High-Tech Cows: The BST Controversy

INTRODUCTION

Recombinant Bovine Somatotropin (rBST), also known as rbGH, continues to be the subject of hot controversy in scientific and political circles. The Food and Drug Administration (FDA) approved the commercial use of rBST to increase milk production in dairy cattle in November 1993.[1] After six years of testing and over 130 studies[2], the agency concluded that milk and meat from cattle treated with rBST was safe for human consumption.[3] Following a 90-day ban, which expired in February 1994, the Monsanto Corporation (Monsanto) began manufacturing and distributing its genetically engineered product under the name Posilac.[4]

Although the FDA and Monsanto tout rBST as safe,[5] opponents of this drug have concerns about the long-range safety, social impact and economic consequences of the drug's commercial use. Opponents claim that the FDA failed to consider relative health and safety issues and improperly conducted necessary environ-

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[1] *Biotechnology, Interim Voluntary Guidance on BST Issued by FDA for Milk Producers*, Daily Rep. Exec., Reg. Econ. and Law, A (BNA) 26(DER Feb. 9, 1994) [hereinafter *Biotechnology*].

[2] Ann Gibbons, *FDA Publishes Bovine Growth Hormone Data*, 249 SCIENCE 852 (1990), *See also* Robert A. Bohrer, *Food Products Affected by Biotechnology*, 55 U. PITT. L. REV. 653, 654 (1994).

[3] *Use of Bovine Somatotropin (BST) in the United States: Its Potential Effects*, 17 CRR 1814 (OMB 1994). *See* also Kevin L. Ropp, *New Animal Drug Increases Milk Production*, FDA CONSUMER, May 1994, at 24.

[4] *Biotechnology, supra* note 1, at 26.

[5] FDA Commissioner David A. Kessler, M.D. stated, "This has been one of the most extensively studied animal drug products to be reviewed by the agency . . . ." The public can be confident that milk and meat from bST-treated cows are safe to consume." Kevin L. Ropp, *New Animal Drug Increases Milk Production*, FDA CONSUMER, May 1994, at 24; Tom McDermott, director of biotechnology communication for Monsanto, stated, ". . . there is no difference in milk from cows treated with rBST and cows not treated." *Biotechnology, Federal Bill Introduced to Require Labeling Milk of Hormone-Treated Cows*, DAILY REPORT FOR EXECUTIVES, June 22, 1990, A, 118.

mental impact studies before approving rBST.[6] As a result, opponents allege the FDA's approval of rBST was arbitrary and capricious.

Some opponents now seek to compel the FDA to suspend or revoke its approval of the drug until further studies are conducted.[7] Others want the FDA to require labeling of milk from cattle treated with rBST and lower the price producers receive for milk from treated cattle.[8] So far, the FDA is standing firm on its decision to approve the commercial use of rBST and has issued only restrictive guidelines for voluntary labeling of products from cattle *not* treated with the hormone.[9] To date, there are no labeling requirements for milk from treated cattle.

This article explores the controversy surrounding the commercialization of rBST. The article begins with a brief description of both naturally occurring and recombinant BST and explains the process by which the genetic hormone is manufactured. Next, the article addresses the most common concerns espoused by opponents of rBST and discusses proponents' responses to those concerns. Finally, this article examines the current regulation of rBST including objections to the proposed "qualified" voluntary labeling now contemplated by the FDA.

I. WHAT IS RBST?: NATURAL VERSUS CLONED

Somatotropin or Growth Hormone (GH) is a naturally occurring protein hormone which is produced by the anterior pituitary gland of all animals and humans.[10] It is the hormone responsible

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[6] Barnes v. Shalala, No. 94-C-0090-C, 1994 U.S. Dist. LEXIS 13549, at 2 (W.D. Wis., 1994).

[7] *Id.*

[8] H.R. REP. No. 4618, 103rd Cong., 2d Sess. (1994).

[9] 59 Fed. Reg. 6279 (1994).

[10] *BST Fact Sheet*, NEWSCAST, Summer, 1993, at 4. In May, 1993, CAST published a fact sheet discussing the benefits and safety of bovine somatotropin. This sheet was sent to congressional committee members and news media; Judith C. Juskevich & C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety*, SCIENCE, August 24, 1990, 875. J.C. Juskevich was formerly with the Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation, Division of Toxicology. C.G. Guyer is with the Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation, Division of Chemistry; *Questions and Answers About BST*, FDA VETERINARIAN, May/June, 1994, at 7; *Statement on FDA Approval of Bovine Somatotropin*, News Release (Animal Health Institute), Nov. 5, 1993 and William H. Daughaday, MD, David M. Barbano, PhD, *Bovine Somatotropin Supplementation of*

for controlling the growth and development of the animal as well as regulating normal milk production in mammals.[11] Each species produces GH which is compositionally different from GH produced by any other animal and is generally "species-specific" to that particular animal.[12] Bovine Somatotropic Hormone (also referred to as BST, Bovine Growth Hormone or BGH) is the species-specific hormone produced by cattle which is responsible for controlling the normal growth process, mammary gland development and milk production in cattle.[13] Along with other hormones, BST is present in minute concentrations in all milk produced from cows.[14]

As early as the 1930's scientists were researching BST in an effort to increase milk production in dairy cattle.[15] BST was extracted from the pituitary glands of cattle, purified and then injected into dairy cows during peak lactation times.[16] This process was not cost-effective however, because it required 200 cow pituitary glands for the production of a single injection of BST.[17] This prompted several companies to initiate research on developing a growth hormone that could be mass-produced at low cost.[18]

It was not until the significant advancement of biotechnology[19]

Dairy Cows, 264 JAMA, 1003, Aug. 2²/₂₉, 1990.

[11] Juskevich & Guyer, *supra* note 10, at 875.

[12] *BST Fact Sheet*, NEWSCAST, Summer, 1993, at 4. The term "species-specific" is technically not correct. However, it is accepted and understood by the relevant scientific community to mean that there is a difference in sensitivity as it relates to the phylogenetic tree. Higher primates, humans, are unresponsive to growth hormone from lower species such as bovine, ovine, whale and porcine. Judith C. Juskevich & C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety*, SCIENCE, August 24, 1990, 875, 877.

[13] *BST Fact Sheet, supra* note 10, at 4.

[14] Daughaday, *supra* note 10. *See also Questions And Answers About BST*, FDA VETERINARIAN, May/June, 1994, at 7. The concentration of BST in cow's milk is approximately 1 part per billion. *NIH Technology Assessment Conference Statement On Bovine Somatotropin*, 265 JAMA, 1423, 1424 (1991).

[15] Juskevich & Guyer, *supra* note 12, at 875.

[16] Council on Scientific Affairs, American Medical Association, *Biotechnology and the American Agricultural Industry*, 265 JAMA 1429, 1430 (1991).

[17] *Id.*

[18] *Id.*

[19] The Congressional Office of Technology Assessment defines biotechnology as "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses." *Developments in Agricultural Biotechnology*, 19 WM. MITCHELL L. REV. 457, 458 (1993).

in the 1980's[20] that a cost effective process was developed to produce this biological product.[21] The principle technique involved in manufacturing rBST is primarily the same technique which has been used for years in manufacturing synthetic human insulin and other biotechnologically derived products.[22] To generate the end product rBST, the BST gene is inserted into special bacteria which are grown in large quantities.[23] The bacterium use the gene as a template to replicate and synthesize the cognate protein.[24] Next, the bacteria are "killed off" so the animal product may be separated, collected and highly purified.[25] Once purified, the genetically engineered hormone is ready to be injected into cattle in specified amounts.[26] Although the genetically engineered hormone is chemically and structurally similar to the naturally occurring hormone,[27] rBST includes additional amino acids that are necessary for cloning the recombinant protein in bacteria.[28]

While the manufacturing process itself may generally be recognized by the relevant scientific and political communities as safe,[29] concerns continue to escalate regarding the drug's use on cattle. Unlike other biotechnologically derived substances which were quietly introduced with very little concern,[30] rBST has generated immense discussion and alarm with regard to potential health risks and adverse economic impact.

