

POTENTIAL PUBLIC HEALTH HAZARDS OF BIOSYNTHETIC MILK HORMONES

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The use of biosynthetic milk hormones raises fundamental ethical, social, and economic considerations, including the continued viability of the small family dairy farm and adverse veterinary effects. The past and expanding use of synthetic bovine growth hormone manufactured by the Agricultural Chemicals Division of Elanco (Eli Lilly and Co.) in conjunction with Dow Chemical Co. and Upjohn Co., and its methionyl analog, manufactured by American Cyanamid Co. and Monsanto Co., also poses significant potential public health hazards which have not so far been investigated. These concerns are exacerbated by the domination of synthetic hormone research by industry and its indentured academics, by failure of the industries concerned to disclose their unpublished data, by their manipulation of published data, and by refusal to label milk and meat from cows treated with biosynthetic hormones, and by denial of consumers' rights to know. These concerns are further exacerbated by the abdication of regulatory responsibility by the Food and Drug Administration and U.S. Department of Agriculture.

TRACK RECORD OF THE FOOD AND DRUG ADMINISTRATION AND THE U.S. DEPARTMENT OF AGRICULTURE

The Food and Drug Administration (FDA) is responsible for approving the registration and use of animal drugs and issuing residue tolerances. Section 512 of the 1968 Animal Drug Amendments to the 1938 Federal Food, Drug, and Cosmetic Act (FFDCA) mandates the FDA to require manufacturers submitting new animal drug applications to provide "a description of practical methods" for analysis and monitoring of drug residues in food. The U.S. Department of Agriculture (USDA) is responsible for monitoring food animals and their products by FDA-approved methods in order to detect and prevent the occurrence of illegal food residues.

The granting by the FDA of an Investigative New Animal Drug (INAD) exemption for the synthetic hormones on the basis of allegedly confidential data and their allowing the sale of unlabeled hormonal milk and meat reflects the agency's highly relaxed view of its responsibilities. As stated in a recent FDA Talk Paper, and elsewhere, sponsors have not been required to measure the increase of bovine growth hormone (BGH) in milk of treated cattle over that in milk from untreated cattle. Rather, the

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safety of BGH is allegedly based on the limited quantity of the hormone administered on a daily basis and the fact that BGH is not biologically active in humans or other primates (1). Furthermore, in granting the INAD exemption, the FDA is in apparent violation of the 1968 FFDCAs mandating that the agency must have a "prescribed and approved" test method, which the industry is required to provide, for determining whether the drug is being improperly used, with resulting illegal residues in food.

Of additional concern is the fact that the FDA has inappropriately relied on standard protocols that are largely irrelevant for the safety evaluation of biosynthetic milk hormones. In fact, the only reported evidence of adverse effects has emerged from incidental findings in efficacy trials based on Technical Advisory Document (TAD) protocols designed primarily for milk production trials. In particular, the agency has failed to require evaluation of the toxicological effects of the milk hormones in large-scale multigenerational and multilactational tests, and evaluation of the safety of milk and dairy products, with regard to a wide range of critical public health concerns.

The conduct of the regulatory agencies in the matter of milk hormones is consistent with their track record. As evidenced in an extensive series of Government Accounting Office investigations and Congressional hearings, USDA and FDA regulation is in near total disarray, aggravated by denials and cover-ups. A 1986 Congressional report concluded: "FDA has consistently disregarded its responsibility, . . . repeatedly put what it perceives are interests of veterinarians and the livestock industry ahead of its legal obligation to protect consumers, . . . jeopardizing the health and safety of consumers of meat, milk, and poultry" (2). Further illustrative is the April 1989 USDA proposal to end inspection of the nation's 6,300 meat and poultry processing plants and instead to rely on voluntary compliance. The proposed plan, originally entitled "Discretionary Inspections," and then euphemistically renamed "Improved Processing Inspection System," has met with a storm of criticism from sources including the American Meat Institute and major meat packers.

It should be noted that an earlier draft of this report was submitted to FDA Commissioner Young on July 19, 1989. A reply of August 11, 1989, from Dr. G. Guest (Director of the Center for Veterinary Medicine) alleges, in the total absence of supporting data, that the report "contains many misstatements of scientific fact," although none are specified. Dr. Guest also offered the irrelevant assurance that the FDA is preparing a report on the scientific basis of its decision to allow the sale of unlabeled dairy products from hormone-treated cows to the general public. As of September 6, 1989, the FDA has failed to provide a documented scientific critique of the report. It may also be noted that in an internal memorandum of July 18, 1989, Dr. Guest admitted "the likely problems with cattle safety" in cows on clinical trials, and questioned whether "some sense of security to the consumer" would be gained by allowing use of synthetic hormones only as a prescription drug.

