



BST FREE: The Debate Over Whether to Allow Voluntary Labeling of Products as "BST Free" Not Derived from Dairy Cows Given the Milk Production Hormone BST

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The Debate Over Whether to Allow Voluntary Labeling of Products as
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Hormone BST

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'Fm tired of being force-fed chemicals without having agreed to them [University of Washington Business School Professor John] Baden can give his wife and children BST milk. I won't give it to my cat.

—Darlene Kaiser Lynwood¹

The debate over whether to label milk and other dairy products as coming from cows injected with the milk production hormone bovine somatotropin (BST or rBGH-recombinant bovine growth hormone) pits consumers, like Darlene Lynwood, who see milk as that wholesome and pure liquid you give your children against biotechnology entrepreneurs who want to move the United States into the Twenty-first Century. As one of the first agricultural biotechnology products to come to market, BST milk is seen as a test case for bioengineered foods. The outcome of the labeling debate and the degree of public acceptance of the product will send a message to the developers of a range of other genetically engineered foods (including vegetables, pork, and poultry) waiting in the wings.²

BACKGROUND

Bovine somatotropin is produced using recombinant DNA technology to replicate a hormone naturally produced in small quantities in a cow's pituitary gland. Injection of a cow with synthetic BST at regular stages during the lactation cycle, coupled with proper feeding management, can increase milk production by ten to twenty percent. The St. Louis-based company Monsanto has spent approximately \$500 million developing BST; Monsanto's product will be marketed under the trade name Posilac. A new animal drug application (NADA) for Posilac was under review by the Food and Drug Administration

¹Darlene Kaiser Lynwood, *Milk-Production Hormone — We Must Resist Being Force-*

Fed Chemical Additives in Our Food, Ti-IF SEATTLE TIMES, Dec. 31, 1993, at B5.

²See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, A NEW TECHNOLOGICAL

ERA FOR AMERICAN AGRICULTURE 135 (U.S. Government Printing Office, August 1992)

(estimating the timing of commercial introduction of advancing animal technologies).

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(FDA) for almost a decade. On November 5, 1993, the FDA approved the NADA for Posilac.³ Following a ninety-day moratorium passed by Congress last August,⁴ BST sales will begin on February 4, 1994.

LABELING OPTIONS

The available approaches to BST-free labeling include:

- a) Mandatory Labeling: All dairy products would be labeled whether or not they contained BST.
- b) Voluntary Labeling: The FDA would police operations to ensure compliance under current regulations governing misbranding.⁵ The FDA could also impose new regulations requiring that processors and producers who voluntarily choose to make 'BST free' claims be licensed or certified.
- c) Mandated Nondisclosure: BST free claims would be banned from products.

The FDA considered whether to mandate BST labeling, holding a series of hearings in May, 1993, on the issue. In the debate, opponents of mandatory BST labeling argued that the FDA did not have the statutory authority to mandate labeling of dairy products as being from BST-treated cows.⁶ This argument carried the day.⁷ In

-'See HI-IS NEWS P93-40, BST (U S Department of Health and Human Services, Washington, D.C.), Nov. 5, 1993.

⁴ See Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 1105(c), 107 Stat. 312 (1993).

⁵ Sections 403(a) and 201(n) of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 343, 321 (1988), govern misbranding. Section 403(a) states that a food is misbranded [i]f its labeling is false or misleading in any particular, 21 U.S.C. § 343 (1988). In determining whether a label is misleading, Section 201(n) requires the FDA to take into account not only representations about the product, but also the extent to which the label fails to reveal facts material in the light of such representations, or material with respect to consequences which may result from the use of the food, 21 U.S.C. § 321 (1988). ⁶For a discussion of FDA's statutory authority to mandate labeling, see OFFICE OF MANAGEMENT & BUDGET, THE USE OF BOVINE SOMATOTROPIN (BST) IN THE UNITED STATES: ITS POTENTIAL EFFECTS 16-17 (January 1994) (noting that, in the past, the FDA

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approving BST, the FDA agreed that it did not have the statutory authority to mandate labeling of dairy products as being from BST-treated cows.⁸

The FDA did allow voluntary labeling of BST-free products, provided the information is truthful and not misleading.⁹ The FDA has not yet offered guidelines as to what a BST free label should say to avoid a charge of being misbranded but is currently actively engaged in that evaluation.¹⁰

