the incidence of retained placenta may be higher....

"...cows injected with [BGH] had increased numbers of enlarged hocks and lesions (e.g. lacerations, enlargements, calluses) of the knee (carpal region), and... disorders of the foot region.

"Safety to replacement bulls from dairy cows injected with [BGH] has not been established."



*Campaign Against Factory Farming*

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*Additional copies of this report are available for 25¢ each or in quantities of 100 for \$12, 500 for \$50, or 1,000 for \$80.*

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## Cows Can't Say No - But We Can

**F**our multi-national drug companies have invested more than half a billion dollars in the development and promotion of BGH. The battle over the use and labeling of this hormone has significance for all areas of animal agriculture.

If BGH gains acceptance, it will pave the way for the use of genetically engineered growth stimulants for pigs, sheep, and other farm animals. BGH itself has already been used in experiments to produce larger, faster growing chickens.

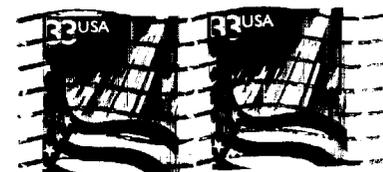
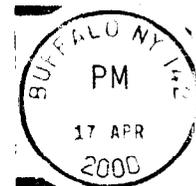
The Humane Farming Association is working to make sure that BGH never becomes an industry standard. Here is what you can do to help:

**Boycott hormone treated milk.** HFA supports the Pure Milk Campaign. We urge you to contact your grocery store and dairy product company directly to let them know that you will not buy any dairy product derived from BGH treated cows.

**Educate your family and friends.** Distribute copies of this brochure to inform others as to the hazards BGH poses to consumers, family farms, and dairy cows.

**Support HFA.** The Humane Farming Association is leading a national campaign to protect consumers from the misuse of agri-chemicals – and to protect farm animals from the cruelty inflicted upon them for the sake of agribusiness profit. **Please join us!**

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