INDUSTRY CLAIMS ON MILK HORMONES

The industry claims, as exemplified in a recent promotional report by the Animal Health Institute (3), are highly misleading. It is claimed that the synthetic hormones increase milk yields by an average of 10 to 25 percent, that milk quality is unchanged,

that increased hormone levels are not found in milk, that there are no adverse reproductive or other effects in treated cows, and that the synthetic hormones are safe because they are not biologically active in humans. The Animal Health Institute report quotes from a milk hormone production trial conducted by Cornell University to the effect that "it appeared that the cows were simply unaffected," and emphasizes that "subsequent studies at more than 20 universities confirm many of these observations." The report omits reference to the wide range of adverse effects noted in about half the limited number of methionyl-BGH (met-BGH) production trials (see "Adverse Veterinary Effects") and makes no reference to met-BGH, except incidentally in an efficacy graph. Finally, the report makes no reference to the highly variable and inconsistent yields in the milk production trials.

Apart from misrepresentations, the industry claims are usually restrictedly based on small numbers of cows (seven to ten per test group), reflecting TAD efficacy protocols in which adverse veterinary effects were only incidentally noted. Claims that increased hormone levels are not found in milk are suspect since they do not reflect anticipated dose-response relationships and do not reflect increased plasma levels noted in several studies (see "Potential Adverse Public Health Effects").

The industry claims for the synthetic hormones are based on a complex of strategies. These exaggerate efficacy; omit reference to, trivialize, or dismiss documented adverse veterinary effects; and reflect misleading manipulation of data. Furthermore, these claims fail to reflect the absence of critical studies that could elicit further information on adverse veterinary effects and, even more critically, on adverse public health effects. The past success of the industry strategies also reflects suppression of data, on the alleged grounds of trade secrecy, and the unbalanced and indentured nature of in-house and academic research on synthetic milk hormones. Certainly, the documented evidence of adverse veterinary effects of milk hormones justifies the highest index of suspicion as to undocumented industry claims on human safety.

ADVERSE VETERINARY EFFECTS

Available data on adverse veterinary effects in cows hyperstimulated by daily injections of the synthetic hormones are sparse and are largely based on incidental findings in small-scale milk production trials, in the absence of multilactational and multigenerational toxicological studies. The significance of these findings, to which no reference is made in industry promotional literature, is emphasized by the small size of the trial groups, ranging from seven to 47 cows for each treatment group. The gross statistical insensitivity of such trials has recently been emphasized. "At least 2,423 cows would be needed in each group to detect an increase in disease frequency from 5 to 10 percent, and at least 11,773 cows in each group for a change from 1 to 2 percent" (4). The importance of stress-related diseases associated with prolonged elevation in plasma levels of BGH has been strikingly confirmed in transgenic pigs in which there were "significant improvements in both daily weight gain and feed efficiency." However, these pigs also developed "a high incidence of gastric ulcers, arthritis, cardiomegaly, dermatitis, and renal diseases" (5). It should be noted that these scientists, unlike their indentured dairy science counterparts, carefully investigated adverse veterinary effects as well as productivity.

Negative Energy Balance

Biosynthetic milk hormones induce a prolonged negative energy balance, similar to that in the rising phase of lactation, for at least eight weeks, during which increased milk production is paralleled by "reduced total body fat," excessive tissue loss, and hypertrophy of foregut tissue (6). This sustained negative energy balance appears to be associated with increased stress, susceptibility to infectious disease, and measurable changes in the composition of milk.

Increased Incidence of Infectious Diseases

In the Cyanamid-Pennsylvania met-BGH trial, mastitis developed in four of eight cows at 12.5 mg/day and in two of seven at 50 mg/day. High somatic cell counts were observed at all dosages in the Monsanto-Missouri trial, and at 25 mg/day in the Cyanamid-Missouri trial (4). Additionally, a high level of unspecified infectious disease was noted in one of nine trials. An increased incidence of unspecified (and unpublished) infectious disease has recently been confirmed (7).