During this evaluation, the FDA should examine whether voluntary labeling is the proper compromise in this case. The May, 1993, hearings focused on mandatory labeling and did not address the issue of voluntary labeling versus mandated nondisclosure.¹¹ Although the FDA permits voluntary avoidance claims—such as 7-Up's Never had it [caffeine], never will claim—BST is a unique product; strong arguments can be made that the FDA should ban BST free claims. The issues that arise in the voluntary labeling

has declined to mandate warning statements on food labels except in specific instances where there is scientifically-based evidence of a potential health hazard; since available data indicates there are no adverse health consequences from BST, labeling is not required). *See also* Memorandum from King & Spalding to the Food and Drug Administration (May, 1993) (on file with author) [hereinafter King] (giving additional arguments that the FDA has no statutory authority to mandate BST labeling under the ingredient listing or common or usual name provisions of the Food, Drug, and Cosmetic Act).

⁷See Letter from Richard A. Merrill, Special Counsel, Covington & Burling, to David Kessler, Commissioner, Food and Drug Administration 4 (May 25, 1993) (on file with author) [hereinafter Merrill Letter] (I note in passing that many witnesses who favor labeling did not trouble to discuss the question of the agency's legal authority – with good reason.).

⁸1-H-IS NEWS, *supra* note 3, at 1 (noting that FDA Commissioner Kessler said, [BST] 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 is safe to consume.).

⁹*Id.* at 3.

¹⁰Letter from Linda A. Suydam, Associate Commissioner for Operations, Food and Drug Administration, to Alan T. Tracy, Secretary, State of Wisconsin, Department of Agriculture, Trade and Consumer Protection 1 (Jan. 7, 1994) (on file with author). *See* King, *supra* note 6, at 3 n. 1 (noting that voluntary labeling presents a different set of legal and practical issues, which are only touched on incidentally in this memorandum, prepared for the FDA hearings).

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versus mandated nondisclosure debate include: a) misleading claims, b) enforcement, c) label clutter, d) the consumers' right to know, e) effect of labeling on consumer acceptance, and f) economic effects and U.S. competitiveness.

THE DEBATE OVER VOLUNTARY LABELING VERSUS MANDATED NONDISCLOSURE

Misleading Claims

Since the Food, Drug, and Cosmetic Act focuses on whether a claim is misleading,¹² accurate statements on labels are protected. The issue of whether a BST free claim can ever be accurate arises. Supporters of voluntary BST labeling say there is nothing false or misleading about a BST free claim when the cows were not injected with the hormone. Just as products can say caffeine free, fat free, or cholesterol free, producers should be allowed to say BST free.

Those who oppose voluntary BST labeling argue that a BST free claim is inherently misleading, because it wrongly implies there's less BST in BST-free milk or that BST affects the character, quality or safety of milk. 13 Products with no caffeine, fat, or cholesterol are different from their counterparts with caffeine, fat, or cholesterol. However, the BST level in milk of treated cows is indistinguishable from the traces (2 to 10 parts per billion) generally found in the milk of untreated cows; there is no less BST in BST free milk. 14 Whereas caffeine, fat, and cholesterol levels can affect health, humans have been exposed to these BST levels with no consequences.¹⁵ In addition, BST milk

¹² See Food, Drug, & Cosmetic Act, *supra* note 5.

¹³ Merrill Letter, *supra* note 7, at 9.

¹⁴ RALPH M. CUM, BOVINE SOMATOTROPIN (BST OR BGH): QUESTIONS AND ANSWERS ON A NEW DAIRY TECHNOLOGY 2 (Congressional Research Service, The Library of Congress, Report No. 93-1041 ENR, 1993).

¹⁵ *Id.* (noting that BST is broken down in the human gastrointestinal tract, where it becomes inactive, and that BST is species specific: even when injected into a human, it produces no response).

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has the same nutritional value and composition as milk from untreated cows. 16 Monsanto executives argue that the FDA should not create an artificial distinction between like foods, because this creates a perceived risk where none exists. 17

Those who support voluntary BST labeling argue that BST-free milk is safer. Use of synthetic BST will cause increased incidence of mastitis—an infection of the bovine udder that occurs more frequently in high-producing cows. This would lead to increased antibiotic residues in milk.