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[20] Daughaday, *supra* note 10.

[21] *BST Fact Sheet, supra* note 10.

[22] CHY-MAX, a biotechnologically engineered substitute for rennet, a substance indigenous to calves' stomachs which is used to make cheese, is manufactured by encoding a bovine gene onto a non-pathenogenic form of Escherichia coli. Biotechnology, Cheesemakers Use Bioengineered Substance in 30-35% of U.S.-Made Cheese, Daily Rep. Exec. (BNA) at A-12 (Dec. 13, 1991), [hereinafter Cheesemakers]. *See also,* Ropp, *supra* note 3.

[23] *Cheesemakers, supra,* note 22; Ropp, *supra* note 3; *New Animal Drug For Increasing Milk Production,* FDA Backgrounder at 1; Norman Kretchmer, *Why Not Have More Milk,* 88 PEDIATRICS 1056 (1991).

[24] Kretchmer, *supra* note 23, at 1056.

[25] Biotechnology and the American Agricultural Industry, *supra* note 16; *BST Fact Sheet, supra* note 10.

[26] Biotechnology and the American Agricultural Industry, *supra* note 16.

[27] Kretchmer, *supra* note 16.

[28] Daughaday, *supra* note 10.

[29] Ropp, *supra* note 3, at 25.

[30] *Cheesemakers, supra* note 22.

II. CONCERNS ABOUT rBST

Concerns over the commercial use of rBST center around three main areas: (1) the impact that long-term commercial use of rBST will have on the environment; (2) the economic impact, with particular focus on small or family-owned dairy farms as well as increased federal spending for price-support programs; and (3) health and safety considerations involving human consumption of products from treated cattle in addition to concern for the animal's overall health and diminished longevity.

A. Environmental Impact

1. Advocates' Argument

Advocates of rBST assert commercial use of the hormone will have beneficial effects on the environment. "On a global level the positive impact of [r]BST is significant. Beyond the financial benefits of increasing milk yield, rBST can help to reduce waste, control pollution. . ."[31] Advocates of the hormone argue that if farmers implement rBST into their dairy programs, they (farmers) will be able to reduce herd sizes while still maintaining the quantity of milk produced, because the same amount of milk can be produced with fewer cows.[32] It is estimated that a grand-scale application of rBST could reduce the nation's dairy herd from 11 million to 8 million cows.[33] As herd size is reduced, so is the amount of byproduct produced, such as urine and manure. Approximately 15 percent of the total methane emissions produced are attributed to cattle and widespread adoption of rBST would reduce this number by 5.5 percent per unit of milk produced.[34] Central to advocates' argument, however, is the widespread adop-

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[31] *Use of Bovine Somatotropin (BST) in the United States: Its Potential Effects, supra* note 3.

[32] *BST Fact Sheet, supra* note 10.

[33] These numbers were derived from a study done by Kalter in 1989 and were merely a *prediction* of how the size of the national dairy herd would be altered if there were widespread adoption of rBST. L.J. (Bees) Butler & Gerry Cohn, *The Economics of New Technologies in Dairying: BGH vs. Rotational Grazing*, Research Paper, Research and Education Program, UC Davis, July 1992, at 5.

[34] These statistics were derived from the Office of Technology Assessment, 1991. *"U.S. Dairy Industry at a Crossroad: Biotechnology and Policy Choices."* Congress of the United States, Office of Technology Assessment, Washington, DC. OTA-F-470, U.S. Government Printing Office.

tion of rBST by dairy farmers, and more importantly, consumer acceptance of milk from treated cattle.

In a 1988 survey conducted by the University of California Department of Agricultural Economics, UC Davis, it was found that most dairymen will wait to see how rBST works on other dairies before using it themselves.[35] Although there were regional differences (see Table 1 below) and the survey was limited to California dairymen, on the average, dairymen indicated they would possibly wait approximately twenty-two months before trying rBST. As many as twenty-nine percent of the respondents said they would not use rBST at all.[36] The main reason given by farmers who would not use the product was concern over negative consumer reaction to the hormone and its adverse effect on milk sales.[37] Sales and response, since rBST (Posilac) was approved, validate these concerns.[38]

TABLE 1

DELAY IN ADOPTION OF RBST

Region	Length of Time Would Wait to Use rBST
Northern California	17.0 months
South Valley	25.0 months
Southern California	26.5 months

Approximately six months after the FDA approved rBST, Tom McDermott, director of Biotechnology Communication for Monsanto Co., announced that rBST had been given to approximately 800,000 cows.[39] Although this number may sound significant, this is only 8 percent of the entire U.S. dairy herd.[40] In August, 1994,

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[35] Lydia Zepeda, *A Survey of California Dairy Farmers: Potential Adoption of Bovine Somatotropin*, University of California Department of Agricultural Economics, UC Davis and Agricultural Issues Center, UC AIC Issues Paper No. 88-1, Jan. 1988, at 8.

[36] *Id.*

[37] *Id.*

[38] *BST Opponents Rejoice Over Darigold Reversal on Hormone*, THE SEATTLE TIMES, Food, Aug. 31, 1994, at F7; *Dairies Find Niche in Organic Food Market; Demand Soars For Chemical-Free Milk*, STAR TRIBUNE, News, Dec. 21, 1994, at A1.

[39] *Monsanto Says Few Mastitis BST Cases Seen*, REUTERS, Financial Report, Sept. 15, 1994.

[40] *Id.*; *See also*, Robert Steyer, *Monsanto's BST Figures Rebut Critics of Drug*, ST.

Darigold-Washington's largest dairy cooperative-reinstated a partial ban on milk from rBST treated cattle, attributing it's decision to the public pressure put on grocery stores over the use of rBST.[41] Darigold's spokesman Pete Delaunay noted that less than 5 percent of the company's 1,600 member-farmers in Washington, Oregon and Idaho had expressed any interest in using rBST.[42] Not suprisingly, a small cooperative of farmers in Minnesota, who produce and sell "organic" milk, noted that their sales have more than quadrupled since the approval of rBST.[43]

The "significant positive impact" argument set forth by advocates of rBST hinges on national widespread adoption of rBST by dairy farmers and consumer acceptance of milk produced from treated cattle. Dairy farmers will not adopt rBST unless they know they can make a profit.[44] If consumers reject milk from treated cattle, farmers will not use the hormone no matter how safe it is. Given that more than three-quarters of the public are concerned about consuming genetically engineered food, and are particularly concerned about genetically engineered meat and dairy products, noncompulsory consumer acceptance is not likely, and the advocates' argument fails.[45] However, as discussed below in section V, the method and procedures employed by the FDA in approving rBST (Posilac) arguably amount to compulsory acceptance by consumers. If this is the case, advocates may win the environmental argument, but it will likely be at the expense of the public's confidence in the FDA.

LOUIS POST-DISPATCH, Bus., Sept. 15, 1994, at C3.

[41] *BST Opponents Rejoice Over Darigold Reversal on Hormone, supra* note 38.

[42] *BST Opponents Rejoice Over Darigold Reversal on Hormone, supra* note 38.

[43] *Dairies Find Niche in Organic Food Market; Demand Soars for Chemical-Free Milk, supra* note 38.

[44] A 1988 survey of Wisconsin dairy farmers revealed that approximately 44 percent of the 270 respondents surveyed would not adopt rBST unless they could make an additional profit of $200 per cow per year. In the same survey another 34 percent said they would not use rBST unless they could make an additional profit of between $100 to $200 per cow per year. Only 22 percent would be willing to accept less than $100 additional profit per cow per year. In a separate survey it was noted that some farmers would not adopt rBST unless they would receive a $2:1 or $3:1 return on their investment. L.J. Butler & H.O. Carter, *Potential Economic Impacts of Bovine Somatotropin on the U.S. Dairy Industry - A West Coast Perspective,* US AIC Issues Paper No. 88-4, Feb. 1988, at 4.

