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Time for Government to Get Mooo-ving: Facing Up to the RBST Labeling Problem

by

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TIME FOR GOVERNMENT TO GET MOOO-VING: FACING UP THE TO RBST LABELING PROBLEM

I. INTRODUCTION

Headlines read: "Udder Insanity," "Frankenfood," and "Crying Over Unnatural Milk,"[1] in response to approval of a hormone that helps cows make more milk. The Food and Drug Administration (FDA) approved the hormone recombinant bovine somatotropin (rbST) as the first-ever use of genetic engineering on a living animal to produce food.[2] Farmers inject the hormone into dairy cattle, increasing milk output by up to twenty percent.[3]

Response to its approval and use has been mixed.[4] Some producers call the hormone a great technological breakthrough, while others question its safety or think that it will wipe out what little is left of the American family farm.[5] Yet, many do not dispute the FDA's approval of rbST as much as they do the FDA's refusal to require labeling of rbST products.[6] The FDA did not mandate labeling of rbST products when it approved the hormone.[7] As a result, consumers, consumer groups, and farmers have called on the FDA to enact uniform federal labeling regulations.[8]

This Comment presents an overview of rbST, its approval by the FDA, and FDA labeling regulations. First, the Comment overviews FDA regulation of rbST. Second, the Comment examines the various health and social concerns related to rbST use. Third, the Comment discusses labeling regulation by the FDA and the various options facing federal and state governments when enacting rbST-labeling regulation. Finally, the Comment analyzes the FDA's refusal to require labeling of rbST products.

II. BACKGROUND

A. *Recombinant Bovine Somatotropin*

RbST is a nearly identical genetic replica of the naturally occurring hormone, bovine somatotropin (bST), which cows produce in the pituitary gland.[9] The hormone stimulates milk production by controlling the manner in which

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1 *See* Elmer-Dewitt, *infra* note 64, at 52; *see also Scientists Must Fight the Fear of "Frankenfood,"* BARRON'S, May 31, 1993, at 10; *Crying Over Unnatural Milk*, BUSINESS WEEK, Nov. 22, 1993, at 48.

2 21 C.F.R. § 522.2112 (1994). *See also* Final Rule, Animal Drugs, Feeds, and Related Products: Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946 (1993) (containing FDA policy statements on approval process) [hereinafter RbST Approval]. RbST is also known as bovine growth hormone (bGH), and is often referred to as "bST."

3 Don P. Blayney, *Milk and Biotechnology: Maintaining Safe, Adequate Milk Supplies*, FOOD REVIEW (USDA, Washington, D.C.), May-Aug. 1994, at 28. Don Blayney is an agricultural economist with the Commodity Economics Division, Economic Research Service, U.S. Dept. of Agriculture.

4 Mara Bovsun, *Hormone Battle Takes to Streets After bST Finally Hits U.S. Market*, BIOTECHNOLOGY NEWSWATCH, Feb. 21, 1994, at 1, 3-4.

5 *Id.*

6 *BST-Free Labels Constitute Implied Health Claims, State Says*, FOOD LABELING NEWS, Apr. 7, 1994, at 10 [hereinafter *BST Free Labels*]

7 *Id.*; RbST Approval, 58 Fed. Reg. 59,946.

8 *BST-Free Labels*, *supra* note 6, at 10-11.

9 Judith C. Juskevich & C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety Evaluation*, 249 SCIENCE 875 (1990).

energy and nutrients are used for growth.[10] For decades dairy farmers and scientists have known that dosages of the naturally occurring hormone increase milk production, but researchers could not capitalize on use of the hormone because it was difficult to obtain.[11]

Genetic engineering techniques now enable researchers to mass-produce the hormone in the laboratory.[12] Monsanto[13] developed and tested rbST for approval and sells it under the brand name Posilac.[14] Prior to approval, scientists extensively tested rbST to determine if it posed a threat to human health, to the environment, or to injected cows.[15] These tests showed that the hormone was safe to cows and to the environment and that milk produced from cows treated with rbST was safe for human consumption.[16] Farmers are now able to purchase enough of the hormone to significantly increase milk production in their operations.[17]

B. RbST Regulation

The FDA regulates food, drug, animal drug, medical device and cosmetic safety[18] to ensure that interstate channels are "free from deleterious substances."[19] Under the Food Drug and Cosmetic Act (FDCA), the FDA must act in the public interest when regulating safety standards.[20] Congress enacted the FDCA "[t]o the end that public health and safety might be advanced."[21] When regulating standards for food, the FDA must promulgate regulations "[w]henever . . . such action will promote honesty and fair dealing in the interest of consumers."[22] The FDA also regulates product labeling and misbranding under the FDCA.[23] The FDA's labeling requirements apply to labels on all food products[24] and therefore apply to milk from rbST-treated cows.[25]

The FDA regulates the use of new animal drugs under the FDCA.[26] RbST, which is injected into a cow to affect her internal processes, is a new animal

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10. *Id.*
11. *Id.* Researchers extracted the hormone from pituitary glands of butchered cows, a technique which produced only limited quantities of the hormone. *Id.*
12. *Id.*
13. Monsanto is a St. Louis-based chemical company. *See Monsanto Sues Two Dairies With Hormone-Bashing Labels on Milk*, BIOTECHNOLOGY NEWSWATCH, Mar. 7, 1994, at 1.
14. RbST Approval, 58 Fed. Reg. 59,946. Monsanto has spent $400 million on Posilac development, according to some estimates. *See* WILLIAM L. OEMICHEN, MINN. DEPT. OF AGRIC., THE RBST CONTROVERSY: MILK IS STILL NATURE'S MOST PERFECT BEVERAGE E-3-2 (1994) (presented to the American Agricultural Law Association Conference, Oct. 21, 1994).
15. Juskevich & Guyer, *supra* note 9, at 875-83.
16. Blayney, *supra* note 3, at 27.
17. Juskevich & Guyer, *supra* note 9, at 875.
18. *See generally* 21 U.S.C. §§ 301-395 (1988 & Supp. V 1993).
19. United States v. Walsh, 331 U.S. 432, 434 (1947); 21 U.S.C. § 331 (1988 & Supp. V 1993).
20. 21 U.S.C. § 341 (1988 & Supp. V 1993).
21. *Walsh*, 331 U.S. at 434. *See also* United States v. Dotterweich, 320 U.S. 277 (1943). In *Dotterweich*, the Court stated:
> [The] purposes of [the FDCA] thus touch phases of lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the [FDCA] if it is to be treated as a working instrument of government and not merely as a collection of English words.

Id. at 280.
22. 21 U.S.C. § 341. The FDA may fix and establish a "reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container." *Id.*
23. 21 U.S.C. §§ 321(n), 331, 343(a) (1988 & Supp. V 1993).
24. 21 U.S.C. § 343(a) (1988).
25. *See infra* notes 92-95 and accompanying text.
26. 21 U.S.C. § 360b (1988 & Supp. V 1993).

drug[27] and thus falls under the FDA's regulatory reach.[28] Prior to FDA approval, new animal drugs such as rbST must complete a two-step process to establish the drug's efficacy and safety: the Investigational New Animal Drug (INAD) and the New Animal Drug Application (NADA) processes.[29] The first step, INAD completion, refers to the investigational stage of the approval process.[30] The manufacturer of the new animal drug must submit an application for approval that describes the manner in which the company will conduct preliminary investigational research.[31] The FDA may authorize use of food products derived from drug-treated animals if sufficient data indicates the products are not "inconsistent with the public health"[32] and that the food "does not contain drug residues or metabolites."[33]

If the FDA approves the manufacturer's INAD, the manufacturer next submits an NADA for final approval of the new animal drug.[34] The NADA requires the manufacturer to provide both information and results from investigational studies.[35] The FDA analyzes statistics and information and approves the new animal drug if the information sufficiently indicates the safety and efficacy of the drug.[36]

The FDA requires that the new animal drug does not accumulate as unsafe residues in edible tissues of the animal.[37] To this end, the FDA requires the manufacturer to submit methods for measuring the amount of any drug residue in edible tissues.[38] If the manufacturer can show that the drug will not become a "component" of the food from drug-treated animals, the FDA does not require a method for detection.[39] The FDA has, however, noted the absence of adequate

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27. A new animal drug is "any drug intended for use for animals other than man." 21 U.S.C. 321(w) (1988).