BST labeling opponents argue that adequate safeguards are in place to prevent unsafe levels of antibiotic residues from entering the milk supply.¹⁸ In particular, farmers must destroy milk from any dairy cow being treated with antibiotics. If any antibiotics are found at the processing plant, the milk is destroyed. Offending dairy farmers lose income from sale of the entire shipment of milk, and are prohibited from marketing milk for a specific number of 19 In addition, Monsanto has agreed to take additional actions to ensure that any unsafe residues in BST milk are detected well before the milk or its products reach the grocery shelves.²⁰

Enforcement

Those who oppose voluntary BST labeling contend that enforcement problems would lead to a large number of fraudulent BST free claims. There is no way to test milk to determine if it comes from a cow treated with BST. The only way to prove a label is false would be to trace the milk to the individual cows. Given the degree to which milk from numerous farms is mixed, the only way to guarantee a BST-free milk supply would

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¹⁷Linda Gasparello, *BST Labeling Would Reverse Food Labeling Reform, May Mislead*

Consumers, Industry Tells FDA, FOOD & DRINK DAILY, May 7, 1993, at 1

I ⁸HHS NEWS, *supra* note 3, at 1.

¹⁹Cilm, *supra* note 14, at 3.

²⁰HH5 NEWS, *supra* note 3, at 2.

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be to have a dedicated supply of BST-free cows whose milk you would isolate at all stages of processing—from the farm to the processing plant to the manufacturer. Unlike other product claims, such as caffeine free, where you can test the finished product to see if the label's claim is accurate, testing the accuracy of a BST free claim means that an agent would have to go to the manufacturer, processor, and farm to ensure the purity of the milk.

Supporters of BST labeling say that a scheme of regulated voluntary labeling could be set up to require certification of BST-free farms and affidavits from those who process BST-free milk. However, there are still enforcement problems. Since the BST is undetectable, it would be easy for a fraudulent operator to make false claims. The only way the FDA could ever impose a penalty is if a farmer was caught red-handed, injecting the BST supplement into a BST-free cow. It is unrealistic to impose such requirements on FDA agents, since only 1500 inspectors are responsible for the nation's entire supply of food, drugs, and cosmetics.

Those who support BST free labeling might argue that the FDA could limit cases of enforcement to when someone blows the whistle. However, the issue of one man's word against another's would arise; there is no independent way to test to determine whether the whistleblower or the farmer/processor is correct.

Label Clutter

Opponents of BST labeling contend that, even if a non-misleading label could be developed, it would crowd out important messages. ²¹ A label should focus on the information that is of the greatest health significance. Social consciousness messages like BST free are collateral to the main need to provide nutrition and safety information on a label. Too much clutter on a label leads to information overload; consumers would take

²¹Merrill Letter, *supra* note 7, at 9.

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one look at the massive amount of information on the label and decide to ignore it all, including the important nutrition information.

These opponents could point to the BST free label developed by the state of Wisconsin. The Wisconsin label requires that a BST free claim should include the following statements: 1) It is not the policy of the packager or processor to accept milk or dairy products from cows administered BST, 2) According to FDA, synthetic BST poses no threat to human health, and 3) There is no laboratory test that can prove whether synthetic BST has or has not been used to produce a dairy product.²² Opponents would contend that all these statements are bewildering to the average consumer.

Proponents of BST labeling would contend that BST labeling is worthwhile information. Consumers want to know how their products are made; just look at the interest in organic and natural foods. People may be bewildered about some things in life (like tax returns), but they are smart when it comes to what they put in their bodies every day. People will take the time to sort through label information.

The Consumers' Right to Know

Supporters of BST labeling would vehemently argue that the FDA should not ban labeling just because it paternalistically thinks consumers would be confused or misled. Convincing people like Darlene Lynwood that they have no right to choose B ST-free milk and telling manufacturers that they have no right to cater to people like Darlene Lynwood by selling BST-free milk is an infringement upon personal liberty. Proponents contend, Consumers have a right to know whether BST is used, regardless of whether the

²²Letter from Alan T. Tracy, Secretary, State of Wisconsin, Department of Agriculture, Trade and Consumer Protection to Representative Barbara Grone-mus, Wisconsin Assembly, Agriculture, Forestry & Rural Affairs Committee 2 (Oct. 8, 1993) (on file with author).