Reduced Fertility

Evidence of reduced fertility has been noted incidentally in four of nine milk production trials (4, 8). Such evidence is further supported by evaluation of the results of 59 industry or industry-sponsored trials recently reported in two supplements of the *Journal of Dairy Science* (Volume 70, Supplement 1, 1987, and Volume 71, Supplement 1, 1988). Reproductive data were cited in six of these 59 trials—only two of which involved second lactations—all of which uniformly demonstrated significant adverse reproductive effects (9). The overall conception or pregnancy rates of controls in these six trials were 89 percent versus 59 percent in injected cows. More marked effects were noted in one study with pregnancy rates of 82 percent in controls versus 41 percent in high-dose-level cows, although conception rates were similar in all groups (10). In general, these adverse reproductive effects were ignored or trivialized. Illustratively, in one of the six trials it was claimed that "reproductive performance did not differ from contemporary herdmates," although conception rates in controls were 100 percent versus 50 percent in injected cows (11). Again, another study claimed that "health measurements were not consistently altered by somatotrope" (met-BGH), although conception rates were 95 percent in controls versus 79 percent in injected cows (12).

In addition to the inhibition of conception rates noted in some of the six trials, one of these demonstrated reduction in pregnancy rates in the absence of effects on conception (10). As recently recognized, "BST [bovine somatotropin, i.e., BGH] may affect embryo survival. In one study, the conception rate of BST-treated cows was not influenced. However, there was evidence that BST-treated cows particularly those receiving high doses maintained fewer pregnancies" (13).

Thus, even from a narrowly focused economic perspective, and ignoring costs of other adverse veterinary effects, increased productivity from the use of synthetic milk hormones could be more than offset by economic losses due to reproductive impairment (9).

Heat Intolerance

Heat intolerance was noted at two dosage levels in one of nine trials (4). Such intolerance could pose particular problems for uses of biosynthetic hormones in tropical climates.

Changes in Nutritional Quality of Milk

Available data on the effects of hormones on the nutritional status and composition of milk, including protein subfractions, vitamins, and minerals, are minimal. However, it is clear that the hormones induce a wide range of measurable changes in milk composition. Increased fat yields and concentrations have been noted (14). Additionally, there is a statistically significant increase in long-chain fatty acids and decrease in short-chain fatty acids (15); this is associated with reduction in casein, in relation to both total and true protein, which is likely to decrease cheese yields. Such significant changes in the composition of milk in hormonally treated cattle are becoming increasingly recognized (e.g., 8).

Questionable Efficacy of Milk Hormones

The adverse veterinary effects so far noted are not necessarily offset by improved milk production. Contrary to promotional claims, the effects of synthetic hormones on milk production are highly variable and inconsistent. In nine met-BGH trials, outstanding responses were obtained in two herds and very poor responses in another two herds. "About one-third of all BST-treated herds would be predicted to fall between the consensus low limit of 10 percent more milk and my estimate of minus 1 percent based on the nine trials" (16). In spite of strident industry denials, burnout or lactational crash has been noted in hormone-treated cattle, particularly at high dose levels (7, 9), although no data have as yet been made available on its incidence.

Other Growth Hormones in Milk

Apart from unresolved questions on incremental levels of synthetic hormones in milk, somatomedins such as insulin-like growth factors (IGF-1), whose endogenous production is stimulated by milk hormones, have been detected in the milk of cows treated with synthetic hormones. Based on the very limited available data, the milk of treated cows appears to sustain high levels of IGF-1, similar to those found in untreated cows after the first week of lactation (17, 18). Additionally, the normal inverse relationship between endogenous growth hormone and blood insulin levels is disturbed following BGH treatment (19).

Misuse of Milk Hormones

Apart from concerns about overdosage of lactating cows, the off-label use of synthetic BGH as a growth-promoting hormone in calves and sheep has also been reported. Such misuses are all the more likely in view of the absence of practical and

sensitive methods for detecting and monitoring hormonal levels in milk and meat. Also, the documented record of extensive misuse of growth-promoting animal sex hormones does not inspire confidence that milk hormones will be handled any more responsibly.

Critical Data Gaps

It should be stressed that no information is available from large-scale multilactational and multigenerational dose-response tests with synthetic hormones on a wide range of veterinary and related concerns. These include: milk production efficacy; alterations in the detailed biochemical composition of milk, its nutritional quality, and its suitability for cheese production; alterations in reproduction and fertility; detailed studies on the growth and health of calves of injected cows; endocrinological effects; biochemical, endocrine, and metabolic evidence of stress; stress-induced susceptibility to and increased incidence of viral infections, including bovine leukemia; increased levels in milk of antibiotics necessitated by increased bovine infections; allergenicity and immunogenicity of hormonal milk; response of hormone-treated cattle to vaccines; mobilization in milk of fat-soluble carcinogens from depot fat by the sustained lipolytic action of milk hormones; and identification and measurement in milk and meat of synthetic hormone residues and of incremental levels of IGF-1 and other somatomedins.