28. RbST is produced using genetic engineering techniques that are classified as "biotechnology." *See* JOHN H. GIBBONS, OFFICE OF TECHNOLOGY ASSESSMENT, 1 NEW DEVELOPMENTS IN BIOTECHNOLOGY iii (Mar. 1987).

Before undergoing regulation by a particular agency, products developed using biotechnology must initially pass through the "Coordinated Framework." The Coordinated Framework, developed by several agencies including the FDA, the U.S. Dept. of Agriculture and the Environmental Protection Agency, describes the procedure followed when regulating biotechnology products. Specific regulation of a biotechnology product is accomplished by a single agency. However, the Coordinated Framework describes how that single agency is determined. *See* Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984); Coordinated Framework for the Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174 (1985); Announcement of Policy, Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986). For a discussion of the development of the Coordinated Framework, *see* Stephen H. McNamara, *FDA Regulation of Food Substances Produced by New Techniques of Biotechnology*, 42 FOOD DRUG COSM. L.J. 50, 53-55 (1987).

29. 21 C.F.R. pts. 511, 514 (1994). A "new drug" is one not generally recognized by scientific experts as safe and effective for use. 21 U.S.C. § 321(w).

30. 21 C.F.R. § 511.1(b) (1994).

31. *Id.*

32. 21 C.F.R. § 511.1(b)(5)(i) (1994).

33. 21 C.F.R. § 511.1(b)(5)(ii) (1994).

34. 21 C.F.R. § 514.1 (1994).

35. 21 C.F.R. § 514.1(b)(8)(i)-(ii) (1994).

36. 21 C.F.R. § 514.1(8) (1994).

37. 21 C.F.R. § 514.1(b)(7) (1994). The FDA wants to ensure that food from drug-treated animals is safe for human consumption. *See* FDA Policy Statement, 51 Fed. Reg. 23,311 (1986).

38. 21 C.F.R. § 514.1(b)(7). The regulation requires applications to

> include a description of practicable methods for determining the quantity, if any, of the new animal drug in or on food, and any substance formed in or on food because of its use, and proposed tolerance or withdrawal period or other use restrictions to ensure that the proposed use of this drug will be safe.

Id.

39. *Id.* The regulation states that "[w]hen data or other adequate information establish that it is not reasonable to expect the new animal drug to become a component of food at concentrations considered unsafe, a regulatory method is not required." *Id.*

methods of residue detection when withdrawing approval of animal drugs.[40] The FDA did not require Monsanto to develop a method for residue detection when it approved rbST.[41]

C. Response to rbST Approval

The FDA announced its approval of Monsanto's rbST on November 12, 1993,[42] and almost immediately Congress issued a three-month moratorium on the sale and use of the hormone.[43] Initial concerns centered on the product's safety, but consumers, manufacturers and government officials also cited concerns about the effect of rbST on small farms, on the federal milk subsidy scheme, and on the health of injected cows.[44]

1. Cited Health Risks of rbST

Although the FDA, when approving rbST, declared products from rbST-treated cows safe for human consumption,[45] there are several health risks associated with rbST.[46] The first is the possible effect of the actual hormone on human health. In the 1950s, studies showed that bST (the naturally occurring hormone) was inactive in humans if injected.[47] Prior to approval of rbST, tests showed that rbST produced no effects in any species, when administered orally.[48] The implication is that even if rbST travels from the cow to the milk and into the human bloodstream, the hormone does not "activate" human physiological systems.[49] Studies also indicate that humans do not absorb rbST into their bloodstreams.[50]

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40. *See, e.g.*, Final Rule, Animal Drugs, Feeds and Related Products; Dimetridazole, 52 Fed. Reg. 35,212 (1987) (withdrawing approval of dimetridazole); Final Rule, Nitrofurans; Withdrawal of Approval of New Animal Drug Applications, 56 Fed. Reg. 41,902 (1991) (withdrawing approval of nitrofurazone and furazolidone). At the initial withdrawal hearing for nitrofurazone and furazolidone, the Administrative Law Judge (ALJ) found that the manufacturers "failed to provide a reliable method of residue detection for either drug." 56 Fed. Reg. 41,902. The ALJ also found both animal drugs were suspect carcinogens. 56 Fed. Reg. 41,902. The FDA affirmed the ALJ's findings, stating that a "detection method is necessary to enable FDA to ensure that no dangerous residues enter the human food supply." 56 Fed. Reg. 41,902.

41. RbST Approval, 58 Fed. Reg. 59,946. In its final approval of rbST the FDA did not state why it did not require a residue test. *Id.* However, the General Accounting Office stated that because rbST is orally inactive, any residues would not be harmful. U.S. GENERAL ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTERS, RECOMBINANT BOVINE GROWTH HORMONE 22 (Aug. 1992) [hereinafter GAO REPORT]. *See also infra* notes 47-50 and accompanying text.

42. RbST Approval, 58 Fed. Reg. 59,946.

43. OEMICHEN, *supra* note 14, at E-3-3. Canada issued a moratorium as well. *Canadian Government Committee Urges One-Year bST Moratorium*, BIOTECHNOLOGY NEWSWATCH, May 2, 1994, at 11.

44. *See infra* part II.C.2. Leading the consumer campaign is Jeremy Rifkin, head of the Pure Food Campaign and the Foundation on Economic Trends. Both groups oppose not only rbST but all use of biotechnology in food production. Rifkin's Foundation on Economic Trends vigorously petitioned the FDA to ban use of rbST. *FDA Denies Second Petition by Rifkin Group on bST*, FOOD CHEMICAL NEWS, Aug. 22, 1994, at 8.

45. *Id.*

46. Blayney, *supra* note 3, at 28-29; Brian A. Crooker, *Human and Animal Safety in Relation to Use of Bovine Somatotropin (bST)*, BOVINE SOMATOTROPIN (BST) AND THE DAIRY INDUSTRY 1, 1-8 (1990). *See also* Juskevich & Guyer, *supra* note 9, at 876, 879-83.

47. Blayney, *supra* note 3, at 28. Such tests apply to the hormone that occurs naturally in cows, not to the genetically engineered hormone. Scientific organizations, such as the American Medical Association and the National Institutes of Health, have conducted studies on rbST that support findings that rbST is safe for human consumption. Blayney, *supra* note 3, at 28.

48. Blayney, *supra* note 3, at 28.

49. In a report written by the Department of Animal Science, Minnesota Extension Service, University of Minnesota, researchers noted that the somatotropin, or growth hormone, in cows is 35% different from the somatotropin naturally produced in humans. That difference accounts for the reason that bST is inactive in humans. Crooker, *supra* note 46, at 4.