[45] Citing a 1987 study by the Office of Technology Assessment. Milton C. Hallberg, *Emerging Trends, Consequences and Policy Issues,* Bovine Somatotropin & Emerging Issues, (1992) p. 5, 6.

In addition to farmer adoption and consumer acceptance, advocates assume farmers who use rBST will in fact reduce the size of their herd, thereby reducing pollution. It is hard to say if those farmers who used rBST (Posilac) for the past year have actually decreased their herd sizes. In the case of California dairy farmers, only Monsanto knows for certain which farmers are using the genetically produced hormone.[46] Absent disclosure by Monsanto, it is difficult, if not impossible, to know if advocates' statistics and predictions are correct.

2. Opponents' Argument

Opponents of rBST share advocates' concern over waste reduction and pollution control. Opponents' environmental concerns concentrate on the consequences of confined dairying and the potential for a marked increase in such operations due to the touted financial benefits of rBST. While intensified systems make it possible to milk up to 1000 cows on as few as twenty to thirty acres, there is also a negative impact.[47] There is a great potential for nitrate leaching of groundwater due to manure confinement, overuse of fertilizers, and soil erosion.[48]While advocates argue adoption will decrease pollution, opponents fear commercial use of rBST may ultimately lead to greater pollution and costly clean-up requirements.[49] Opponents argue that if farmers find they can decrease their herd sizes and still maintain or increase their production, farmers will be eager to abandon alternate forms of dairy farming such as rotational grazing[50] and adopt confined dairying at the expense of the environment.[51] This argument has little weight. First, in some areas of the country, drylot dairies are the predominant form of dairying.[52] Second, as noted earlier,[53]

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[46] Jane Kay, *Artificial Hormone Causes Stir; School District in California Wants Labels on Boosted Milk*, HOUSTON CHRONICLE, Dec. 15, 1994, at D2.

[47] Butler & Carter, *supra* note 44, at 1.

[48] Butler & Cohn, *supra* note 33, at 34.

[49] Butler & Cohn, *supra* note 33, at 34.

[50] Rotational grazing involves, ". . . a flexible management system of pasture grazing that promotes sustainable pasture management, decreases or eliminates confinement feeding, and shifts much of the work of harvesting and maintaining soil fertility back to the animal." Butler & Cohn, *supra* note 33, at 2.

[51] Although the traditional form of dairying employs a confined system, opponents fear the few alternate systems will be abandoned in favor of confined dairying. Butler & Cohn, *supra* note 33.

[52] Drylot dairying is a confined dairying system. Butler & Carter, *supra* note

dairy farmers do not seem eager to adopt rBST. Additionally, the added costs and care involved in maintaining the animals' health in an intensified agricultural operation[54] may more than offset any gain from increased production and actually discourage widespread use of confined dairying and possibly rBST.

B. Economic Impact

1. Impact On Small Farmers

Some critics of rBST oppose its use because they believe it will force small dairy farmers to go out of business.[55] As the nation's milk supply increases, owing to the widespread use of rBST, milk prices will decrease and small dairy farmers will be driven out of business by larger dairies.[56] In response to these concerns, the Office of Management and Budget (OMB) conducted a social, economic, and environmental impact study during the 90-day moratorium imposed between November, 1993, and February, 1994.[57] The OMB concluded that rBST should be equally effective and profitable for both small and large dairies.[58] Because rBST does not require implementation or the use of any particular equipment or practice that is not readily available to small and large farmers alike, smaller farmers should not be at a disadvantage.[59]

It is arguable whether the small farmer can utilize rBST as effectively and profit as favorably as the larger dairy. Smaller farms generally have lower-producing cattle.[60] It is uncertain whether the lower yield is due to inadequate farm management or to the limited genetic potential of the individual cow.[61] Nevertheless, higher-producing cattle have a greater response rate to rBST[62]

44, at 1.

[53] *See* Butler & Carter, *supra* note 44 for advocates argument.

[54] This is discussed more fully in section III (2)(a) of this comment.

[55] *Biotechnology, FDA Approves Engineered Hormone to Increase Milk Production in Cows,* Daily Rep. Exec., Reg. Econ. and Law, (BNA) No. 215, at D-36, (Nov. 9, 1993). Statement made by Sen. Russ Feingold.

[56] *Cheesemakers, supra,* note 22; *New Animal Drug For Increasing Milk Production,* FDA Backgrounder at 1; Norman Kretchmer, *Why Not Have More Milk,* 88 PEDIATRICS 1056 (1991).

[57] *Questions and Answers About BST,* FDA VETERINARIAN, May/June 1994, at 9.

[58] *Id.*

[59] Milton C. Hallberg, *supra* note 45, at 208.

[60] Milton C. Hallberg, *supra* note 45, at 209.

[61] Milton C. Hallberg, *supra* note 45, at 209.

[62] Butler & Cohn, *supra* note 33, at 13.

and the smaller farmer with a lower-yielding herd cannot realize the same profit margin as a farmer with a more productive herd.

Second, as noted by the OMB, increased milk production will likely lead to lower milk prices over the next six years.[63]Lower milk prices translate into less profit for dairy farmers.[64] Even if a small family-owned operation adopts and benefits from rBST to the same extent as a larger farm,[65] they still may not be able to economically survive the reduction in net profits per cow, because they have fewer head of cattle.[66] Farms with fewer than thirty-six cows are the most vulnerable to fluctuations in milk prices and may not be able to withstand the decline.[67] When the rate of return was compared to farm assets it was found that farms with less than 36 cows had a rate of return of only about 5 percent.[68] On farms with 36 to 600 head of cattle the rate of return was 10 percent and on farms with more than 600 cows the return was as high as 16.4 percent.[69] Although collectively, farms with less than 36 cows produce only about 11.9 percent of the nation's milk supply, they make up 41.1 percent of the nation's dairy farms.[70] This means that if rBST is widely adopted, and milk prices fluctuate as predicted, the majority of farmers will be the hardest hit. As profit margins tighten, smaller farmers may find themselves squeezed out of the industry by the larger corporate operations.

In addition, rBST may not be as profitable as advocates claim, due to the hidden costs associated with its use. Although rBST-treated cattle utilize feed five to fifteen percent more efficiently for milk production than non-treated cattle, feed costs are higher.[71] It is estimated that for every ten percent increase in milk production an additional six percent expenditure on feed costs is necessary to maintain the energy requirements of the

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[63] *Use of Bovine Somatotropin (BST) in the United States: Its Potential Effects*, *supra* note 3, at iii.

[64] *Biotechnology, Bills Offered as FDA Signals Approval of Milk From Cows Treated With Hormone*, BUREAU OF NATIONAL AFFAIRS, DAILY REPORT FOR EXECUTIVES, May 7, 1993, Regulation, Economics and Law, at 87.

[65] Hallberg, *supra* note 45, at 213.

[66] Hallberg, *supra* note 45, at 213.

[67] Hallberg, *supra* note 45, at 213.

[68] Hallberg, *supra* note 45, at 213.

[69] Hallberg, *supra* note 45, at 213.

[70] Hallberg, *supra* note 45, at 213.

[71] Butler & Cohn, *supra* note 33, at 5.

cow.[72] Labor costs are expected to increase as well because additional manpower is generally necessary to administer the injections of rBST.[73] Costs of hauling milk will be higher due to the increase in milk production.[74] Veterinary costs are also expected to rise an average of 7 to 8 percent due to increased stress and mastitis.[75] Where mastitis is problematic, costs of antibiotics, testing of milk for pus and antibiotic residue and costs of hauling and dumping of tainted milk may increase dramatically. Finally, the cost of rBST itself is a factor to be considered. Presumably, in an effort to boost sales and encourage widespread adoption of rBST, the initial introductory cost of the drug (Posilac) was $5 per shot.[76] On a small farm of 50 head of cattle the cost would be $4500 per year.[77] In September, 1994, less than a year after approval for commercial sale of rBST, Monsanto increased the price of its product to $5.80 per shot; a 16% increase.[78] The farmer with fifty head of cattle now pays $5,200 (a $720 increase in cost) to treat his cattle with the milk producing hormone. These added costs may more than offset any profit attributable to the increase in production. As a result, the farmer may wind up losing more than he would have gained.