POTENTIAL ADVERSE PUBLIC HEALTH EFFECTS

An editorial in a highly conservative British medical journal recently warned that before the use of BGH can be considered commercially, "one would need to be completely reassured that the appropriate tests have been carried out thoroughly and professionally and that there is not the slightest hazard to human health" (20). In fact, the use of milk hormones poses serious risks of adverse public health effects that have not been adequately considered (7, 8), in spite of continued unfounded but strident industry and industry contractee assurances of safety. Apart from a wide range of information gaps that negate such assurances, there are some highly suggestive contrary data.

Relationship of Biosynthetic to Natural Milk Hormones

Industry claims that synthetic BGH is "natural" are false. Both BGH and met-BGH are xenobiotics (8). Natural BGH consists of 191 amino acid residues in linear sequence. The Elanco BGH, however, has a series of eight additional amino acid residues, known as linker proteins, at one end of the molecule (21); the more potent met-BGH has an alien methionyl terminal residue. In addition to such chemical differences, synthetic BGH is synthesized on a bacterial rather than a mammalian ribosome and its bacterial links have not been clipped off, resulting in possibly different biological activities from natural BGH. The FDA has recently admitted that

biosynthetic milk hormones "are about 0.5 to 3 percent different in molecular structure" from the natural hormone (22).

Biological Activity of Milk Hormones

The industry initially claimed that BGH was "species-specific" to cattle, and thus could not possibly have any effects in humans. However, BGH is now known to be active in a wide range of species, including goats, pigs, sheep, mice, and even fish. Accordingly, the industry has changed its position and now claims that BGH is "species-limited" (23).

Natural BGH derived from pituitary glands was shown in the 1950s to have "no effect on human growth, sexual development or well-being" (24). Natural BGH is immunologically different from the human hormone and differs structurally in some 30 percent of its amino acid residues. While natural BGH is inactive in all primates, it should be noted that human growth hormone is only active in humans when given in high (milligram) doses. Additionally, some human dwarfs, Laron-type, are resistant to the treatment with human growth hormone unless it is administered together with androgens (25). Moreover, no studies on humans have been conducted with the synthetic hormones, especially the more potent met-BGH. Furthermore, it was demonstrated some 30 years ago that chymotrypsin digests of natural BGH are biologically active in humans, in whom they induce nitrogen retention (26); these considerations prompted unheeded recommendations to Monsanto some 26 years ago to undertake detailed studies on the biological activity of peptide fragments of synthetic milk hormones (7). Thus, the synthetic hormones could be biologically active in humans following absorption of novel peptides, formed during pasteurization or during proteolytic digestion in the alimentary canal. Also, the intact hormone molecule could be absorbed into the blood from the digestive tract, particularly in newborn infants prior to closure time and in infants or adults with impaired protein digestion in diseases such as cystic fibrosis; absorption of intact protein molecules has been demonstrated in newborn babies and some adults (7, 8). The industry recently admitted that "some proteins are absorbed into the blood stream without being fully digested" (24).

Industry claims that increased levels of synthetic hormones are not found in the milk of injected cows (3) using radioimmune assays. However, there are no available data on the comparative sensitivity and specificity of these assays for natural as opposed to synthetic hormones. Additionally, it is likely that administration of synthetic hormones will inhibit endogenous production of natural BGH and its levels in milk (25). In a recent publication purporting to confirm these claims, the upper range of levels in cows treated with 25 mg/day of synthetic BGH was more than 50 percent in excess of controls (27). Furthermore, dose-response relationships for plasma levels of synthetic BGH in the range of 5-30 ppb (ng/ml) have been reported (28). Up to 700 percent increased plasma levels have been reported following synthetic BGH dosing in late lactation (29); others have confirmed such elevations (e.g., 30). Paradoxically, excess levels of synthetic hormones have not been reported in milk assays by industry and its contractees. Clearly, the milk of treated cows should be assayed by independent scientists using techniques that have yielded clearcut results with plasma.