50. *See* Crooker, *supra* note 46, at 4. The American Council on Science and Health has stated that rbST does not increase bST levels in milk and that rbST cannot be absorbed into the bloodstream of humans. The council also stated that milk from cows injected with rbST was "the same" as milk from hormone-free cows and that more than 2,000 studies on rbST show that the hormone is safe. *FDA Denies Second Petition by Rifkin Group on bST*, *supra* note 44, at 9.

Because cows produce bST naturally, some researchers argue that milk from cows treated with rbST is no different than milk from non-treated cows.[51] Researchers at the Department of Animal Science at the University of Minnesota have stated that bST concentration in milk remains constant in cows treated with doses of the manufactured hormone.[52] They did note, however, that the rbST is slightly different structurally from bST.[53]

A second cited health risk concerns levels of insulin-like growth factors, particularly insulin-like growth factor-I (IGF-I), in milk produced from rbST-treated cows.[54] IGF-I is a protein hormone that both acts as a mediator of actions of somatotropins (growth hormones) and is necessary for normal growth.[55] Both humans and cows use IGF-I in their physiological processes, and the IGF-I found in cows is identical to the IGF-I found in humans.[56]

Critics argue that the similarity between human IGF-I and bovine IGF-I may actually contribute to adverse health effects. Dr. Samuel Epstein, chairman of the Cancer Prevention Coalition, contends that IGF-I increases the risk of breast cancer.[57] Because IGF-I stimulates growth, Epstein contends that it "'induces malignant transformation of normal human breast epithelial cells.'"[58] Therefore, increased consumption of IGF-I through rbST-treated milk could increase risks of breast cancer. The FDA denies contentions that IGF-I levels induce development of breast cancer.[59]

The third commonly cited health risk is increased antibiotic residues in milk as a result of treating mastitis, inflammation of a cow's udder.[60] Many studies indicate that rbST increases the incidence of mastitis.[61] When a cow contracts mastitis, she requires treatment from antibiotics to relieve the condition.[62] As a result, rbST use could lead to increased levels of antibiotics in milk (residues).[63] Humans drinking milk with antibiotic residues may develop resis-

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51. Crooker, *supra* note 46, at 4.

52. Crooker, *supra* note 46, at 4.

53. Crooker, *supra* note 46, at 3. Researchers noted that rbST contains different amino acids at the front of the protein chain. However, the different amino acids are "common" amino acids such as methionine. Researchers noted that modification to the genetically engineered hormone was "small." Crooker, *supra* note 46, at 3-4.

54. Blayney, *supra* note 3, at 28-29; Juskevich & Guyer, *supra* note 9, at 875.

55. Crooker, *supra* note 46, at 5; Blayney, *supra* note 3, at 28; *FDA Spokesperson Denies bST IGF-I Adverse Effects Claims*, FOOD CHEMICAL NEWS, Mar. 28, 1994, at 6.

56. Blayney, *supra* note 3, at 28-29. Prior to approval of rbST, the FDA concluded that IGF-I levels in milk rise "slightly" when rbST is used, and other studies have indicated the same result. Researchers at the Univ. of Minnesota concluded that IGF-I levels rise, but that the higher levels "present no safety problems." Crooker, *supra* note 46, at 5. *But see FDA Spokesperson Denies bST IGF-I Adverse Effects Claims*, *supra* note 55, at 6, where an FDA spokesperson claimed that "FDA review of several comprehensive studies demonstrates that rbST does not increase IGF-I content."

57. *Suit Claims bST Will Cause Health Effects in Humans*, FOOD CHEMICAL NEWS, Feb. 21, 1994, at 55.

58. *Id.* (quoting a letter to Dr. David Kessler, FDA Commissioner, from Dr. Epstein).

59. *FDA Spokesperson Denies bST IGF-I Adverse Effects Claims*, *supra* note 55, at 6. An FDA spokesperson stated that "[a]ny suggestion that IGF-I in milk can induce or promote breast cancer in humans is scientifically unfounded and misguided." *FDA Spokesperson Denies bST IGF-I Adverse Effects Claims*, *supra* note 55, at 6.

60. *See* RbST Approval, 59 Fed. Reg. 59,947. The FDA stated that cows treated with rbST were "at an increased risk for clinical mastitis and subclinical mastitis." RbST Approval, 59 Fed. Reg. 59,947. The FDA based its conclusion on data provided by Monsanto, the manufacturer of rbST. Monsanto's study indicated that rbST had less effect on the incidence of mastitis than did other practices, such as herd-to-herd variation, environment, season, age of the cow, and stage of lactation. Blayney, *supra* note 3, at 29. The FDA did not provide statements about the health effects of antibiotic residue as a result of treating mastitis. 59 Fed. Reg. 59,946-47. *But see* D.G. McClary, et. al., *The Effects of a Sustained-Release Recombinant Bovine Somatotropin (Somidibove) on Udder Health for a Full Lactation*, 77 J. OF DAIRY SCIENCE 2261, 2665-67 (1994). The McClary study showed no increase in clinical or subclinical mastitis in cows treated with rbST. *Id.*

61. RbST Approval, 58 Fed. Reg. 59,947.

62. GAO REPORT, *supra* note 41, at 6.

63. GAO REPORT, *supra* note 41, at 6.

tance to those antibiotics, which may make infections difficult to treat.[64] The United States General Accounting Office (GAO) considered the mastitis health concern prior to FDA approval of rbST.[65] In 1992, the GAO presented a report, concluding that the FDA did not include a "critical consideration" in its review: the indirect safety effects of food from rbST-treated cows.[66]

2. *Social, Political and Ethical Concerns*

Critics of rbST cite not only health and safety concerns as reasons to oppose use of the hormone, but also the potential negative effects on the small dairy farmer.[67] Opposition stems from the worry that prices for milk will drop because of increased milk production from rbST use.[68] Because the dairy industry currently produces more milk than the market can bear, critics state that rbST use will further exacerbate the problem of oversupply.[69]

Representatives for biotechnology companies such as Monsanto, as well as from the federal government, argue that rbST is a "size neutral" technology, meaning small-herd farmers can utilize the technology as easily as large-herd farmers.[70] Because Monsanto's hormone is available in small-dose packages,[71] small-herd farmers can purchase and use the hormone as well as large-herd farmers.[72]

Use of rbST may indirectly benefit large milk producers more than small producers, however. First, large farms can easily adapt to increased milk production that will result from rbST use.[73] Second, large farms can absorb the cost of increased feed requirements of cows treated with rbST and can monitor nutritional needs that will change as a result of using rbST.[74] Third, large farms can more easily dispose of the increased waste associated with greater feed intake.[75] Finally, large farmers can adapt to increased labor needs for administering the hormone and managing the amount of milk produced.[76] The operational adaptations as a result of increased milk production require greater capital and labor resources, which are more accessible to large than to small operations.[77]

In addition, widespread rbST use would lead to a larger milk supply,

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64. Philip Elmer-Dewitt, *Udder Insanity!*, TIME, May 17, 1993, at 53.
65. GAO REPORT, *supra* note 41, at 6.
66. GAO REPORT, *supra* note 41, at 6. The GAO recommended that the FDA examine indirect effects of rbST products prior to approval. GAO REPORT, *supra* note 41, at 10.
67. Bovsun, *supra* note 4, at 4.
68. *Udder Insanity*, CONSUMER REPORTS, May 1, 1992, at 331.
69. *Id.*
70. Blayney, *supra* note 3, at 31.
71. Monsanto sells rbST in 25-dose packages. Blayney, *supra* note 3, at 31.
72. Blayney, *supra* note 3, at 31.
73. Roy C. Barnes & Peter J. Nowak, *Bovine Somatotropin's Scale Neutrality and Constraints to Adoption*, *in* AGRICULTURAL BIOETHICS 143, 147 (Steven M. Gendel, et al. eds., 1990).
74. *Id.*
75. *Id.*
76. *Id.*
77. *Id.* These predictions are proving to be accurate. *See* Barnaby J. Feder, *Monsanto Has Its Wonder Hormone. Can It Sell It?*, N.Y. TIMES, Mar. 12, 1995, at F7. Farmers are finding that the increased production is offset by the managerial complications of administering rbST. *Id.*

which would increase the need for milk subsidies.[78] The United States currently subsidizes the milk industry by purchasing surplus milk and reimbursing farmers who voluntarily reduce herd size.[79] Use of rbST would increase the amount of subsidies to be provided to dairy farmers.[80] Also, the increased milk supply would also lead to reduced prices for dairy farmers, prices that most farmers argue are already too low.[81]

