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#382 - Some Dangers Of Hormones In Milk
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Last month, the first genetically-engineered food product went on sale in the U.S., after final approval by the Food and Drug Administration (FDA). The product is a cow growth hormone (called recombinant bovine growth hormone, or rBGH), intended for needle injection into milk cows every two weeks to make them produce more milk. Norway, Sweden, Denmark, the Netherlands, and the Canadian provinces of Alberta, British Columbia, and Ontario have banned commercial use of synthetic bovine growth hormones. (The rBGH hormone is sometimes called rBST, recombinant bovine somatotropin.)

Bovine growth hormone (BGH) is a normal product of the pituitary gland of cows. To make the synthetic product, rBGH, drug companies have learned to snip out a fraction of cow DNA that codes for this hormone, insert it into the DNA of E. COLI bacteria, grow the bacteria in vats, and extract large quantities of rBGH from the vats. (A synthetic human growth hormone has been manufactured by similar techniques for several years.)[1]

Introduction of the rBGH product last month was met by an uproar from consumers who want the product banned until safety questions have been resolved and who want milk labeled if it is produced from rBGH-treated cows. Monsanto, the chemical company that has brought the first rBGH product to market, vigorously opposes labeling.

FDA has sided with Monsanto in opposing labeling of milk produced by drug-treated cows, and has gone one step further. FDA opposes labeling of products that are free of rBGH. FDA has even threatened legal action against milk suppliers and grocers who label their milk as free of the rBGH drug.[2] FDA says there is "no significant difference" between milk from rBGH-treated cows and milk from cows not treated, and thus a label saying "rBGH-free" would imply a difference that did not exist, and this would constitute false labeling.[3] Monsanto has filed two lawsuits against milk processors who labeled their product as free of rBGH and has mailed warnings to others who might be tempted to label their milk as rBGH-free.[4] The FDA's position on labeling was developed under the direction of Michael R. Taylor, a lawyer who joined FDA in 1991 after almost a decade as a partner in the law firm that Monsanto hired to gain FDA approval of rBGH and that last month brought Monsanto's lawsuits against milk producers who labeled their products rBGH-free. (See RHWN #381.)

Despite what FDA statements might lead consumers to think, Monsanto's rBGH is not identical to a cow's natural growth hormone. The two hormones have a different amino acid sequence. The Monsanto product is the cow's natural hormone with an extra amino acid (methionine) attached.[5]

According to agricultural researchers at the University of California at Davis, the FDA faced a similar situation once before, when the agency evaluated synthetic human growth hormone (rHGH).[6] A manufacturer of rHGH produced a product that differed from the natural product (HGH) in the same way that Monsanto's rBGH differs from natural BGH; that is to say, the rHGH had an additional methionine residue at one end. The PHYSICIANS DESK REFERENCE, a standard medical reference book on drugs, says that 30% of rHGH-treated patients developed antibodies (in other words, had an allergic reaction) compared to only 2% of HGH-treated patients. By analogy, this seems to raise the distinct possibility that some people will have an allergic reaction to Monsanto's rBGH who might not have an allergic reaction to natural BGH. FDA has steadfastly refused to evaluate the potential for human allergic reactions to rBGH.

There is considerable evidence that rBGH appears in the milk of rBGH- treated cows.[7] However, FDA has not developed, and has not required Monsanto to develop, a measuring technique that can distinguish between Monsanto's rBGH product and the cow's natural hormone. This appears to be a violation of law by FDA. Section 512 of the 1968 Animal Drug Amendments to the 1938 Federal Food, Drug and Cosmetic Act requires manufacturers submitting new animal drug applications to provide "a description of practical methods" for analysis and monitoring of drug residues in food.[8] The American Medical Association pointed out in 1991 that it is possible to develop a measuring technique to distinguish between the natural product BGH and the genetically- engineered product rBGH.[9] For reasons that are known only to FDA, the agency has not developed such a technique. Because FDA has not developed the necessary analytic technique, the agency can continue to say that rBGH is indistinguishable from BGH, implying falsely that the two hormones are identical.

Although human health effects of milk from rBGH-treated cows are uncertain, health effects on cows are better understood. Normally for about 12 weeks after a cow calves, she produces milk at the expense of her own tissues. She loses weight, she is infertile, and she is more susceptible to diseases such as mastitis (inflammation of the udder). Eventually her milk output diminishes, her food intake catches up, and she begins to rebuild her body. By injecting rBGH, a farmer can postpone for another 8 to 12 weeks the time when the cow begins rebuilding her body. This means that the cow is stressed for another 8 to 12 weeks and is more susceptible to infection during that period. [10]

The Monsanto rBGH product, sold under the trade name Posilac, comes with an insert sheet containing information about the drug. The Posilac insert sheet says, in part, "Cows injected with Posilac are at an increased risk for clinical mastitis (visibly abnormal milk). The number of cows affected with clinical mastitis and the number of cases per cow may increase. In addition, the risk of subclinical mastitis (milk not visibly abnormal) is increased. In some herds, use of Posilac has been associated with increases in somatic cell counts."[11] Somatic cell counts are another name for pus in milk. The insert sheet mentions other health effects of rBGH on cows: "Use of Posilac has been associated with increases in cystic ovaries and disorders of the uterus during the treatment period." And: "Use of Posilac may result in increased digestive disorders such as indigestion, bloat, and diarrhea."