One would think these facts would put opponents' concerns to rest. Theoretically, economics should promote the use of rBST. Unfortunately, small and large dairies may adopt rBST in an effort to survive. Many California farmers believe they will be forced to use rBST to stay in business.[79] One study indicates that

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[72] Butler & Cohn, *supra* note 33, at 5.

[73] Butler & Cohn, *supra* note 33, at 5.

[74] Butler & Cohn, *supra* note 33, at 5.

[75] Butler & Cohn, *supra* note 33, at 5.

[76] The initial list price was $6.60. However, an introductory discount price of $5 per shot was given to farmers who were willing to purchase enough Posilac (rBST) to treat their entire herd. *Milk Drug Price Raised,* CHICAGO TRIBUNE, Sept. 21, 1994, at Bus. 1.

[77] This figure was derived at by multiplying the cost per shot ($5) by the injection treatment cycle (18). Treatments are generally started at approximately 60 days of lactation and given every 14 days for 252 days (18 injection cycles). T.C. White et al., *Clinical Mastitis in Cows Treated with Sometribove (Recombinant Bovine Somatotropin) and Its Relationship to Milk Yield,* 77 J DAIRY SCI, 2249 at 2251 (1994).

[78] *Milk Drug Price Raised, supra* note 76, at Bus. 1

[79] One farmer stated, "I'm not for BST, but if my neighbor uses it, I'll use it." Lydia Zepeda, A SURVEY OF CALIFORNIA DAIRY FARMERS: POTENTIAL ADOPTION OF BOVINE SOMATOTROPIN, UNIVERSITY OF CALIFORNIA DEP'T OF AGRICULTURAL ECO-

farmers who reject the hormone have only a fifty percent chance of surviving in the industry, while those who are willing to use rBST have a seventy-five percent chance of succeeding.[80] Given these choices, widespread adoption by farmers may be forthcoming. As of February 1995, only about eleven percent of dairy producers were using the drug.[81]

2. The Federal Government's Dairy Price-Support Program Costs

The main thrust of opponents' argument in this area is, "[W]hen milk supplies are already plentiful, why produce more milk when the government is obligated to buy up the surplus?"[82]

The United States dairy industry is highly regulated, and has a complex set of laws for regulating the price of milk.[83] On the up side, this elaborate scheme ensures there will always be an adequate milk supply to consumers.[84] On the down side, it means the government will purchase, in the form of storable dairy products (butter, nonfat dry milk powder and cheese), any surplus milk produced.[85] The government then disposes of these products through school lunch programs, giveaway programs and through other noncompetitive outlets.[86] If the market price exceeds the support price by 10 percent, the Commodity Credit Corporation (CCC) may sell the excess purchased dairy products on the open market.[87] The amount acquired by the CCC is a good indication of the United States dairy sector's performance.[88]

NOMICS, UC Davis and Agricultural Issues Center, Jan. 1988, at 11.

[80] *Biotechnology, Minnesota Governor Vetoes Extension of Ban on Usage of Bovine Somatotropin*, BUREAU OF NATIONAL AFFAIRS, DAILY REPORT FOR EXECUTIVES, May 31, 1991, at A13.

[81] Alison Lucas, *BST Scores Strong First-Year Growth*, CHEMICAL WEEK, Feb. 15, 1995, News, at 18.

[82] *Udder Confusion*, (University of California at Berkeley) WELLNESS LETTER, May 1994, at 3.

[83] The laws governing milk production, marketing, advertising and pricing are primarily incorporated in Title 7 USC. A more detailed discussion is beyond the scope of this article. *See also* Butler & Cohn, *supra* note 33, at 5.

[84] 7 U.S.C. § 608c (1995).

[85] The Commodity Credit Corporation is the entity responsible for purchasing the excess dairy products on behalf of the government. 7 U.S.C. § 1446e (1995).

[86] *Id.*

[87] Ropp, *supra* note 22, at 27.

[88] Kevin L. Ropp, *New Aminal Drug Increases Milk Production*, FDA CONSUMER,

Since 1980, the amount of excess dairy products purchased by the federal government has averaged between eight to ten billion pounds a year.[89] This is three to five billion pounds over the acceptable annual level.[90] Considering the average dairy cow produces about 225 pounds of milk a year, that more than 800,000 dairy cows in the United States have been treated with rBST since commercial use began in February, 1994,[91] and that rBST will increase the average annual yield per cow by about 26 pounds, this can only lead to an even greater surplus of milk with a corresponding increase in federal spending.

In a study by the OMB on the expected overall economic effects from the commercial use of rBST, the OMB estimated United States milk production should increase by only one percent per year through fiscal year 1999.[92] As a likely consequence, the OMB admitted, milk prices should be about two percent lower per year over the next six years.[93] Lower milk prices mean lower farm income for dairy farmers and higher dairy price-support costs for the Federal Government.[94] In spite of the increase in price-support costs, the OMB asserts Federal costs for nutrition programs like Food Stamps and the Special Supplemental Food Programs for Women, Infants, and Children (WIC) should decrease.[95] Although the lower cost of nutrition programs is projected to completely offset the increased cumulative costs of the Federal dairy price-support program over a ten year period, the earliest any savings from these programs will be realized is fiscal year 1997.[96] These figures and costs could be skewed if rBST is not widely adopted by farmers or accepted by consumers.

Despite the government's assurance that the overall economic effect will be positive for the nation, Rep. Bernard Sanders (I-Vt), one of the principal leaders in the fight against commercializa-

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May 1994, at 24.

[89] *Id.* at 27.

[90] *Id.* The arbitrarily established acceptable level of surplus dairy products purchased by the government is five billion pounds annually. From 1950 to 1980 only twice has the surplus exceeded five billion pounds. *Id.*

[91] *Monsanto Says Few Mastitis BST Cases Seen*, *supra* note 39, REUTERS Sept. 15, 1994, Fin. Rep.

[92] The Executive Branch of the Federal Government, *supra* note 3, at iii.

[93] The Executive Branch of the Federal Government, *supra* note 3, at iii.

[94] The Executive Branch of the Federal Government, *supra* note 3, at iii.

[95] The Executive Branch of the Federal Government, *supra* note 3, at iii.

[96] The Executive Branch of the Federal Government, *supra* note 3, at iv.

tion of rBST, claims synthetic rBST will cause serious economic problems.[97] In interpreting the significance of the OMB's social, environmental and economic study, Sanders projects that, by using the OMB's own estimates, dairy surpluses caused by rBST will cost farmers $1.3 billion in income over the next five years and will increase the federal budget by more than $500 million.[98] Again, these figures depend on consumers' acceptance of milk and milk products from cattle treated with rBST. To date, there is conflicting data on consumer satisfaction. While advocates assert milk demands have remained constant,[99] critics claim milk sales have dropped since the hormone was approved and went on sale.[100]

C. Health and Safety

According to former United States Surgeon General C. Everett Koop, M.D., "Milk from cows given supplemental bovine somatotropin is the same as any other milk . . . . Every issue and every question about BST has been thoroughly and carefully studied by the federal government and several independent scientific institutions."[101] FDA Commissioner David A. Kessler also noted, "[T]his has been one of the most extensively studied animal drug products to be reviewed by the agency . . . [t]he public can be confident that milk and meat from rBST-treated cows is safe to consume."[102] Yet notwithstanding the FDA's comprehensive review of the drug's safety and efficacy, before approval was given for commercialization, some safety questions remain unanswered.

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[97] *Biotechnology, Federal Bill Introduced to Require Labeling Milk of Hormone-Treated Cows*, DAILY REP. EXEC., or THE BUREAU FOR NATIONAL AFFAIRS, INC, June 22, 1994, at A118.

[98] *Id.*

[99] *BST-free Labels May Lead to Prosecution; Nutritional Labeling Certifying Dairy Products to be Free From Bovine Somatotropin Hormones*, DAIRY INDUSTRIES INTERNATIONAL, April, 1994, at 5.