Finally, many oppose rbST use for ethical reasons.[82] For example, consumer groups such as Jeremy Rifkin's Pure Food Campaign[83] oppose rbST because it is manufactured using genetic engineering techniques.[84] Other groups, such as Consumer's Union, oppose rbST because of the hormone's detrimental effects to the health and well-being of injected cows[85] or because they prefer to buy organic foods.[86]

D. Labeling of Dairy Products From rbST-treated Cows

The FDA does not require rbST products to include a label stating that they contain the hormone.[87] The FDA stated that mandatory labeling of products from rbST treated cows was "unnecessary" and that under its regulatory scheme, it did not have the authority to require labeling of products affected by rbST.[88]

1. Overview of Labeling and Misbranding of Food by the FDA

Under the FDCA, the FDA has the authority to require labeling of food products, to authorize voluntary labeling of food products, and to guard against misbranded food labels.[89] The FDA must fix a "reasonable definition and standard of identity"[90] for food in order to "promot[e] honesty and fair

78. *See Udder Insanity, supra* note 68, at 331. Full discussion of the economic and political implications as a result of increased subsidies is beyond the scope of this article.

79. Milk is the only commodity for which the government sets a minimum price that farmers must receive. Some estimate that the cost to taxpayers is $9 billion per year. *Udder Insanity, supra* note 68, at 330-31. Sen. Russel Feingold (D-Wis.), stated that the estimated effect of rbST on the federal budget would be $15 million in 1994 (representing the cost of buying surplus milk). In later years, the cost would increase to $25 million. *Readers Report, The Budget and Bovine Growth Hormone*, BUSINESS WEEK, Sept. 13, 1993, at 10.

80. Lower milk prices could, however, reduce the cost to the federal government of providing milk and dairy products to WIC (Special Supplemental Food Program for Women, Infants and Children) recipients, as well as the cost of food stamps. A savings estimate is $18 million per year for WIC and $53 million for food stamps, beginning in 1997. Blayney, *supra* note 3, at 30.

81. Susan Hermann Lewis, *The bGH Dilemma: Do We Need More Milk?*, L.A. TIMES, July 1, 1993, at 36.

82. Bovsun, *supra* note 4, at 4. Full discussion of ethical considerations is beyond the scope of this article, but an overview is necessary as ethical concerns are relevant to labeling of rbST products. For a thorough presentation of ethical and social considerations of rbST use, *see* Gary Comstock, *The Case Against bGH, in* AGRICULTURE BIOETHICS 309 (Gendel et. al. eds., 1990).

83. *See FDA Denies Second Petition by Rifkin Group on bST, supra* note 44, at 8.

84. Robert Lee Hotz, *Fruits of Genetic Tinkering Are Headed for U.S. Tables*, L.A. TIMES, Nov. 12, 1993, at A38. The Pure Food Campaign opposes use and development of all genetically engineered products. *Id. See also A Scientist's Qualms*, WASH. POST, Nov. 21, 1994, at A24. John Fagan, a molecular biologist, returned $600,000 in federal grants because of his concerns about "the momentum of genetics research." *Id.*

85. *See* Feder, *supra* note 77, at F7. The FDA has reportedly received several hundred reports from farmers describing deaths and health problems or cows. The farmers attribute the problems to Posilac. Feder, *supra* note 77, at F7.

86. Bovsun, *supra* note 4, at 4.

87. RbST Approval, 58 Fed. Reg. 59,946-47.

88. *See FDA Denies Second Petition by Rifkin Group on BST, supra* note 44, at 8. The FDA stated that the agency "ensures the safety of all food products derived from animals treated with new animal drugs before they are allowed to enter the food supply. Therefore, placing a label on these products would be meaningless and misleading to consumers." *FDA Denies Second Petition by Rifkin Group on bST, supra* note 44, at 8.

89. 21 U.S.C. §§ 321(k), 331(a)-(c), 343(a)-(r) (1988 & Supp. V 1993).

90. 21 U.S.C. § 341 (1988 & Supp. V 1993).

dealing in the interest of consumers."[91]

The FDA also must ensure that food is not misbranded.[92] Under the FDCA, a food is misbranded if "its labeling is false or misleading in any particular."[93] To determine if a label is false or misleading, the FDA considers

> not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling . . . *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 article* to which the labeling . . . relates under the conditions of use prescribed in the labeling.[94]

The FDCA does not specifically define what constitutes a "material fact," but has declared information such as amount of fat, cholesterol, nutrients and serving size to be material.[95]

In its regulations, the FDA has considered a material fact to include information that consumers consider important.[96] For example, the FDA requires labeling of foods processed using irradiation techniques, even though it has declared such techniques safe.[97] The FDA requires the labeling because irradiation is a material fact that should be included on the food label.[98] The FDA stated that, in the case of irradiated foods, the materiality of the information "depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer."[99]

The FDA also allowed supplemental information on the label of irradiated foods for the sole purpose of better informing consumers.[100] The FDA recognized

> the potential for consumer confusion because there is no safety problem with [irradiated food] . . . [but] any confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs, and the presence of a retail label

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91. *Id.*
92. 21 U.S.C. § 343 (1988 & Supp. V 1993).
93. 21 U.S.C. § 343(a) (1988).
94. 21 U.S.C. § 321(n) (1988) (emphasis added).
95. 21 U.S.C. § 343(q)(1) (Supp. V 1993); 21 C.F.R. § 101.9 (1994). *See also* Statement of Policy. Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,981, 22,984 (1992) (requiring labeling of food derived from new plant varieties if it differs from its counterpart).
96. *See* Final Rule, 51 Fed. Reg. 13,376 (1986), *amended by,* Final Rule, 53 Fed. Reg. 12,757 (1988), *amended by,* Final Rule, 55 Fed. Reg. 14,413 (1990).
97. 21 C.F.R. § 179.26(c) (1994). Manufacturers using irradiation in food processing must include a special logo on the label that symbolizes irradiation and a statement saying that the product was treated with irradiation. *Id.*
98. Final Rule, Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,388 (1986).
99. 51 Fed. Reg. 13,388.
100. 51 Fed. Reg. 13,388. The FDA noted that because irradiation was a new technology, "manufacturers may want to use additional labeling statements as part of a consumer education effort." 51 Fed. Reg. 13,388.

statement should not deter the development of this technology.[101]

The FDA required labeling of irradiated products in part because irradiation may change the nutritional value, flavor or texture of food.[102] Initially, the FDA required the rule to be in effect until 1988, but on review has extended the effective date until the required labeling becomes "unnecessary."[103]

2. Interim Guidelines on Voluntary Labeling of Products Not Affected by rbST

Although the FDA has stated that it may not require manufacturers to label products from cows treated with rbST, it has authorized states to enact and enforce their own voluntary labeling regulations.[104] Shortly after approval of rbST, the FDA issued guidelines for voluntary labeling by manufacturers of milk or dairy products not containing rbST, the Interim Guidelines (Guidelines).[105] The FDA authored the Guidelines in response to states' and consumers' requests for guidance on the issue.[106]

Stating that it did not "have the authority in this situation to *require* special labeling for milk from rbST-treated cows,"[107] the FDA allows voluntary labeling of rbST products by the manufacturer, based on state regulations.[108] The FDA stated that because it must regulate against misbranding of rbST products[109] it must ensure that any rbST labeling, even voluntary, does not contain false or misleading claims.[110] According to the Guidelines, a dairy product label that claims the product is "*bST*-free" is false because *all* products produced from milk contain the hormone naturally.[111] Additionally, the Guidelines stated that a label claiming a product is "rbST-free" or "from cows not treated with rbST," though not false, is misleading.[112]

The Guidelines also stated that the statement "rbST-free" implies "a compositional difference" between treated milk and non-treated milk.[113] The preferred label statement is "from cows not treated with rbST."[114] However, because such "unqualified statements imply that milk from untreated cows is

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101. 51 Fed Reg. 13,389.

