GOT CONTROVERSY? MILK DOES

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I. INTRODUCTION

Or more narrowly stated: milk labels do.[1] Between February 2007 and April 2008, milk labeling was the subject of a Federal Trade Commission complaint,[2] a Food and Drug Administration petition,[3] legislation in two states,[4] ad-

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1. Milk (dairy) is a highly-regulated market, primarily by the USDA, Agricultural Marketing Service. That market's history is beyond the scope of this article, which focuses on consumer demand for rBST-free milk. Readers interested in U.S. dairy regulation will find helpful information at http://www.ams.usda.gov.

2. Complaint at 1, FDA Matter No. 072-3480 (Feb. 27, 2007), *available at* http://www.ftc.gov/os/comments/monsanto/070227letterMonsantorBST.pdf.

3. Petition for Labeling of Products Produced with Posilac, FDA Docket No. 2007P-0059 (Feb. 20, 2007), *available at* http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetails=FDA-2007-P-0119-0002.

ministrative rulemaking in two,[5] and a federal district court action.[6] All of these activities focused on how much information the consumer should have about the use of recombinant bovine somatotropin[7] (rBST) in dairy herds and how that information is conveyed to milk consumers. rBST is a hormone that increases milk production used in dairy cows producing milk for human consumption.[8] Some consumers believe rBST poses human health risks; others believe it harms cows; others want to avoid genetically modified material, while some consumers do not care about rBST at all.

Why is rBST controversial? For two main reasons: 1) it is a genetically engineered hormone and 2) it poses health risks to cows treated with it.[9] Many consumers fear genetically engineered materials in foods because they believe there is not enough known about how modifying a food's genes will impact human and environmental health.[10] Setting aside whether consumers' fears are rational, these fears are not shared by the FDA. The FDA first presumed genetically engineered foods "generally regarded as safe" under the Food, Drug, and Cosmetics Act, but later required a premarket clearance procedure – both schemes permitting genetically engineered foods into the food supply without a mandatory disclosure label.[11] The genetically engineered foods issue has multiple layers – do they harm humans? Our environment? Animals? Since there are few definitive answers to these questions, other than studies confirming safety, consumers' fears are driven by the unknown.

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4. S.B. 595, 2008 Sess. (Kan. 2008); H.B. 1300, 115th Gen. Assem. 2d Reg. Sess. (Ind. 2008).

5. Pa. Dep't of Agric.: Milk Labeling Standards, 2.0.1.17.08 (Jan. 17, 2008); Ohio Emergency Rule, Dairy Labeling, 901:11-8.01 (May 22, 2008).

6. Complaint at 1, Int'l Dairy Foods Ass'n v. Boggs, No. 08-cv-00628-JLG-NMK (E.D. Ohio filed July 7, 2008).

7. rBST is a synthetic hormone that increases milk production by as much as 20%. Bradford L. Barham & Jeremy Foltz, *rBST Adoption in the United States: That Was the Juggernaut…That Wasn't* 17 CHOICES 15, 16 (Summer 2002). rBST is manufactured only by Monsanto and is marketed under the trade name Posilac. Readers should note that Monsanto sets milk production increases at 10-15%. *See* BST by Posilac, http://www.monsantodairy.com/about/index.html (last visited Nov. 1, 2008).

8. Robert Collier, *Regulation of rBST in the US*, 3 AGBIOFORUM 156 (2000).

9. *Id.* at 159.

10. *See generally* Mariella Nocenzi et al., *Genetic Modified Organisms: Confronting Needs, Interests, Responsibilities and Fears*, 15 INT'L REV. SOC. 305 (2005); for one consumer perspective and an anti-genetic engineering view see ANDREW KIMBRELL, YOUR RIGHT TO KNOW: GENETIC ENGINEERING AND THE SECRET CHANGES IN YOUR FOOD (2007).

11. Statement of Policy: Foods Derived from New Plant Verities, 57 Fed. Reg. 22,984 (May 29, 1992); Proposed Rules: Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001). *See also* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170 (D.D.C. 2000).