[100] Janice Okun, *No Easy Answers For Hormone-Wary Milk Drinkers*, THE BUFFALO NEWS, March 9, 1994, at Lifestyles, 7.

[101] Statement by C. Everett Koop, M.D., on the introduction of supplemental BST (Feb. 6, 1994).

[102] Susan M. Cruzan, HHS NEWS, (U.S. Dept. of Health and Human Services), Nov. 5, 1993.

1. Safety in Humans

The first of these questions involves the FDA's conclusion that milk and meat from treated cattle is safe to consume because the concentration of BST in milk from treated cattle is no greater than the concentration in untreated cattle.[103] While it may be true that the level of BST in milk remains constant for both treated and untreated cattle, this does not address the issue of what amount of rBST is present in milk. The FDA appears to rest its opinion that food products from rBST-treated cattle are safe on the assumption that BST and rBST are the same. rBST is chemically and structurally similar to BST, however, it is not identical.[104] As noted in section II, the recombinant hormone contains additional amino acids necessary for cloning. The additional effect that "cloning" amino acids may have on human health is unknown.[105] Further, it is uncertain whether the additional amino acids change or affect the interaction between BST, rBST and other hormones.[106] These questions raise legitimate concerns as to the drug's safety in human consumption.

Notwithstanding these concerns, in 1985, the FDA authorized milk from "test cattle" treated with rBST to be commingled with milk from nontreated cattle.[107] The "tainted" milk has been included in the commercial milk supply and consumers have been exposed to unknown risks for the past ten years.[108] The FDA's decision to permit distribution and consumption of food products from treated cattle was based on the FDA's evaluation of research data then available and its conclusion that naturally occurring BST and rBST are indistinguishable.[109] Yet, no test has ever existed or been devised to differentiate between the two

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[103] *NIH Technology Assessment Conference Statement On Bovine Somatotropin, supra* note 10, at 1424. The approximate concentration of BST in cow's milk is 1 part per billion; virtually the same concentration as human growth hormone in human breast milk.

[104] *Biotechnology and the American Agricultural Industry, supra* note 16, at 1431.

[105] *Biotechnology and American Agricultural Industry, supra* note 16, at 1432.

[106] *Biotechnology and American Agricultural Industry, supra* note 16, at 1431.

[107] William H. Daughaday, M.D. David M. Barbano, Ph.D., *Bovine Somatotropin Supplementation of Dairy Cows*, JAMA, Aug. 2²/₂₉, 1990, at 1003.

[108] Potential liability for injury resulting from exposure to rBST is beyond the scope of this article.

[109] FDA Backgrounder at 1; Norman Kretchmer, *Why Not Have More Milk*, 88 PEDIATRICS 1056 (1991).

hormones.[110]

A second area of concern is the increased concentration of insulin-like growth factor I (IGF-I) in milk from treated cattle. Normally the concentration of IGF-I in cows milk is 1.5 ug/L to 8 ug/L.[111] In cattle treated with rBST, concentrations of IGF-I were found to increase by as much as 2 to 5 ug/L.[112]While opponents recognize that pasteurization lowers the level of BST in milk, it has no effect on concentration levels of IGF-I in milk.[113] The health effects to humans from ingesting higher than normal concentrations of IGF-I is unknown.[114] Further research and studies should have been conducted before rBST was approved for commercial use.[115]

2. Safety in Cattle

The effect of rBST on the health of cattle may be measured by examining an increase or decrease in factors such as mastitis, wasting of the animal due to a negative energy balance and reproductive efficiency (pregnancy rates).[116]

a. Mastitis

The primary argument advanced by critics is that cattle treated with rBST demonstrate an increased incidence of mastitis.[117] The

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[110] Council on Scientific Affairs, American Medical Association, *Biotechnology and the American Agricultural Industry*, 265 JAMA 1429, 1430 (1991).

[111] *NHI Technology Assessment Conference Statement on Bovine Somatotropin, supra* note 10, at 1424.

[112] *NHI Technology Assessment Conference Statement on Bovine Somatotropin, supra* note 10, at 1424.

[113] *NHI Technology Assessment Conference Statement on Bovine Somatotropin, supra* note 10, at 1424.

[114] Council on Scientific Affairs, American Medical Association, *Biotechnology and the American Agricultural Industry*, 265 JAMA 1429, 1430 (1991).

[115] *Id.*

[116] Butler & Cohn, *supra* note 33, at 17. GF Gallo and E. Block, EFFECTS OF RECOMBINANT BOVINE SOMATOTROPIN ON NUTRITIONAL STATUS OF DAIRY COWS DURING PREGNANCY AND OF THEIR CALVES, Department of Animal Science, Macdonald College of McGill University.

[117] *Udder Confusion*, supra note 82, at 1. Mastitis is an inflammation of the udder and is generally accepted as the most costly and widespread disease of the dairy industry. The disease affects the quantity of milk by inhibiting milk production in addition to altering the quality of milk produced. It is believed the depressed milk yield is due to damaged secretory tissue attributable to the inflammation. *NIH Technology Assessment Conference Statement on Bovine Somatotropin,*

FDA admits, ". . . there is some increase in mastitis, but it's unclear how much."[118] There is also disagreement as to the cause of mastitis. White et al., studied the effect of rBST on mastitis in fifteen full lactation trials involving 914 Jerseys, Holstein or Holstein-Friesian cows in Europe and the United States.[119] The optimum dose (500 mg.) of rBST was injected every two weeks for 252 days, commencing sixty days postpartum (after delivery).[120] The results indicated (Table 2) that the incidence of mastitis was comparable with that of a well-managed commercial dairy herd.[121]

TABLE 2

THE EFFECT OF rBST ON MASTITIS IN A FULL LACTATION OF 914 COWS

Variable	Control	Bovine Somatotropin (rBST)
Cows,	447	467
Pretreatment		
Total cases	76	134
Cows with mastitis,	11.4	16.3%
Treatment		
Total cases	227	339
Cows with mastitis,	21.3	29.6%

Source: T. C. White et al., *Clinical Mastitis in Cows Treated with Sometribove (Recombinant Bovine Somatotropin) and Its Relationship to Milk Yield,* Table 2 p. 2254.

There was only an 8.3% difference between the control group (21.3%) and the group given rBST treatment (29.6%). This difference is even less significant considering the incidence of mastitis, during pretreatment, was 4.9% higher for the group given

supra note 14, at 1425.

[118] *Udder Confusion, supra* note 82, at 1. *See also,* RECOMBINANT BOVINE SOMATOTROPIN (BST) CONSENSUS DOCUMENT, State of California Interagency Biotechnology Committee, Animal Health, April 21, 1994.

[119] *See also,* T. C. White et al., *Clinical Mastitis in Cows Treated with Sometribove (Recombinant Bovine Somatotropin) and Its Relationship to Milk Yield, supra* note 77, at 2253.

[120] T. C. White et al., *supra* note 77, at 2249.

[121] T. C. White et al., *supra* note 77, at 2253.

rBST (16.3%) than for the control group (11.4%). Additionally, even though nearly one-third (29.6%) of the cows treated with rBST developed mastitis, 16.3% of the same group were found to have the disease prior to treatment. In reality there was only a 13.3% increase in incidence among the group when rBST was used. This is comparable to the 9.9% increase within the control group. The data ultimately indicates that there was only a 3.4% increase in mastitis in cattle treated with rBST over the control group. One explanation for this inappreciable increase is that the cattle in the treatment group were more susceptible to developing mastitis and that rBST had no effect on the incidence of mastitis.[122]

McClary et al. had similar results when they studied the lactational effects of various doses of rBST on 193 primiparous (Table 3) and 159 multiparous (Table 4) Holsteins.[123]

TABLE 3

INCIDENCE OF MASTITIS IN PRIMIPAROUS COWS RECEIVING TREATMENT WITH 0, 160, 320 OR 640 MG OF SOMIDOBOVE (RBST)

Variable	0mg	160mg	320mg	640mg
Total cows	49	48	49	47
Cows affected	12	13	16	15
Total mastitis cases	29	27	34	45

Source: D. G. McClary, et al., *The Effects of a Sustained-Release Recombinant Bovine Somatotropin (Somidobove) on Udder Health for a Full Lactation*, 77 J. Dairy Sci. (1994), Table 2, p. 2265.