102. 51 Fed Reg. 13,388. The FDA defined irradiated food as an "additive." 51 Fed. Reg. 13,376. The FDA has greater authority to require special labeling when regulating food additives. 21 U.S.C. § 342(a) (1988 & Supp V 1993).

103. Final Rule, Irradiation in the Production, Processing, and Handling of Food, 55 Fed. Reg. 14,413.

104. Notice, Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (1994) [hereinafter Interim Guidelines].

105. Interim Guidelines, 59 Fed. Reg. 6280. The Guidelines refer to labeling of products not treated with rbST. The FDA offered the Guidelines to assist states in enacting labeling statutes, and are not binding on any state. Interim Guidelines, 59 Fed. Reg. 6280.

106. Interim Guidelines, 59 Fed. Reg. 6280. The Guidelines described only how states could enact voluntary labeling statutes, not mandatory labeling statutes.

107. Interim Guidelines, 59 Fed. Reg. 6279 (emphasis added). According to the FDA, the chemical makeup of rbST-treated milk is virtually identical to untreated milk and must be regulated "no differently" than untreated milk. Interim Guidelines, 59 Fed. Reg. 6280. Therefore, the FDA could not require a special label for rbST products.

108. Interim Guidelines, 59 Fed. Reg. 6279.

109. 21 U.S.C. § 343(a) (1994). *See also supra* notes 92-95 and accompanying text.

110. Interim Guidelines, 59 Fed. Reg. 6280; 21 U.S.C. §343(a), 321(n).

111. *See supra* note 9 and accompanying text.

112. Interim Guidelines, 59 Fed. Reg. 6280.

113. Interim Guidelines, 59 Fed. Reg. 6280.

114. Interim Guidelines, 59 Fed. Reg. 6280.

safer or of higher quality than milk from treated cows," even this label might be misleading.[115]

The Guidelines conclude that if a product is to be labeled as not containing rbST, it should contain a label stating the product is "from cows not treated with rbST," supplemented with the statement that "no significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows," or a similar statement.[116] The FDA advises that the product label include supplemental information to explain the use and composition of rbST.[117]

The FDA also noted that no test exists to "differentiate analytically between naturally occurring bST and [rbST] in milk."[118] Because there is no way to determine how much rbST, if any, remains in milk or dairy products, it is difficult to substantiate claims that a product is free from rbST.[119] As a result, states authorizing voluntary labeling must use other means to enforce labeling regulations.[120]

The FDA advised states that enact rbST labeling regulations to require manufacturers that wish to label products "rbST-free" to "establish a plan and maintain records to substantiate the claims, and make those records available for inspection by regulatory officials."[121] The FDA stated that manufacturers must establish their products as rbST-free primarily through record maintenance, signed affidavits, or third-party certification programs.[122]

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115. Interim Guidelines, 59 Fed. Reg. 6280. *See also Citing Survey, Monsanto Says Any bST Label Will Be Misleading*, FOOD LABELING NEWS, Apr. 14, 1994, at 12-13. Monsanto conducted a survey that asked consumers to react to rbST labels. The survey indicated that regardless of what disclaimers were used on rbST labels, consumers understood the labeled products to be less safe than milk from non-treated cows. Monsanto stated that "[i]n every instance, no matter what disclaimers were included, more than half of the consumers surveyed understood any reference to bST usage as implying that the milk from supplemented cows is less safe or less nutritious or tastes different than milk from cows that have not received bST supplements." *Id.* at 13.

116. Interim Guidelines, 59 Fed. Reg. 6280. The FDA has stated that supplemental information puts the claim that the product is free from rbST in the "proper context." Interim Guidelines, 59 Fed. Reg. 6280. Statements conveying the manufacturer's reasons "other than safety or quality" for choosing to use milk from non-treated cows also achieves proper context. Interim Guidelines, 59 Fed. Reg. 6280.

117. Interim Guidelines, 59 Fed. Reg. 6280.

118. Interim Guidelines, 59 Fed. Reg. 6280.

119. Interim Guidelines, 59 Fed. Reg. 6280. A common enforcement technique for agencies such as the FDA is testing food products to confirm that the label correctly represents what is in the food. Enforcement and substantiation problems are discussed *infra*, part II.D.4.

120. Interim Guidelines, 59 Fed. Reg. 6280.

121. Interim Guidelines, 59 Fed. Reg. 6280.

122. Interim Guidelines, 59 Fed. Reg. 6280. The FDA provides the following suggestion:

> Participating dairy herds should consist of animals that have not been supplemented with rbST. The program should be able to track each cow in the herd over time. Milk from non-rbST herds should be kept separate from other milk by a physical segregation, verifiable by a valid paper trail, throughout the transportation and processing steps until the finished milk or dairy product is in final packaged form in a labeled container. The physical handling and record keeping provisions of such a program would be necessary not because of any safety concerns about milk from treated cows but to ensure that the labeling of the milk is not false or misleading.

Interim Guidelines, 59 Fed. Reg. 6280.

3. Labeling Regulation by the States

Several states, including Minnesota and Wisconsin, have enacted rbST labeling legislation.[123] Minnesota's labeling statute authorizes voluntary labeling of dairy products that do not contain rbST.[124] Labels on rbST-free products may state, "[m]ilk in this product is from cows not treated with rBGH," or indicate that the milk is "farmer-certified rBGH-free."[125] The labels need not contain further information.[126] Minnesota's rbST statute also requires certification of rbST-free milk.[127] To label products as free from rbST, a manufacturer must require farmers to submit an affidavit stating that the milk is from cows not treated with the hormone.[128] The state requires a thirty-day notice if a farmer wishes to later use the hormone in his or her dairy operations.[129]

Wisconsin's rbST statute authorizes dairy producers, retail food establishments, and restaurants to label products free from rbST as "[f]armer-certified rBGH-free" or to use an "equivalent statement that is not false or misleading."[130] Wisconsin also requires farmers who wish to label their products as rbST-free to submit affidavits certifying they do not use the hormone.[131]

Although most states based their rbST labeling statutes on the FDA Guidelines, many state officials and members of the dairy and food industries fear that individual state regulations will produce inconsistent results and consumer confusion and burden interstate commerce.[132] Therefore, they believe the FDA

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123. States that have enacted voluntary labeling statutes include Minnesota, Wisconsin and Maine. *See* MINN. STAT. § 32.75 (1994); WIS. STAT. ANN. § 97.25 (West Supp. 1994); ME. REV. STAT. ANN. tit. 7, § 2901-B (West Supp. 1994).