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information is significant from the standpoint of product quality, health, or nutrition.²³ Our free market is based on catering to consumers' tastes, regardless of how sound or logical they may seem; the enormous popularity of pet rocks, Chia pets, and miracle thigh cream are but a few examples of our free market at work.

Opponents of BST labeling would argue that, certainly new products can be developed to cater to customers' tastes, but BST milk is not a new product. Trying to tell consumers that BST-free milk is different from milk with BST is wrong, as the arguments on misleading claims above indicate.

Effect of Labeling on Consumer Acceptance

Most consumers are currently not aware of the development of milk from cows treated with BST. In a survey taken in November, 1993, by the Grocery Manufacturers Association, more than 80 percent of American households said they had not heard of BST.²⁴ A similar study by the National Dairy Promotion & Research Board found that only 7 percent of respondents were aware of issues relating to BST on an unaided basis.²⁵ If labels were banned, supporters of BST use would benefit, because many consumers might never find out about BST. These consumers would likely just continue buying their regular milk without realizing it comes from cows injected with synthetic BST. However, if opponents of BST use wage a successful campaign to make consumers hostile to BST, milk consumption would drop.

Opponents of BST use say the FDA should allow labeling, so the market can determine the outcome of BST. Surveys indicate that consumers want to know when

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PROTECTION, REGULATION OF SUPPLEMENTAL BOVINE SOMATOTROPIN IN WISCONSIN:

AN EVALUATION OF DAIRY PRODUCT LABELING 1 (March 1991) [hereinafter WISCONSIN].

²⁴Steven Pratt, *Cattle Growth Hormone BST Boosts Milk Production, But Labeling,*

Safely Still (oncerni Some Critics, CHICAGO TRIBUNE, Dec. 16, 1993, at 8A.

²⁵Gail Rosenbaum Doeff, *The people ~ choice: (onsumer reaction to bovine somatotropin; The Reality. ~' of BST*, DAIRY FOODS, July 1993, at 44.

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their food is developed using biotechnology. One study showed that 85 percent of consumers said labels indicating use of biotechnology were very important.²⁶ Another survey of 400 women with milk-drinking children found an even greater interest in BST-free milk: [t]wo-thirds of the respondents said they would change their milk brand in order to get milk that is produced by BST-free cows²⁷

A government report showed that consumer reactions to BST were based on the following concerns: 1) a fear of new technology, 2) lack of long term data, 3) emotional link between milk and children, 4) concerns with animal cruelty, 5) consumers' right to know, 6) distrust of government. and 7) support for small scale agriculture.²⁸ The National Dairy Promotion & Research Board study found that a large majority [of survey respondents], particularly those with children under 18, reported a fear that ill effects caused by BST would be discovered in the future.²⁹ Supporters of BST would argue these reactions are based on emotion rather than science;³⁰ we should not allow such unfounded fears to hamper scientific development. Opponents of BST would counter that purchases of every product are based on emotional reactions; to divorce emotions from science or product development is absurd

If BST free labeling were allowed, the success or failure of BST would depend on whether consumers switched to the new milk. This would, in turn, depend on how much the price of BST-free milk exceeds that of regular milk and whether consumers would pay the differential. Given the need to segregate BST-free herds, it is likely that BST-free milk could cost substantially more than milk with BST. There are conflicting indications as to whether consumers would pay the price differential. A government

2601 FICL 01 MANAGEMENT AND BUDGET, *supra* note 6, at 42.

²⁷Doeff, *supra* note 25, at 44.

²⁸SOFJ:ICE OF MANAGEMENT AND BUDGET, *supra* note 6, at 44.

²⁹Doeff *supra* note 25, at 44.

³⁰Gasparello, *supra* note 17, at I (statement by Vermont Farm Bureau President Walter Pyle).

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report indicated that studies done for pesticides show that even though consumers prefer labeling, they are not willing to pay significantly higher prices to get labeling.³ However, the survey of 400 women found that 63 percent of the women would be willing to pay more for milk that comes from BST-free cows³²

Given the unpredictability of demand for BST-free milk, opponents of BST labeling would argue that the government should not impose labeling and certification requirements based on such speculative long-term consumer concern. Unless substantial consumer interest—beyond the speculative interest currently found—develops, the costs of labeling and of getting milk from a dedicated herd will outweigh the information benefits provided to consumers.³³ Supporters of labeling argue that, if a producer wants to risk developing a product, like BST-free milk, that may not eventually sell profitably, that is the producer's choice. The FDA should not intervene at this point to ban labeling.