Biological Activity of Growth Factors

There is a growing consensus that the mechanism of action of the pituitary growth hormone is through the induction of somatomedin growth factors, particularly IGF-1 (31). From all criteria, bovine and human IGF-1 appear identical (31, 32). Most of the specific activities of natural BGH, including milk production, gluconeogenesis, diabetogenesis, nitrogen retention, lipolysis, mitogenesis, and adipose tissue and bone growth, are mediated through somatomedins. Moreover, mammary gland receptors for IGF-1 have been identified (33).

Increased IGF-1 levels have been reported in goat's milk following synthetic BGH treatment (17). As subsequently briefly reported, high levels of IGF-1 are found in normal cow's milk immediately after calving, falling to 1-5 ng/ml by 200 days (18). However, levels induced by daily injections of BGH were sustained at 6-20 ng/ml. Thus, irrespective of the possible activity in humans of synthetic BGH digestion products, mitogenic effects could be indirectly induced in humans by sustained incremental levels of IGF-1 and other somatomedins following absorption of their intact molecules or biologically active fragments from the gastrointestinal tract. Such effects could include premature growth stimulation in infants, gynecomastia in young children, and breast cancer in women.

A recent publication insisting that BGH technology is sound nevertheless warned that (31):

Investigation of IGF's requires attention, particularly where animal health and food residues are concerned since they possess many biological activities and are immunologically and biologically similar among species. . . . Some concerns arise as to the possibility of abnormal levels of IGF-1 in the milk of BGH-treated cows and, with it, consumer health.

Another publication warns (18):

The implications of IGF-1 in milk for the human infant cannot be determined until we know more about the activity and function of milk IGF-1 in the newborn. However, total growth factor activity in cow's milk, as assessed by a cell proliferation test *in vitro* which also detects components other than IGF-1, is not altered by BST treatment.

In addition to detailed studies on IGF-1 levels in the milk of BGH-treated cows, the effects in humans of increased levels should be studied with priority, particularly since some consumers have already and unknowingly been exposed to BGH milk; this population at risk should be identified and subjected to long-term surveillance. Systematic studies on IGFs should include dose-response *in vitro* investigations with human cells and tissues and dose-response studies in infant and adult primates, with a view to defining the effects of incremental milk levels in humans.

Activity of Hormonally Induced Stressor Metabolites

The levels in milk of stressor metabolites induced by synthetic hormones and somatomedins, such as epinephrines, catecholamines, and cortisol, should be

determined by sensitive and specific assays. The stressing action in humans of these metabolites should be investigated.

Infectivity of Hormonal Milk

The stressing effect in cows of synthetic hormones and somatomedins may induce immunosuppression and activate latent viruses, such as bovine leukosis virus (BLV) and bovine immunodeficiency virus (BIV), which may well increase susceptibility to other infectious agents. Levels of such viruses in hormonally treated milk and their human infectivity should be investigated with particular reference to risks of immunosuppression and leukemia. The relationship between these viruses and the AIDS (acquired immune deficiency syndrome) complex is of further concern, particularly in view of the high level of homogeneity between BIV and human immunodeficiency virus type I, and the infectivity of BLV to chimpanzees.

Antibiotics in Hormonal Milk

The increased incidence of infectious diseases, which has been noted in efficacy trials and which is presumably stress induced, is likely to result in increased antibiotic treatment and antibiotic levels in milk. Accordingly, the incidence of infectious diseases and of antibiotic levels in milk should be investigated with particular reference to the risks of induction of antibiotic resistance in the general population.

Allergenicity of Hormonal Milk

The allergenic and immunogenic effects in humans of met-BGH in milk, and of novel peptides resulting from its pasteurization or digestion, should be investigated. This is of particular concern in view of the substantial evidence on the high incidence of antibody development in humans treated with methionyl human growth hormone, rather than with the natural hormone (34).

Fat-Soluble Carcinogens in Hormonal Milk

The fat and milk of cattle are contaminated with a wide range of carcinogens, including pesticides such as heptachlor epoxide and dieldrin and xenobiotics such as polychlorinated biphenyls (PCBs) and tetrachlorodibenzodioxin. The lipolytic effect of hormonal treatment is likely to mobilize carcinogens from body fat and increase their milk levels, a matter of particular concern to young infants. For these reasons, possible incremental levels of fat-soluble carcinogens in hormonal milk should be determined.

