The U.S. Food and Drug Administration (FDA) has approved the use of a genetically-engineered growth hormone for injection into milk-producing cows, recombinant bovine growth hormone (rBGH), produced by Monsanto. As a result, the genetically-engineered hormone (called rBGH, or recombinant bovine growth hormone) will now appear in milk, cheese, yogurt, ice cream, dairy-derived hamburger, many processed foods such as baked goods, and baby formula. FDA says the genetically-engineered product is the same as “not significantly different from”) naturally-occurring bovine growth hormone (BGH) but some scientists have pointed out that this is not true. Natural BGH and the recently-approved rBGH differ in their chemical structures.[1] FDA says neither BGH nor rBGH has any biological effect in humans, but David S. Kronfeld of Virginia Polytechnic Institute and others ask whether rBGH may stimulate an immune response or an allergic reaction in some people. FDA says this possibility is “insignificant” and has refused to conduct human tests. [2] Whether people exhibit immune responses or allergic reactions to rBGH will now be discovered by exposing the general public to this drug. In essence, FDA has given rBGH producers permission to conduct a large-scale experiment on the public, without a control population.

Bovine growth hormone causes cows to produce more milk, but it does not act directly. Instead, BGH releases a chemical called IGF-1 (“insulin-like growth factor #1”) which then causes increased milk production.[3] IGF-1 is a normal constituent of milk from both cows and humans. Several studies have shown that milk from rBGH-treated cows contains elevated concentrations of IGF-1. This is important because IGF-1 is chemically identical in cows and in humans—a fact FDA did not know when the agency first declared rBGH “safe” for human consumption in 1985. Thus rBGH-treated cows will very likely produce milk that contains increased levels of a growth factor known to be biologically active in humans. The consequences of this are unknown, but FDA has said the risks—even if they are rare—i.e. worth taking. FDA does not balance risks against benefits, but two benefits of rBGH use have been identified: an estimated $300 to $500 million in annual income to Monsanto, the only company presently marketing an FDA-approved rBGH, and an estimated 12% increase in the nation’s supply of milk. Since the nation already produces more milk than it can use, the federal government will purchase the additional milk at an estimated cost to the taxpayer of $200 million or more per year.

When an independent committee of the federal National Institutes of Health (NIH) examined the rBGH issue, it concluded that milk and meat from rBGH-treated cows are as safe as from cows not treated. However, they noted that, “Whether the additional amount of IGF-1 in milk from [rBGH-treated] cows has a local effect on the esophagus, stomach or intestines is unknown.” Among the report’s six recommendations was, “Determine the acute and chronic local effects of IGF-1, if any, in the upper gastrointestinal tract.”[4] This has not been done. Perhaps the uncontrolled experiment now being conducted on the public by FDA and Monsanto will reveal new information on this point.

The NIH panel chose not to consider the issue of cow health or the secondary human health consequences of cow health. As we pointed out in RHNW #381 and #382, there is abundant evidence indicating that cows treated with genetically-engineered food products approved by FDA. As a result, genetically-engineered hormone (called rBGH, or recombinant bovine growth hormone) will now appear in milk, cheese, yogurt, ice cream, dairy-derived hamburger, many processed foods such as baked goods, and baby formula. FDA says the genetically-engineered product is the same as “(not significantly different from”) naturally-occurring bovine growth hormone (BGH) but some scientists have pointed out that this is not true. Natural BGH and the recently-approved rBGH differ in their chemical structures.[1] FDA says neither BGH nor rBGH has any biological effect in humans, but David S. Kronfeld of Virginia Polytechnic Institute and others ask whether rBGH may stimulate an immune response or an allergic reaction in some people. FDA says this possibility is “insignificant” and has refused to conduct human tests. [2] Whether people exhibit immune responses or allergic reactions to rBGH will now be discovered by exposing the general public to this drug. In essence, FDA has given rBGH producers permission to conduct a large-scale experiment on the public, without a control population.

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against suits that might cause bankruptcy.

This new legal doctrine has recently been used to limit the liabilities of companies that marketed silicone breast implants. It is a creative legal invention which sharply limits the liability of corporations that market possibly-harmful products that have not been fully tested for safety. Recently more than 8 million Vietnam veterans asked the U.S. Supreme Court to review this new legal doctrine, on the ground that their Constitutional rights had been taken from them. The attorney generals of all 50 states joined with the vets asking the Supreme Court to review this new doctrine.[13] The Supreme Court refused. And that is one reason why companies are willing to risk exposing the general public to drugs in their food without fully understanding the consequences. Under doctrines invented by the Reagan/Bush courts, corporations are protected but the public is not.

--Peter Montague

[1] A reader, Robert Plano, points out that in RHWN #382 we erroneously understated the degree of difference between natural BGH and Monsanto's synthetic rBGH; in RHWN #382 we said rBGH is natural BGH with an amino acid (methionine) added; in fact, Plano points out, FDA says Monsanto's product is the natural BGH with one amino acid removed (alanine) and another added (methionine); see Judith C. Juskevich and C. Greg Guyer, "Bovine Growth Hormone: Human Food Safety Evaluation." SCIENCE Vol. 249 (1990), pg. 877. FDA says these differences make no difference.


Descriptor terms: fda; genetic engineering; biotechnology; bgh; food safety; david kronfeld; immune system; allergies; allergens; milk; hormones; igf-1; nih; monsanto; cows; animal health; mastitis; antibiotics; sulfa drugs; tetracycline; sulfamethazine; carcinogens; donna shalala; hhs; gao;