Vermont is the only state that has enacted a mandatory labeling statute. VT. STAT. ANN. tit. 6, § 2754(c) (Supp. 1994). Monsanto has filed suit in response to Vermont's statute. *FDA Said To Be Working On Uniform Labeling Rules*, FOOD LABELING NEWS, May 26, 1994, at 1. The manufacturer argues that the mandatory statute conflicts with the FDA's Guidelines, which only authorize states to enact voluntary labeling. *Id.*

Several state legislatures have introduced bills that address rbST labeling: California Milk Labeling: Bovine Growth Hormone Bill, Senate Bill No. 653 (introduced Feb. 22, 1995) (requiring labeling of milk and milk products that contain milk from rbST treated cows); Maine House Paper, No. 208 (introduced Jan. 27, 1995) (requiring labeling of milk or milk products sold in Maine if derived from rbST treated cows); Massachusetts Senate Bill, No. 1146 (introduced Feb. 23, 1995) (requires labeling of dairy products from rbST treated cows and registration of rbST); Missouri House Bill, No. 737 (introduced Mar. 7, 1995) (authorizes voluntary labeling of rbST-free products and restricts dairy products produced from herds that were administered rbST out of state); Missouri House Bill, No. 163 (introduced Jan. 5, 1995) (establishes procedures for labeling rbST products); New Jersey Assembly Bill, No. 2209 (introduced Sept. 9, 1994) (requires labeling of rbST treated milk and milk products); New York Senate Bill, No. 4760 (introduced May 3, 1995) (requires labeling of dairy products from rbST treated cows); New York Assembly Bill, No. 3845 (introduced Feb. 15, 1995) (requires labeling of dairy products from rbST treated cows); Rhode Island House Bill, No. 5683 (introduced Feb. 7, 1995, amended Apr. 26, 1995) (requires milk producers, distributors and retailers to inform consumers of rbST content); Rhode Island Senate Bill, No. 262 (introduced Jan. 26, 1995) (provides guidelines for voluntary labeling of milk products that do not contain rbST).

124. MINN. STAT. § 32.75 (1994).

125. MINN. STAT. § 32.75(2)(a) (1994). "RbGH" is another name for rbST. RbGH refers to "recombinant bovine growth hormone." MINN. STAT. § 32.75(1) (1994). *See also supra* note 2.

126. MINN. STAT. § 32.75(2)(a) (1994).

127. MINN. STAT. § 32.75(3)(a) (1994).

128. *Id.*

129. *Id.*

130. WIS. STAT. ANN. § 97.25(3) (West Supp. 1994).

131. *Id.*

132. *See Espy "Personally" Backs bST Labeling; Nationwide Battle Rages*, FOOD LABELING NEWS, May 5, 1994, at 25-28 [hereinafter *Espy "Personally" Backs bST Labeling*]. *See also BST Labels Constitute Implied Health Claims, State Says*, FOOD LABELING NEWS, Apr. 7, 1994, at 10-11.

should enact uniform labeling regulations at the federal level.[133]

4. Substantiation and Enforcement Problems

In its Interim Guidelines the FDA noted the problem of enforcing state labeling provisions.[134] Even though the FDA often requires the manufacturer of a new animal drug to develop a test to detect the presence of the drug in edible animal tissues,[135] it did not require Monsanto to develop such test prior to rbST approval.[136] Because no test exists to determine whether milk or dairy products contain rbST,[137] enforcement of labeling regulations pose a problem for the regulatory body enforcing them.[138] This enforcement body must instead rely on assurances from farmers and food producers that their products do not contain the synthetic hormone.[139] The FDA stated that the assurances could take the form of affidavits or certification.[140]

If a state enacts a labeling statute, it must enforce labeling not only on milk but also on dairy products such as cheese, yogurt and ice cream.[141] The lack of a method to measure rbST in milk presents a problem for enforcement of labels on such dairy products. Many manufacturers of dairy products collect milk from several dairies and "pool" the milk into large tanks.[142] The manufacturers then produce dairy products from milk stored in those tanks.[143] If manufacturers purchase some milk from dairies using rbST and some milk from dairies that do not,[144] they would need to separately store the two types of milk, separately manufacture products from rbSt and non-rbST milk, and separately label dairy products to comply with labeling requirements.[145]

Because researchers may soon develop a test that can detect the presence

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133. *See Espy "Personally" Backs bST Labeling, supra* note 132, at 25. Idaho Governor Cecil Andrus objected to the FDA "foisting" labeling enforcement onto the states. *Citing Survey, Monsanto Says Any BST Label Will be Misleading, supra* note 115, at 14.

Wisconsin state legislator Bob Kreibich, in a letter to USDA Secretary Mike Espy, stated that he supports "creation of uniform, nationwide guidelines for the labeling of dairy products with respect to rbST content." *Id.* at 15. Several food industry trade associations stated that "[i]n addition to usurping FDA's proper leadership role in the arena of food labeling, such state laws could unfairly prejudice foods derived from biotechnology - which FDA has recognized as having enormous potential to benefit American consumers." *Espy "Personally" Backs bST Labeling, supra* note 132, at 25.

134. Interim Guidelines, 59 Fed. Reg. 6280.

135. 21 U.S.C. § 360b(b)(1)(G) (1994); 21 C.F.R. § 514.1(h)(7) (1994). *See also supra* notes 37-41 and accompanying text.

136. Interim Guidelines, 59 Fed. Reg. 6279. The FDA did not explain its reasons for not requiring a residue test in either its approval of rbST or in the Interim Guidelines. RbST Approval, 58 Fed. Reg. 59,946; Interim Guidelines, 59 Fed. Reg. 6279. *See also supra* notes 37-41 and accompanying text. *But see supra* note 41 (rbST residue, if present, would not be harmful to humans, and thus, a residue test is not necessary).

137. Interim Guidelines, 59 Fed. Reg. 6279. However, Lilly Research Laboratories is developing a test that detects presence of rbST in bulk materials. *Non-Denaturing Assay for the Determination of the Potency of Recombinant Bovine Somatotropin by High-Performance Size-Exclusion Chromatography*, July 22, 1994 (abstract available in WESTLAW MEDLINE database).

138. Interim Guidelines, 59 Fed. Reg. 6280. A residue test would allow the enforcement body to conduct random tests on milk, to determine if it contained rbST. If the product contained rbST, it would need to be labeled accordingly.

139. Interim Guidelines, 59 Fed. Reg. 6280.

140. Interim Guidelines, 59 Fed. Reg. 6280. Affidavits may state that the farmer was not using rbST on cows or that the farmer's operation had been "state certified" that cows were not treated with rbST. Interim Guidelines, 59 Fed. Reg. 6280.

141. *See* 21 U.S.C. § 343 (1988 & Supp. V 1993).

142. Telephone Interview with Marty Davis, Vice President, Davisco International, Jan. 9, 1995. Davisco is a dairy products manufacturer headquartered in LeSueur, Minn.

143. *Id.*

144. *Id.*

145. This process would be necessary only if a manufacturer wished to market a line of rbST-free products. If the manufacturer does not wish to market a rbST-free line, there would be no need to separate and record which milk is rbST-free and which is not.

of rbST in milk,[146] enforcing rbST labeling may not present problems in the future. Moreover, the FDA or its parent agency, Health and Human Services,[147] may be required to develop a test for detecting presence of rbST in milk if Congress passes the Bovine Growth Hormone Act.[148]

III. ANALYSIS

Before FDA approval of rbST, researchers conducted years of studies to ensure products from rbST-treated cows were safe for human consumption.[149] However, some argue that the FDA, as an agency for consumer advocacy,[150] has not done enough to guarantee safety of rbST and should at the very least require labeling of dairy products containing rbST.[151] The FDA's solution however, voluntary labeling authorized by state legislatures,[152] will lead to inconsistent regulation and consumer confusion. Therefore, the FDA should promulgate mandatory labeling standards at the federal level.