[122] *See also*, T. C. White et al., *Clinical Mastitis in Cows Treated with Sometribove (Recombinant Bovine Somatotropin) and Its Relationship to Milk Yield, supra* note 77, at 2254.

[123] The term primiparous means this is the cow's first pregnancy. The term multiparous indicates the cow has had previous pregnancies. D. G. McClary, et al., *The Effects of a Sustained-Release Recombinant Bovine Somatotropin (Somidobove) on Udder Health for a Full Lactation*, 77 J. Dairy Sci. (1994), 2261.

TABLE 4

INCIDENCE OF MASTITIS IN MULTIPAROUS COWS RECEIVING TREATMENT WITH 0, 320, 640 OR 960 MG OF SOMIDOBOVE (rBST)

Variable	0mg	320mg	640mg	960mg
Total cows	38	41	40	40
Cows affected	20	24	14	19
Total mastitis cases	59	63	30	50

Source: D. G. McClary, et al., *The Effects of a Sustained-Release Recombinant Bovine Somatotropin (Somidobove) on Udder Health for a Full Lactation*, 77 J. Dairy Sci. (1994), Table 2, p. 2265.

There were only sixteen more cases of mastitis noted among the primiparous group receiving the highest dose of rBST than the control group.[124] The results from the multiparous group were even more impressive. In the higher-dosage groups, the incidence of mastitis actually decreased. The total number of cows affected remained nearly constant for both groups. The results seem to indicate that primiparous cows are more susceptible to developing mastitis when treated with rBST than multiparous cows. However, rarely can mastitis be attributed to a single cause.[125] More often it is the result of a interaction between various causes such as genetics, the environment and management.[126]

b. Wasting

Following injection of rBST, several physiological processes are affected which result in the increase of milk production.[127] First, there is a noted increase in mammary uptake of nutrients necessary for milk synthesis.[128] This is accompanied by an altered metabolism in other tissues such as a decrease of nonmammary use

[124] This is 140 mg. higher than the recommended dose of 500 mg.. *Id.* at 2265, Table 2.

[125] T.C. White et al., *supra* note 77, at 2250.

[126] T.C. White et al., *supra* note 77, at 2250.

[127] *NIH Technology Assessment Conference Statement on Bovine Somatotropin*, *supra* note 103, at 1423.

[128] Milton C. Hallberg, *supra* note 59, at 74.

of blood sugar, decrease in body-fat production and increase in body-fat breakdown.[129] The decrease of body fat continues for anywhere from two weeks[130] to three months[131] until the increase in dry-matter intake is sufficient to provide the extra nutrients needed for increased milk production.[132] Ultimately the availability of nutrients for milk synthesis is increased and milk production is boosted.[133] However, during the initial phase of treatment when the cow enters this prolonged period of negative energy balance, the cow's body reserves are mobilized to bolster the higher rate of milk production and the animal loses weight (wastes) due to the increased conversion of body fat into milk.[134] Cattle treated with rBST may persist in a negative energy balance for nearly half of their ten-month lactational period.[135] To prevent complications during this time, high quality care and proper management are essential.[136]

c. Reproductive Efficiency

Cows treated with rBST for up to two consecutive lactations demonstrated lower reproductive efficiency.[137] These results were not surprising because higher milk-producing cows generally have a more difficult time getting pregnant.[138] In a Canadian study, researchers found that cows treated with only 350 mg of rBST[139]

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[129] Milton C. Hallberg, *supra* note 45, at 74.

[130] Milton C. Hallberg, *supra* note 45, at 74.

[131] Butler & Cohn, *supra* note 33, at 17.

[132] Hallberg, *supra* note 45, at 74.

[133] Butler & Cohn, *supra* note 33, at 17.

[134] Baldwin, RL & Knapp JR, *Recombinant Bovine Somatotropin's Effects on Patterns of Nutrient Utilization in Lactating Dairy Cows*, 58 Am. J. Clin. Nutr. 1993, Aug. 282S.

[135] Butler & Cohn, *supra* note 33, at 17.

[136] Butler & Cohn, *supra* note 33, at 17.

[137] Burton, J.L. et al., *Health and Reproductive Performance of Dairy Cows Treated for up to Two Consecutive Lactations with Bovine Somatotropin*, 77 J DAIRY SCI (1990), 3258.

[138] Butler & Cohn, *supra* note 33, at 17.

[139] Cows were given 350 mg of sustained-released rBST every two weeks beginning 98 to 112 days postpartum (after delivery) and continuing through their entire lactation. Galo, G.F., *Effects of Recombinant Bovine Somatotropin on Nutritional Status of Dairy Cows During Pregnancy and of Their Calves*, 73 J DAIRY SCI (1990) 3266. It should also be noted that the optimal dose of rBST currently recommended is 500 mg every two weeks; 150 mg more than was used in this study.

had an increased calving interval by thirty-one days.[140] While this increase may result in economic loss to the farmer due to increased costs of artificial insemination and bull-servicing,[141] it could also extend the productive life of the animal by eliminating some of the stress of pregnancy over the long term.[142]

IV. Use In Other Countries: A More Conservative Approach

Despite the overwhelming acceptance of the Food and Drug Administration's approval of rBST by notable American agencies and organizations,[143] other nations remain skeptical about the proclaimed benefits of rBST and have concerns about the social and economic impact of rBST.[144] As recently as January, 1995, the European Union's Council of Agricultural Ministers opted to extend its ban on the commercial marketing and use of rBST until the year 2000.[145] Presumably, this decision was based on the recommendations of various committees who primarily oppose the use of rBST for socioeconomic reasons. The Ethics Committee and the EC Committee for Veterinary Medicinal Products found that rBST met the safety, quality and efficacy standards necessary for authorization. Both committees, however, recommended certain requirements and safeguards be implemented before the hormone was authorized for use.[146] Likewise the Economic and Social Committee (ESC) opposed the marketing and use of the hormone.[147] Concerned that consumer resistance to the use of

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[140] Butler & Cohn, *supra* note 33, at 17.

[141] Butler & Cohn, *supra* note 33, at 17.

[142] Butler & Cohn, *supra* note 33, at 17.

[143] Animal Health Institute, News Release Nov. 5, 1993; American Medical Association, News Release Nov. 5, 1993; American Dietetic Association, News Release Nov. 5, 1993; American Academy of Pediatricians, World Health Organization, and National Institutes of Health, *No Easy Answers For Hormone-Wary Milk Drinkers*, The Buffalo News, Mar 9, 1994, Lifestyles, 7.

[144] Bureau of National Affairs, Inc., Daily Report For Exe., July 14, 1993. see also Bureau of National Affairs, Inc., Daily Report For Executives, Dec. 2, 1993, and Reuters Limited, the Reuter European Community Report, Sept. 28, 1994, and McGraw-Hill Inc. Biotechnology Newswatch, Jan. 2, 1995, and Information Access Co., Agra Europe, Aug. 19, 1994.

[145] McGraw-Hill Inc., Biotechnology Newswatch, January 2, 1995. This current ban replaces a moratorium on the use of the hormone that has been in place since 1989. The EC also banned the sale of meat from cattle treated with the hormone.

[146] 133 DER, d16 (1993).

[147] Reuters Limited, the Reuter European Community Report, Sept. 28, 1994.

rBST would have an adverse impact on the dairy sector,[148] the ESC recommended that further research be conducted to develop a test to detect rBST. This would ensure that consumers retained " . . . a genuine choice in matters of labelling."[149]

The European Union's concerns lie not so much with the safety of the drug as they do with the negative economic impact that rBST will have on a sector already plagued by tremendous surpluses. There is a genuine fear that if rBST is implemented into commercial use, the larger more sophisticated producers will exacerbate the existing overabundance of milk products, drive milk prices down, and thereby squeeze out smaller and less efficient dairies.[150] While the United States is willing to accept such a scenario, the European Union takes a more protective attitude.