There is abundant evidence that, when cows get mastitis, farmers give them antibiotics. Mastitis (or the pus it puts into milk) is a major cause of lost revenues to dairy farmers. According to the U.S. General Accounting Office (GAO), FDA has approved use of 30 antibiotics on dairy cows but an additional 50 antibiotics are suspected of being used illegally on dairy cows. A 1988 Illinois survey found over 200 different animal drugs on dairy farms, 58% of them not approved for use on dairy cows. Furthermore, the routine tests that FDA applies to milk nationwide can only detect 4 types of antibiotics, so FDA is not in a position to protect consumers from illegal use of antibiotics (which are sold without prescription at farm supply stores). Antibiotic residues in milk --which seem certain to increase with rBGH use --may cause adverse allergic reactions in some consumers, and very likely will contribute to development of strains of bacteria that are resistant to antibiotics, thus reducing the effectiveness of antibiotic medicinals against human and animal diseases.[12] [More next week.]

--Peter Montague

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[1] Gail Feenstra, "Introduction," in William C. Liebhardt, THE DAIRY DEBATE; CONSEQUENCES OF BOVINE GROWTH HORMONE AND ROTATIONAL GRAZING TECHNOLOGIES (Davis, Cal.: University of California Sustainable Agriculture Research and Education Program, 1993), pgs. 19-20.

[2] Keith Schneider, "F.D.A. Warns the Dairy Industry Not to Label Milk Hormone-Free," NEW YORK TIMES February 8, 1994, pg. A1.

[3] Michael R. Taylor, "Interim Guidance on the Voluntary Labeling

of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin," FEDERAL REGISTER Vol. 59 No. 28 (Feb. 10, 1994), pgs. 6279-6280.

[4] "Statement on Misleading Promotion and Advertising Activities," an anonymous statement on Monsanto letterhead dated March 4, 1994, faxed to us by staff of Tom McDermott [(314) 694-3605] of Monsanto in St. Louis, Mo.

[5] Judith C. Juskevich and C. Greg Guyer, "Bovine Growth Hormone: Human Food Safety Evaluation." SCIENCE Vol. 249 (1990), pgs. 875-884.

[6] Gail Feenstra, cited above, pg. 27.

[7] This evidence is reviewed in Gail Feenstra, cited above, pgs. 20-23.

[8] FDA requirements are discussed in Samuel S. Epstein, "Potential Public Health Hazards of Biosynthetic Milk Hormones," INTERNATIONAL JOURNAL OF HEALTH SERVICES Vol. 20 No. 1 (1990), pgs. 73-84.

[9] Council on Scientific Affairs, American Medical Association, "Biotechnology and the American Agricultural Industry," JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION Vol. 265 (March 20, 1991), pg. 1433 says, "Therefore, an antibody-based detection assay could be devised to determine the percentage of recombinant vs native bST present in the milk from rbST-treated animals."

[10] Donella Meadows, "Out to Pasture," GREEN ALTERNATIVES, February/March 1994, pg. 56. And Kathleen Byrnes, "Synthesis," in William C. Liebhardt, THE DAIRY DEBATE; CONSEQUENCES OF BOVINE GROWTH HORMONE AND ROTATIONAL GRAZING TECHNOLOGIES (Davis, Cal.: University of California Sustainable Agriculture Research and Education Program, 1993), pgs. 319-349.

[11] We asked Monsanto for a copy of the Posilac insert sheet. Staff of Tom McDermott [(314) 694-3605] in St. Louis, Mo., told us March 23 they were not sure whether their division had a copy; they said they would check and call us back, but we did not hear from them again before our press deadline. We received a copy from the Pure Food Campaign [1130 17th Street, N.W., Suite 630, Washington, DC 20036; telephone (202) 775-1132].

[12] Michael K. Hansen, "Testimony before the Agriculture Committee of the Canadian Parliament on Potential Animal and Human Health Effects of rbGH Use by Michael K. Hansen, Ph.D.," dated March 9, 1994. Available from: Consumer Policy Institute, Consumers Union, 101 Truman Ave., Yonkers, NY 10703-1057. Telephone (914) 378-2000.

[13] Marietta Sue Brady and others, "Resistance Development Potential of Antibiotic/Antimicrobial Residue Levels Designated as 'Safe Levels,'" JOURNAL OF FOOD PROTECTION Vol. 56 No. 3 (March 1993), pgs. 229-233.

Descriptor terms: food safety; fda; genetic engineering; biotechnology; bgh; hgh; dna; bacteria; milk; labeling; monsanto; lawsuits; rtk; michael taylor; revolving door; amino acids; methionine; posilac; pus; mastitis; antibiotics; resistance; diarrhea; allergies; allergic reactions; antibodies; animal rights;