A. Why a Uniform Labeling Standard is Necessary

The result of the FDA's decision not to require labeling of rbST products has been various state regulations on rbST labeling,[153] leading to inconsistent standards that will be burdensome for consumers and dairy product manufacturers. The FDA is the regulatory body best equipped to define uniform standards for food product labeling, and therefore must develop rbST-labeling language for all states to follow.

A federal standard is necessary to ensure consistent labeling of rbST products from state to state. In its Interim Guidelines the FDA defined broad standards to guide states when enacting rbST labeling, but did not provide specific, mandatory requirements for states to follow.[154] The FDA's guidance focused primarily on what manufacturers may not include on labels, rather than on what manufacturers must include on labels to comply with the FDCA.[155] The suggestions provided by the FDA left little guidance to states when determining what a proper labeling standards would be.

Because of the various state regulations on rbST labeling, consumers who purchase milk or dairy products across state lines will encounter labels with different language than labels in their home state. The will may be consumer confusion, in that they may think different rbST labels represent a higher or

146. *See supra* note 137.
147. 21 U.S.C. §§ 321(c)-(d) (1988 & Supp. V 1993).
148. H.R. 4618, 103rd Cong., 2d Sess. (1994). Representative Bernard Sanders of Vermont introduced the bill. The bill also proposed to authorize the Secretary of Agriculture 1) to impose labeling requirements for products produced using the hormone, and 2) to amend the Agriculture Act of 1949 to require the Secretary of Agriculture to reduce the price producers receive for milk produced by cows receiving rbST. The House submitted the bill to the Agriculture Committee. *Id.*
149. *See supra* notes 15-16 and accompanying text.
150. *See supra notes* 19-22 and accompanying text.
151. *See supra* notes 132-133 and accompanying text.
152. *See supra* notes 107-108 and accompanying text.
153. *See supra* notes 123-131 and accompanying text.
154. *See supra* notes 111-117 and accompanying text.
155. *See supra* notes 111-112 and accompanying text.

lower rbST content or that the milk itself is somehow altered.[156] As a result, consumers will not enjoy the traditional FDA guarantee of consistent food labeling.

A federal rbST labeling standard will also reduce the burden on manufacturers to comply with the various state labeling regulations. The states that have enacted rbST legislation require certain language on products not containing rbST,[157] and therefore manufacturers selling milk or dairy products in those states must create a label consistent with the state standards. Manufacturers must develop different labels for the dairy products they sell in the various states with rbST labeling regulations, in order to comply with the various state laws. Manufacturers will also need to adjust storage and record-keeping practices to ensure that products shipped to the different states are correctly labeled. The cost of complying with the various state labeling regulations will likely be high for dairy product manufacturers. A uniform standard, then, would allow manufacturers to develop one label for each product they sell and ship the products to any state in the country.

The need for uniform standards is particularly important as more states consider rbST regulation. Currently, only three states have voluntary rbST-labeling, and one has a mandatory labeling statute.[158] Several states, however, have considered some form of rbST labeling statute,[159] which, if enacted, would further increase the number of labels manufacturers must develop and track in the future.

The FDA, which traditionally promulgates food labeling standards, is in the best position to develop rbST labeling standards and has the necessary expertise and resources to promulgate labeling standards. To reduce consumer confusion and burdens on manufacturers, the FDA should develop mandatory rbST labeling standards.

B. The FDA Has Authority to Mandate Labeling

The FDA's response to requests for rbST labeling is that it has no authority under the FDCA to require labeling of rbST products.[160] However, the FDA has broad discretion when regulating food standards in the interest of consumers,[161] and is not limited to regulating labels solely for health or safety reasons.[162]

1. Consumer Interest

The FDA has authority to act in the interest of consumers when develop-

156. Usually, label information is uniform from state to state. An example is the recently revamped nutrition labeling standards (now appearing as "Nutrition Facts" on food product labels). 21 C.F.R. § 101.36 (1994).

157. *See supra* notes 123-131.

158. *See supra* note 123.

159. *See supra* note 123.

160. *See supra* note 107 and accompanying text.

161. *See supra* notes 19-22 and accompanying text.

162. *See supra* notes 96-103 and accompanying text.

ing standards for food,[163] and discretion to choose which policies and regulations to implement, within the ambit of the FDCA. Such authority enables the FDA to do more than merely authorize the states to enact voluntary labeling statutes. Public response after rbST approval demonstrated that consumers would appreciate the information on dairy product labels, so they could choose for themselves whether or not to purchase rbST products. The FDA, as an agency regulating in the consumer interest, should have been more responsive to consumer requests for labeling when approving rbST.

Traditionally, the FDA requires labeling in response to scientific health and safety data, not in response to consumer fears or ethical beliefs.[164] However, the FDA has promulgated food labeling regulations in an effort to better inform consumers. For example, in its mandatory labeling of irradiated food products,[165] the FDA *required* that retail packages of irradiated food contain a special logo and the statement "treated with radiation" or "treated by irradiation."[166] It required labeling not because of safety risks of irradiated food, but in part because consumers found information regarding irradiation to be important.[167] The FDA also authorized the manufacturer to include additional information describing the nature or purpose of using radiation, in an effort to educate consumers about irradiated food.[168]

A similar situation exists with rbST products. As with irradiated food products, the FDA found that there were no human safety risks associated with rbST,[169] but nevertheless could have required all rbST products be labeled. If the FDA had relied on policies similar to those it used when regulating irradiated food labeling, requiring labeling because consumers think the information is important, it could have authorized a mandatory standard for labeling rbST products.[170]

In addition, the FDA issued the initial irradiation rule with a two-year

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163. *See supra* note 20 and accompanying text.

164. Many of the consumer objections to rbST center on social, political and ethical concerns which are beyond consideration by the FDA. The agency cannot, for example, require labeling of rbST products because consumers object to milk subsidies or genetic engineering techniques in food production. *See Espy Personally Backs bST Labeling*, *supra* note 132, at 27.

The International Food Biotechnology Council found the FDA's Interim Guidelines "troubling" because "the primary goal of food labeling -- the communication of meaningful information about food in a simple, clear and consistent manner -- may be abandoned in favor of permitting statements that have nothing to do with the character of food and that are of no public health significance." *Citing Survey, Monsanto Says Any bST Label Will Be Misleading*, *supra* note 115, at 16. The Council viewed mandatory labeling in response to consumer requests as a bad precedent and something the FDA should avoid. *Citing Survey, Monsanto Says Any bST Label Will Be Misleading*, *supra* note 115, at 16.

165. *See supra* notes 96-103 and accompanying text.

166. *See supra* note 97 and accompanying text. RbST is distinguishable from irradiated food in that the FDA did not find rbST products to contain an "additive" as it did with irradiated food. This distinction is important because the classification of food products determines how the FDA can label the products. *See supra* notes 97-98 and accompanying text.

The importance the FDA places on consumer information and education when requiring irradiated food labeling is noteworthy, however, in that the FDA could have used similar reasoning to develop rbST labeling requirements.

167. *See supra* note 99 and accompanying text. The FDA required labeling of irradiated food in part because of reduced nutrition value of irradiated food; however, the FDA carefully noted that it was acting in the consumer interest when requiring labeling of irradiated food. *See supra* notes 100-101 and accompanying text.