In Germany, the climate is much the same. German milk processors stand staunchly opposed to the use of rBST.[151]Concerned that the commercial use of rBST might spoil the "fresh and natural" image dairy products currently enjoy, German Secretary of State at the Ministry of Food, Wolfgang Grobl, favors a seven year moratorium on the drug's use in milk production.[152]Currently, there is only a one-year ban on the commercial use of rBST. [153]

Canada also remains skeptical. In August, 1994, the Canadian government announced it would postpone the sale and use of rBST until July 1, 1995.[154] The decision was based on the determination that more time was needed to test the product and ensure the public is better informed.[155]

While other nations are taking a more conservative approach not only to ensure the drug's safety but also to allow time to consider the economic impact that rBST will have on the dairy industry, the United States is going full-steam ahead. In each case

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[148] *Id.*

[149] *Hormones: ESC Urges More Research Into BST As Opposition Grows*, EUROPE ENVIRONMENT, 439, Sept. 27, 1994.

[150] 230 DER d6 (1993).

[151] *BST-free Labels may Lead to Prosecution; Nutritional Labeling Certifying Dairy Products to be Free from Bovine Somatotropin Hormones*, 59 DAIRY INDUSTRIES INTERNATIONAL, April, 1994, at p. 5.

[152] *Id.*

[153] *Id.*

[154] *Canada Delays Introduction of BST; Bovine Somatotropin*, AGRA EUROPE LTD., Aug. 19, 1994, No. 1607, at N3.

[155] *Id.*

where the use of rBST was opposed, consumer acceptance was a primary concern. Unlike the United States, in an effort to minimize any adverse economic impact, other nations appear to be dealing with consumer awareness and acceptance objectively and up front prior to the drug's approval.

V. REGULATION

A. Authority

In the absence of specific legislation to oversee biotechnology,[156] products produced through the use of genetic engineering are being regulated by three separate federal agencies: The United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). [157] Since the agencies' individual roles are not well defined in this specific area,[158] occasionally there is an overlap of authority among agencies regulating a particular product.[159] rBST (Posilac), for instance could have been regulated as a new animal biological product[160] by the USDA under the Virus-Serum-Toxin Act,[161] or by the FDA as a new animal drug[162] under the Food,

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[156] Congress has not enacted any statutory provisions which specifically address the regulation of biotechnology. Statement of Policy for Regulating Biotechnology Products, Department of Health and Human Services, 51 FR 23309 (1986).

[157] Developments in Agricultural Biotechnology, 19 WM. MITCHELL L. REV. 457 (1993).

[158] *Id.*

[159] Robert A. Bohrer, *Food Products Affected by Biotechnology*, 55 U. PITT. L. REV. 653, 668 (1994).

[160] Biological products. The term biological products, sometimes referred to as biologics, biologicals, or products, shall mean all viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals. 9 CFR 101.2. A new veterinary product will likely be classified as a biological if the product is derived from a virus, serum, toxin, or analogous substance and it achieves its intended affect primarily by immunological means. Bohrer, *supra* note 159, at 668.

[161] 21 U.S.C. §§ 151-159 (1972 & Supp. 1993) A new veterinary product which is derived from a virus, serum, toxin, or analogous substance of natural or synthetic origin and which achieves its intended affect largely by immunological means may be classified as a biological pursuant to 9 C.F.R. 101.2(w) (1993).

[162] 21 U.S.C. § 321 (1994):

(v) The term "new animal drug" means any drug intended for

Drug and Cosmetic Act (FDCA).[163] Where questions arise as to whether a product is an animal biological product governed by USDA licensure, or a new animal drug subject to the FDA's regulatory jurisdiction, the issue is referred to a committee comprised of representatives from both agencies.[164] In the case of rBST, the FDA was granted authority as the primary agency with jurisdiction to regulate the product.[165] The reasoning behind this decision was, presumably, because the FDA is viewed by consumers as a more credible agency for regulating food products than the traditionally "pro-farmer" USDA.[166]

B. Overview of FDA Policy Statement

Empowered by the Food, Drug and Cosmetic Act (FDCA)[167] and the Public Health Service (PHS) Act,[168] the FDA has the au-

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use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

A new veterinary product will likely be classified as a new animal drug where the product is intended to affect a structure or function of a non-diseased animal. Bohrer, *supra* note 159, at 669.

[163] 21 U.S.C. § 321, 360b (1994). Under the FDCA the FDA has broad authority to ensure the safety and wholesomeness of food. The agency is empowered to initiate legal action against a food that is found to be adulterated or misbranded within the meaning of sections 21 U.S.C. §§ 342 and 343, 57 Fed. Reg. 22, 772 (1992).

[164] Statement of Policy for Regulating Biotechnology Products, Department of Health and Human Services, 51 Fed. Reg. 23,309 (1986).

[165] Bohrer, *supra* note 159, at 675.

[166] Bohrer, *supra* note 159, at 675.

[167] 21 U.S.C. § 321 (1994).

[168] 42 U.S.C. § 213 (1995).

thority and responsibility to regulate food products entering the stream of interstate commerce regardless of the manufacturing process.[169] This includes food products produced using biotechnology.[170] The FDA issued a policy statement for regulating biotechnology products, in an effort to clarify policies governing regulation of the products and explain coordination of the Federal agencies.[171] The Statement emphasized the FDA's position that no new administrative procedures are needed to deal with generic concerns about biotechnology and that regulation of products of biotechnology will be conducted under the statutory and regulatory framework which was established prior to the development of recombinant DNA technology.[172] Review of these products will be done on a case-by-case basis in light of the intended use of the product.[173]

C. The Regulatory Process

The requirements for commercial marketing of a new animal drug in the United States are governed by 21 U.S.C. 360b.[174] The

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[169] 51 Fed. Reg. 23,309, 23,312 (1986).

[170] *Developments in Agricultural Biotechnology*, 19 WM. MITCHELL L. REV. 457, 458 (1993).

[171] 51 Fed. Reg. 23,309 (1986).

[172] Bohrer, *supra* note 159, at 665.

[173] 51 Fed. Reg. 23,309, 23,310 (1986).

[174] 21 U.S.C. § 360(b). New animal drugs (1972 & Supp. 1994), in pertinent part:

> (b) Filing application for uses of new animal drug; contents.
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> (1) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe and effective for use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufac-

process generally begins by the sponsor or manufacturer of the drug filing a New Animal Drug Application (NADA) with the Secretary of Health and Human Services.[175] Before approval of an application for commercial marketing, the sponsor must submit raw data from studies conducted at the sponsor's expense demonstrating that the drug is safe and effective when used in accordance with approved label directions.[176] The sponsor must show that food products derived from treated animals are safe for human consumption and that the drug will not have an adverse effect on the health and well-being of the target animal or adversely affect the environment.[177] Effectiveness simply means that the drug will do what the sponsor claims.[178] The sponsor must also prove that it can manufacture the drug consistently to a specific concentration and purity.[179] Generally these efficacy and safety studies are conducted by the sponsor, or by independent scientists at universities, research laboratories, or commercial farms.[180] The FDA then examines the research methods used and verifies the accuracy and completeness of the studies and results obtained.[181]

In addition to the above requirements, the sponsor of a new animal drug must provide the FDA with an acceptable method for determining the quantity of the drug or the presence of any

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> tured, packed, or distributed by the applicant; (G) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and (H) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe. . . .

[175] *Id.*

[176] 21 U.S.C. § 321(u) (Supp. 1994):

(u) The term "safe," as used in paragraph (s) of this section and in sections 409, 512 and 721 [21 USCS section 348, 360b, 379e], has reference to the health of man or animal. *See also* 21 C.F.R. 514; 21 U.S.C. 360b and 51 Fed. Reg. 23,309, 23,315 (1986).

