PUTTING THE bST HUMAN-HEALTH CONTROVERSY TO REST

BY HENRY I. MILLER

No matter what else it elicits, bovine somatotropin (bST) has stimulated one of the most vigorous but misdirected and gratuitous controversies ever to have accompanied the testing of a production drug in agriculture. bST is hardly a scientific novelty. That it can increase milk production by up to 25 percent has been known for more than half a century, while the biochemistry and physiology of recombinant DNA-derived bSTs have been studied exhaustively for a decade. bST has been tested on 21,000 cows worldwide and is the subject of more than 900 research papers. According to a report of six New England commissioners of agriculture, the hormone "has been researched more than any other new technology."

Yet the use of bST has come under strong attack, specifically by certain consumer groups and dairy farmers who oppose the marketing of milk from cattle in experimental herds. Activists have launched a boycott of dairy products from treated herds, even though consumption of the products was authorized by the FDA (Food and Drug Administration, Bethesda, MD) more than six years ago. (The FDA allows the commercial marketing of milk and meat from animals treated with experimental drugs—but only after scientific studies show that the food is safe for human consumption.)

The boycott nevertheless has been joined by four major supermarket chains, two of America's largest manufacturers of dairy products, and a well-known ice-cream producer in Vermont. In addition, Associated Milk Producers, Inc. (San Antonio, TX), the country's largest dairy cooperative, announced that its 21,000 members will not give recombinant DNA-derived hormone to their cows. Most recently, the state legislatures of Wisconsin and Minnesota decided to ban the use of bST temporarily, pending its final review by FDA.

Typically, two charges are leveled at bST—that bST-stimulated milk is unsafe for consumption, and that milk production increases afforded by bST use will lower milk prices. Only the first falls within the purview of FDA. As with all new veterinary drugs, the Agency's review of bST is limited by law to the hormone's safety for humans, treated animals and the environment, and to its efficacy. The second concern, like all others for economic consequences, is best judged in the marketplace by consumers of agricultural technology (dairy farmers) and of agricultural products (grocery patrons).

Much of the concern about the safety of milk from bST-treated cows appears to stem from the source of the drug: new biotechnology. All the companies that have applied for FDA approval to market bST produce it through recombinant DNA technology. FDA is experienced in this area, having already approved more than 500 products of new biotechnology and more than 1,000 clinical trials of human drugs and biologics with these products. As a science-based regulatory agency, FDA is committed to evaluate biotechnology products by the same high standards of product safety that apply to all similar regulated substances. The Agency will soon complete its final evaluation of the safety of bST to the target animals, and of its efficacy.

Science knows bST

That milk from bST-treated cows is safe for humans was amply established well before FDA authorized the marketing of milk and meat from experimental herds. As early as the 1950s, bovine growth hormone was shown to be inactive in humans, when physicians tested it as a remedy for dwarfism. It has been also well-documented that the recombinant bSTs are minimally, if at all, different in amino acid structure or physiological functions from the naturally occurring hormone, and that any small differences do not affect the drug's inaction in humans.

The FDA remains convinced that, on the key question of human safety, products from bST-treated herds pose no risk. If it had entertained any doubts, FDA would not have allowed products from experimental herds to be marketed.

Nevertheless, to answer the persistent few vocal individuals who doubt bST's safety, in 1990 FDA took the unprecedented step of submitting to extensive peer-review evaluation the pivotal scientific evidence about the effect of bovine growth hormone on human health. The authors—Judith C. Juskevich, an FDA consultant, toxicologist and pharmacologist, and C. Greg Guyer, a chemist in FDA's Center for Veterinary Medicine—summarized and analyzed 69 scientific studies, some of which include previously undisclosed proprietary data from bST manufacturers. The study (*Science* **249** (4972), 24 August 1990) concluded:

(a) bST is naturally present in milk of all cows; in cattle treated with bST, no more reaches the milk than the upper limits of normal bST levels. When taken orally, bST is broken down into inactive fragments during digestion and has no effect on human health. Moreover, 90 percent of bST in milk is destroyed by pasteurization.

(b) bST is biologically inactive in humans even if injected, because its amino acid sequence is about 35 percent different from human somatotropin. The bovine growth hormone is "species specific" (i.e., it does not trigger responses in higher species, such as humans and monkeys).

(c) The results of bST toxicity studies were negative, even when rats were fed for 14 days the equivalent of daily doses 100 times higher than those administered to dairy cattle.

In the spirit of openness, and because some controversy remained, the Agency followed the publication of the article by another unprecedented step: it requested that the National Institutes of Health (Bethesda, MD) convene a special panel of experts to evaluate all human health aspects of bST, including the safety of meat and dairy products from treated herds. At the end of its meeting in December 1990, this panel concluded that "the composition and nutritional value of milk from rbST-treated cows is essentially the same as milk from untreated cows," and that "meat and milk from treated cows are as safe as those from untreated cows."

These conclusions, reflecting virtual unanimity in the scientific community, ought to put the controversy to rest. FDA will continue to evaluate whether bST is safe for cows and the environment and whether it increases milk production as claimed. If any of these questions is answered in the negative, the drug will not be allowed on the U.S. market. On all of these questions, FDA is confident that any regulatory decision based on sound science will bear the full weight of public scrutiny and, most important, that public health will continue to be protected. ///

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