Economic Effects and U.S. Competitiveness

Opponents of BST use are concerned about the effects of BST use on small farms. BST will depress farm milk prices, and accelerate the trend toward fewer and larger dairy farms. .. Small farms may not be able to afford the more sophisticated feeding systems and computerized information systems that successful adoption of BST may eventually require.³⁴ Labeling should be allowed so that a market can be developed for BST-free milk supplied by these small farmers. Giving consumers the opportunity to choose from a variety of products and to base decisions on a desire to help small farms is the essence of the free market.

BST supporters counter that FDA's mission is to protect public health and safety; FDA is not concerned with the socio-economic effects of BST. Since BST poses no

³¹U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 2, at 333.

³²Doeff, *supra* note 25. at 44

³³WISCONSIN, *supra* note 23, at 2.

³⁴CHITE, *supra* note 14, at 4.

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health threat, BST-free labeling should be banned. Additionally, the FDA should not interfere with the technological development of the dairy industry to protect farmers who cannot compete successfully. Our economy is built around the competitive allocation of resources. Small and large farmers should be expected to keep up with dairy industry developments; those who lose money in dairying should shift their assets into a more productive use. Competitive development is the hallmark of dairying. Improvements in genetics, medicine, feed and herd management have more than tripled the output per cow and led to a reduction in the number of U.S. dairy cows of over fifty percent since 1955.³⁵ Even without BST, this structural trend toward fewer and larger farms will continue.³⁶ Senator Hatch put the issue succinctly: Banning BST because, although it leads to greater productivity by certain entities, it could negatively affect others is comparable to banning the use of computers because certain small companies cannot afford to purchase them and they might be at a disadvantage.³⁷

BST opponents argue there is already an overabundance of milk.● Through its dairy price support program, the government spends millions of dollars annually to buy and store dairy surpluses. Ultimately taxpayers will pick up the price tag for this development of needless scientific magic; one BST opponent asked why we should bother to increase the production of a commodity that already has attained a troublesome level of abundance³⁸

BST supporters counter that scientific development should not be stopped just because a product is currently plentiful. As a report by the Office of Technology Assessment noted, For U.S. agriculture to retain its status it is necessary to enhance

³⁵Robert Steyer, *Will Monsanto ~ BST Send Flood of Milk into Supermarkets?*, ST.

LOUIS POST-DISPATCH, Dec. 6, 1993, at 12.

³⁶CITE, *supra* note 14, at 5.

³⁷Senator Orin Hatch, Remarks to the Senate Radio-TV Gallery, Federal News Service, Aug. 3, 1993, in LEXIS, Nexis Library.

³⁸Richard Orr, *Despite FDA Blessing, Farmers Union Calls Bovine Hormone a Bad*

Idea, CHICAGO TRIBUNE, Nov. 22, 1993, at 3.

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public and private-sector capacity for scientific research and technology development. The costs, to consumers and producers, of failure to maintain and enhance our efficiency in production would greatly exceed the adjustment costs resulting from overabundance.³⁹ In addition, biotechnology development needs to be encouraged. The US. biotechnology industry leads the world in the development of new products and is something this nation should be proud of. The government should not allow the scare tactics employed by BST opponents to kill this industry.

CONCLUSION

Many of the arguments made revolve around the central issue of whether the market should be allowed to decide the fate of BST or whether overarching concerns dictate that the FDA should intervene to ban BST labeling as inherently misleading under §201(n) of the Food, Drug, and Cosmetic Act. Government decisionmakers should constantly consider whether market intervention is justified.

BST supporters contend the government should intervene to prohibit the marketing of a false product like BST-free milk. BST opponents argue that permitting voluntary labeling is the essence of the free market; it allows producers and consumers, like Darlene Lynwood, to determine the success or failure of BST through their pocketbooks. The future of biotechnology should be decided in the open market.

The arguments on both sides of this issue are strong, and I personally could decide either way (although I am leaning towards supporting FDA's current policy of voluntary labeling). Although BST has been an issue before the FDA for almost a decade now, the FDA should not consider the files on this issue to be closed just because BST will be on the market in a few days. The FDA should consider further debate into the labeling issue.

³⁹U S CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 2, at 148-49.