Nutritional Quality of Hormonal Milk

The nutritional quality of hormonal milk should be investigated in multilactational and multigenerational tests. As recently emphasized, such data "on detailed components of milk, e.g., casein fractions, are not available" (27). Available data, however,

demonstrate major increases in long-chain saturated fatty acids relative to medium- and short-chain saturated fatty acids, and up to 27 percent higher fat levels in hormonal milk (14). Dose-response relationships between milk fat and synthetic BGH have also been reported (28).

Misuse of BGH and Met-BGH

In the event that registration should ever be granted to these biosynthetic hormones, there would be no practical method to prevent their extensive off-label misuse, as is well documented for sex growth hormones, or to detect and even monitor for such misuse. It is thus highly likely that these hormones would be administered at excessive dosages to lactating cows and as growth stimulants to calves, sheep, and other cattle, increasing still further the exposure of the general public to these highly potent biological agents.

PUBLIC POLICY RECOMMENDATIONS

1. The manufacture, domestic sale, and export, including foreign licensing agreements, of biosynthetic milk hormones should be banned immediately. This ban should remain effective until a wide range of concerns on public health and veterinary safety have been posed and fully resolved.
2. The sale of milk, milk products, and meat from hormone-treated cows should be embargoed immediately. To ensure compliance, industry and its academic contractees must be required to immediately identify all past and currently treated herds.
3. Attempts should be made to identify and place under long-term medical surveillance all consumers, especially infants, who are at potential risk from having consumed hormonally contaminated milk, milk products, and meat.
4. The industry and its academic contractees must be required to make immediate full disclosure of all unpublished data and reports; claims for confidentiality must be legally preempted on the grounds of overriding concerns about public health and welfare.
5. The conduct of industry and of its academic contractees with regard to suppression and manipulation of data should be subject to Congressional investigation.
6. The conduct of the FDA in granting an INAD exemption for the testing of synthetic hormones in cows and approving the sale of hormonal milk, in apparent violation of the 1968 FFDCA amendments, together with its unfounded assurances of safety, should be subject to legal challenge and Congressional investigation.
7. The industry must be required to develop and undertake multilactational and multigenerational dose-response and other protocols appropriate for the investigation of potential adverse public health effects from hormonally contaminated milk, milk products, and meat. Such research should be subject to ongoing independent review. These protocols must include: specific and sensitive assays for synthetic hormones and somatomedins; investigation of the biological activity of these hormones and growth factors in milk; analysis of milk for stressor chemicals; investigation of the biological activity of such stressor chemicals at levels expected in hormonal milk; analysis of milk for antibiotics necessitated by treatment of stress-induced infections

in lactating cows; analysis of milk for stress-induced or activated viral agents; analysis of milk for increased levels of fat-soluble carcinogens mobilized by synthetic hormones; investigation of the allergenicity and immunogenicity of synthetic hormones and of any derived novel peptides; investigation of the response to vaccines of treated cows; and detailed analysis of the nutritional quality of hormonal milk.

8. The industry must also be required to fund research in accordance with independently approved protocols, which should be awarded, supervised, and otherwise administered by a neutral, independent intermediary such as the National Institutes of Health or the National Science Foundation.

9. Pending action at the federal level, state legislatures should take immediate initiatives including labeling milk, dairy products, and meat from cows treated with synthetic BGH and banning the state sale of these products. State legislatures should also investigate the conduct of state universities in their contractual relations with industry, their involvement in the sale of unlabeled hormonal milk, and their misleading assurances of the safety of synthetic milk hormones.

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Note added in proof

The following effects in BGH-treated cows have received striking recent confirmation: increased incidence of infectious diseases (Otterby, D. E., et al. *J. Dairy Sci.* 72(Suppl. 1): 329, 1989); reduction in fertility (Morbeck, D. E., et al. *J. Dairy Sci.* 72(Suppl. 1): 345, 1989; five other reports in the same issue are further confirmatory); increased levels of IGF-I in milk (Prosser, C. G., et al. *J. Dairy Res.* 56: 17-26, 1989). On August 23, 1989, the Foundation on Economic Trends, in association with farm, animal welfare, consumer, and environmental groups, petitioned FDA to ban sales of dairy products from BGH-treated cattle; the petition was based on a draft of this article. Simultaneously, national supermarkets banned dairy products from BGH-treated cows. The author's September 6 Wisconsin State testimony triggered a large-scale defensive reaction and public relations blitz by the industry. Illustrative is a Consumer Information Program by Elanco, Monsanto and Upjohn entitled, "You've had BST and Cookies All Your Life," which, apart from gross misrepresentations, falsely equates synthetic with natural BGH.

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