168. *See supra* note 100 and accompanying text. The FDA stated that "because [irradiation] is a new technology, manufacturers may want to use additional labeling statements as part of a consumer education effort." Irradiation in the Production, Processing and Handling of Food, 51 Fed. Reg. 13,388.

169. *See supra* note 97 and accompanying text.

170. First, consumers find rbST content in dairy products to be important information. Second, genetic engineering, like irradiation, is a new technology, information of which consumers should be notified. Third, supplemental information could be included on rbST labels, as a part of a consumer education effort.

effective date,[171] to allow time for consumers to familiarize themselves with the irradiation logo and what it represented. The FDA could similarly require labeling of rbST products for a period of time, to allow consumers to recognize the terms "rbST" or "bovine growth hormone." Including this information would also enable consumers to educate themselves about the nature of rbST products. Consumers can only educate themselves, however, if product labels contain relevant, accurate information.

2. *Clear FDA Authority: Congressional Action*

Although the FDA could have required labeling of rbST products when it approved the hormone, its authority to require labeling of rbST products could be more firmly rooted if specifically authorized by a Congressional act. Congress could enact legislation that required labeling of rbST products or that strengthened the FDA's ability to require labeling of genetically engineered products as a whole. Legislation speaking to labeling of genetically engineered food products may become particularly important as the food and agriculture industries develop genetically engineered food.[172] Having a mechanism in place in the near future may alleviate future problems with labeling of genetically engineered food.

In the past, when FDA authority to require labeling is not clear, Congress has responded by enacting regulation to strengthen FDA authority. Congress adopted this stance when the FDA revamped the nutrition labeling regulations.[173] In 1990, Congress passed the Nutrition Labeling and Education Act,[174] which it enacted to "strengthen the FDA's authority to require nutrition labeling on foods and to avoid the possibility of protracted litigation over the comprehensive nutrition labeling regulations that the agency adopts."[175] A similar stance could be adopted regarding labeling of rbST products: Congress could enact legislation that allowed the FDA to require labeling if it felt that such labeling would provide information consumers may consider important.

In addition, by failing to promulgate mandatory labeling requirements, the FDA relieved itself of the burden of enforcement. As a result, states with rbST labeling regulations are left with the responsibility and financial burden

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171. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,391.

172. Monsanto and other companies are currently developing genetically engineered varieties of vegetables and other plants. Calgene, Inc., a California-based company, developed a genetically altered tomato that resists bruising and allows tomatoes to vine-ripen longer. Diane Toops, *Welcoming Biotechnology With Open Arms*, FOOD PROCESSING, Nov. 1994, at 1. Calgene will label its tomato to indicate that it has been genetically altered. Hotz, *supra* note 84, at A38.

173. *See* Final Rule, Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079, 2080 (1993). The rule was based on Congress' amendments to the FDCA, which allow the Secretary of Health and Human Services (parent agency of the FDA) to adjust nutrient regulations as he or she feels necessary to "assist consumers in maintaining healthy dietary practices . . . ." Final Rule, Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079.

174. 21 U.S.C. § 343 (q)-(r) (Supp. V 1993).

175. Final Rule, Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079. In the FDA's final rule on nutrition labels, it noted that it had received an objection to the FDA's "being given the authority to mandate nutrition labeling on most foods on the basis that current nutrition labeling rules were legally questionable." The FDA stated that comments such as this, questioning the FDA's authority to revamp nutrition labeling, led Congress to pass the 1990 amendments. There was, therefore, "no question about FDA's authority to require nutrition labeling on most food products." Final Rule, Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079.

of enforcing labeling standards. Enforcement is particularly burdensome for the states because the FDA failed to require a residue test for rbST.[176] The enforcement problem may not last long, however, because a test capable of detecting rbST residue may soon be perfected.[177] When this happens, the FDA will need to reevaluate its stance on enforcement of rbST labeling, and it may be more willing to promulgate federal labeling standards.

C. *Labeling of rbST Products is Not Misleading*

In its Interim Guidelines, the FDA stated that certain statements on rbST product labels may mislead consumers, because the statements would imply a compositional difference between rbST and non-rbST products that does not exist.[178] As a result, the FDA was reluctant to require labeling of rbST product. The FDA did not make a sincere effort, however, to develop a labeling standard that clearly and accurately state the presence of rbST in dairy products without the danger of misleading consumers.

For example, the FDA could require a prominent label statement such as "this product is produced from cows treated with recombinant bovine growth hormone," or place a symbol representing the presence of rbST (such as the face of a cow) on the product label. In addition, the FDA could require supplemental information about the nature of rbST. Such information could state 1) that rbST is a nearly identical genetic copy of a hormone which occurs naturally in milk, 2) that in nearly a decade of testing for safety and efficacy, studies have shown that food from rbST cows is safe, and 3) that milk from rbST-treated cows is nearly identical to milk from non-treated cows.[179]

Critics of mandatory labeling state that any rbST labeling will be misleading.[180] However, even if we accept the argument that consumers could be "misled" by rbST labeling, that fact does not relieve regulators of the responsibility to guarantee accurate and clear labeling of some sort. The FDA seems to think that because consumers may not fully understand the use or safety of rbST, it is relieved of all responsibility to properly inform consumers of the nature of the milk or dairy products on the market.[181]

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176. *See supra* note 41 and accompanying text. *But see supra* note 39.

177. *See supra* note 137. In addition, recent Congressional action has broadened FDA authority to require residue tests in future new animal drug applications. *See supra notes* 147-148 and accompanying text.

178. *See supra* notes 109-116 and accompanying text.

179. On small food packages with limited surface area, the FDA could require a symbol be placed on the package with a shelf sign or pamphlet placed nearby, fully explaining the use and nature of rbST. This scheme is similar to the one implemented by the FDA when requiring labeling of irradiated food. *See supra* notes 147-148 and accompanying text.

180. *See supra* note 115 and accompanying text.

181. It is possible that the FDA and Monsanto were concerned that labeling would cause consumers to purchase rbST-free products, which would in turn reduce profit from sales of rbST treated products. The FDA, however, should first address the concerns of consumers, not of manufacturers. *See GAO Asked to Probe Conflict of Interest Re: FDA bST Approval*, FOOD CHEMICAL NEWS, Apr. 25, 1994, at 1, 4-5. The GAO was asked to review potential conflicts of interest of three FDA officials. All three were responsible for addressing rbST labeling. One was a former Monsanto employee (who wrote the opinion that rbST-treated products should not be labeled), one previously worked for a consultant to Monsanto, and one, FDA Deputy Commissioner for Policy Michael Taylor, had Monsanto as his personal client while at the law firm King and Spaulding. *Id.* at 1, 4.

IV. CONCLUSION

Once declaring that milk and dairy products from rbST-treated cows were safe for human consumption, the FDA was correct in that it did not have to require labeling of rbST products. However, the statement that it did not have the authority to require labeling is not entirely accurate. The FDA's authority to act in the public interest allows it to inform consumers about the content of dairy products on the market. The FDA could have relied on this authority to at minimum develop uniform federal labeling standards for this first-ever genetically engineered product used in food production.

A better solution, however, is for Congress to step in and enact legislation on rbST labeling. If Congress or the FDA is reluctant to single out rbST products in a statute or regulation, either could address the broader issue of all food or agricultural products manufactured using genetic engineering techniques. Because consumers have not only safety concerns, but also ethical and moral concerns relating to rbST use, they are entitled to information of the contents of dairy products. Only when consumers are armed with this important information will they be able to make buying decisions that reflect their beliefs.

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