[177] *Question and Answers about BST,* FDA VETERINARIAN, May/June (1994) at 7.

[178] *Id.*

[179] *Id.*

[180] *Id.* The studies must include trials from several different geographical locations within the United States and must be performed under similar conditions. Judith C. Juskevich and C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety Evaluation,* 249 SCIENCE, 875 (1990).

[181] *Questions and Concerns about BST,* FDA VETERINARIAN, May/June (1994) at 7.

byproduct of the drug in food derived from the animal.[182]The sponsor must also provide a proposed tolerance or residual level of the drug permitted to remain in food without rendering the product adulterated under the FDCA.[183] In the case of rBST, the FDA did not enforce either of these requirements. The FDA determined that a tolerance level was not required because the naturally occurring hormone (BST) and the genetically engineered product (rBST) are indistinguishable.[184] While under current testing methods this may be true,[185] it completely ignores the "testing" requirement mandated by subsection (G).[186] The statute specifically demands that a test be provided before approval of the drug will be granted.[187] The FDA failed to discharge its statutory duty and compel Monsanto to devise a test to distinguish the two hormones. This failure provides a valid ground for challenging the FDA's decision to approve rBST for commercial use.

Further, as noted in section III, Safety in Humans, the level of insulin-like growth factor I (IGF-I) is 2 to 5ug/L higher in milk from treated cattle than nontreated cattle. Under section 342(a)(2)(A) of the FDCA, this may render the milk adulterated.[188] Where a technological adjustment to a product causes the

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[182] 21 U.S.C. § 360b (b)(1)(G) (Supp. 1994).

[183] 21 U.S.C. § 360b (b)(1)(H) (1994). 21 U.S.C. § 342 (1994) governs regulation of adulterated foods.

[184] New Animal Drug for Increasing Milk Production, FDA Backgrounder, 1. *See also* Robert A. Bohrer, *Food Products Affected by Biotechnology*, 55 U. PITT. L. REV. 653 at 677, fn. 111, (1994).

[185] While there is no current test to distinguish the two hormones, a test could be devised without much difficulty. A test presently exists (and was in use several years before rBST was approved) to distinguish human growth hormone from recombinant human growth hormone. This test could be easily adapted to distinguish rBST from BST. *American Medical Association, Biotechnology and the American Agricultural Industry*, Counsel on Scientific Affairs, American Medical Association, 265 JAMA 1429 (1991).

[186] The sponsor must provide the FDA with "a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use." 21 U.S.C. § 360b (b)(1)(G).

[187] 21 U.S.C. § 360b (1994).

[188] 21 U.S.C. § 342(a)(2)(A) (1988 & Supp. 1993):

> A food shall be deemed to be adulterated . . . if it bears or contains any added poisonous or added deleterious substance other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug which is unsafe within the meaning of section 346

quantity of a constituent to exceed the amount that would normally be present, the excess quantity constitutes an "added substance" within the meaning of section 342.[189] Although the FDA concluded the increased level was harmless,[190] only minimal data is available regarding the effect of consuming increased levels of IGF-I may have on human health.[191] The agency's decision may be arbitrary and capricious, because it failed to require adequate trials before approving the drug.

D. Labeling

The FDA's assertion that rBST and BST are indistinguishable was also used as a basis for the agency's election not to require labeling of dairy products from cattle treated with rBST.[192]Instead, the FDA issued voluntary guidelines for producers of milk who choose *not* to use the genetically engineered hormone. Although a producer is not required to include such labeling, if he does label his product, any statement made must not be false or misleading.[193] In addition, the statement must include a "qualified" statement[194] expressing the FDA's opinion that there is no significant difference between milk from treated cattle and non-treated cattle.[195] This last requirement runs afoul of the First Amendment

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of this title.

[189] 51 Fed. Reg. 23309 at 23318 (1986).

[190] Judith C. Juskevich and C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety Evaluation*, 249 SCIENCE, 875 at 883 (1990). Juskevich was formerly with the FDA's Center for Veterinarian Medicine, Office of New Animal Drug Evaluation, Division of Toxicology. Guyer is with the FDA's Center for Veterinarian Medicine, Office of New Animal Drug Evaluation, Division of Chemistry.

[191] Council on Scientific Affairs, American Medical Association, *Biotechnology and the American Agricultural Industry*, 265 JAMA 1429, 1430 (1991).

[192] 59 Fed. Reg. 6279 (1994).

[193] 21 U.S.C. § 343 (1994). *See also* Thomas B. Smith, *Udder Truth; Labels for Genetically Engineered Food*, LEGAL TIMES, Aug. 1, 1994, at Opin. and Comm. at 23.

[194] On February 9, 1994, the FDA issued guidelines for voluntary labeling of milk and milk products from cows not treated with rBST. The agency stated that labeling such as "rBST-free" would be false and it implies that there is a compositional difference between milk from treated and untreated cows. The FDA suggested instead that producers use the statement "from cows not treated with rBST" accompanied by the "qualified" statement "no significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows." *Interim Voluntary Guidance on BST issued by FDA for Milk Producers*, DAILY REP. EXEC., REG., ECON. & LAW (BNA) No. 26, at D-31 (Feb. 9, 1994).

[195] 59 Fed. Reg. 6279 (1994).

which prohibits the government from abridging free speech absent a compelling and overriding interest for doing so.[196] Notwithstanding the well-settled law that commercial speech is subject to more stringent regulations than would generally be permissible for noncommercial speech, commercial speech is nonetheless entitled to some degree of protection under the First Amendment.[197] The degree of protection required depends on the weight of the interests involved.[198]

In the case of rBST, the interest of the FDA in requiring the "qualified" statement must be weighed against the interest of not only the milk producers who choose not to use rBST but also the interest of consumers who are entitled to accurate and truthful information. The FDA asserts the "qualifier" is necessary because consumers may believe milk from untreated cows is safer or better than milk from treated cows.[199] Yet, the FDA has failed to show there is a genuine risk that consumers will be mislead by a single statement, "from cows not treated with rBST".[200] In addition, the FDA's qualified statement is not based on factual evidence but is merely the FDA's opinion.[201] Permitting the agency to impose such arbitrary restrictions could set an undesirable precedent for future labeling of other foods.

CONCLUSION

The biotechnological era has arrived and, as with most new technologies, great hesitation and confusion has accompanied its arrival. Some welcome genetic engineering and believe it holds the solution to many of the environmental and economic problems society now faces. Others, however, are fearful of the unpredictable consequences of its unbridled application.[202] The

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[196] The First Amendment to the United States Constitution (1791) provides that "Congress shall make no law. . . abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances." This right is not absolute however, and will vary with the circumstances. Schenck v. United States 249 U.S. 47 (1919).

[197] Bigelow v. Virginia, 421 U.S. 809 (1975).

[198] *Id.*

[199] Loren W. Taver, *Impact of BST on Small Versus Large Dairy Farms, supra* note 70.

[200] Smith, *supra* note 69, at 25.

[201] Smith, *supra* note 69, at 25.

[202] Looking for the Big Picture - Developing a Jurisprudence for a Biotechnological Age, 10 PACE ENVTL. L. REV. 711 (1993).

spectrum of economic, environmental and health issues which were previously thought to exist only in science fiction, are now at the forefront of this new technology. In the case of rBST, the hormone's development and introduction is one of the most visible and controversial applications of genetic engineering primarily because of its potential impact on human health.[203] The development and success of future biotechnology products depend a great deal on the success of this product.[204]

While there are numerous benefits to be derived from biotechnology, we should not hastily embrace these new techniques before safety is confirmed. By approving the commercial use of rBST without abiding by its own requirements and regulations, the FDA may have eroded public confidence in the agency and heightened public anxiety over biotechnology.

KRISTINE CERRO

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[203] Council on Scientific Affairs, Americana Medical Association, Biotechnology and the American Agricultural Industry, 265 JAMA 1429, 1432 (1991).

[204] *Id.*