The rBST science shows negative side effects on dairy herds. Specifically, Monsanto's safety studies showed an increased risk of mastitis, twinning rates, and injection site infections.[12] Yet, the law does not require zero risk to animals when approving a new veterinary drug.[13] Despite little scientific evidence that genetically engineered foods are unsafe and a legally tolerable risk to animals, many consumers still reject rBST as unnatural, unsafe, and undesirable.

Since many consumers avoid rBST, why would farmers use it? Simply put, it increases milk production.[14] Theoretically, a more productive dairy is a more profitable one. rBST is also an innovation and is attractive to farmers who want to be competitive. Finally, farmers use it because Monsanto markets it to them. As any company with a potentially profitable product should, Monsanto has sold many farmers on the benefits of rBST.[15]

Today's dairy farmers face a complex industry – consolidation and organic production force difficult economic choices. Milk consumers also face difficult choices – conventional? hormone free? organic? What do these labels mean about the choices farmer's make when producing the milk? These questions and choices exist because of the FDA's 1993 approval of rBST.[16] Since that approval, the dairy industry and consumers have struggled with the consequences of rBST milk in the marketplace.

The current skirmishes over the use of the genetically engineered hormone in US dairy herds are important. Ultimately, the controversy is about marketing. Realistically, consumers already have rBST information on milk labels.[17] rBST-free milk carries the statement "from cows not treated with rBST," followed by the disclaimer "no significant difference has been shown between milk derived from rBST-treated and non-rBST treated cows."[18] However, some producers also add claims such as "no added hormones" or "artificial hormone free."[19] These claims and deviations from the FDA guidelines area are what upset Monsanto, farmers who use rBST, and producers. They believe that the unsanctioned claims mislead consumers into believing that rBST-free milk is supe-

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12. Stauber v. Shalala, 895 F. Supp. 1178, 1183-84 (W.D. Wis. 1995).
13. *Id.* at 1191 (The FDA determined that the risk to animals was "manageable"—meaning that through appropriate farming techniques the farmers could manage side effects on the cows).
14. Barham & Foltz, *supra* note 7, at 15.
15. *See id*.
16. *See* Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombiant Bovine Somatotropin, 59 Fed. Reg. 6279 (Feb. 10, 1994).
17. *See id.* at 6280.
18. *Id*.
19. Complaint, FDA Matter No. 072-3080, *supra* note 2, at 1, 9.

rior or more healthful.[20] They are right: this is exactly what consumers seeking out rBST-free milk believe – or what media outlets who cover the issue want the public to believe.[21]

Early predictions were that consumers would adjust to rBST in milk, but the opposite is true. While it took nearly fifteen years for a clear consumer preference for rBST-free milk to emerge in the marketplace – 2008 marked the year that it did. Most milk producers' labels adhere to the FDA guidance, including the disclaimer. However, this information has made little difference to consumers.[22] Quite the opposite is true: consumers express a preference for rBST-free milk raising the important question: Why haven't consumers embraced the FDA's rBST safety ruling? The probable reason is that consumers distrust that safety ruling. The primary reason for the distrust is that rBST is genetically modified and does pose some health risk to animals.

Thus, the current controversy pits consumers against producers, unproven safety concerns against regulatory approval of rBST, and tradition against innovation. There are three things that the industry, consumers, and lawmakers could do to solve this problem. These three things are: 1) conduct consumer surveys determining the true extent of consumer confusion and consumer preference; 2) conduct consumer research to determine the most effective milk labels at providing consumer information; and 3) based on the consumer research of the previous two suggestions, make a decision to promote USDA organic milk as the one solution for consumers who want rBST-free milk or devise a symbol, similar to the USDA organic symbol, that represents rBST-free milk. Unless the parties engage in solutions like these, the controversy will continue.

II. WHY DO CONSUMERS CARE? A SHORT HISTORY OF RBST, 1987-2007

Controversy surrounded rBST from the time Monsanto first applied for it as a new animal drug in 1987.[23] Many consumers recoiled at the thought of a genetically engineered hormone[24] being injected into cows to increase milk pro-

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20. *Id*. at 1.

21. An internet search for "rBST" results in a plethora of websites that decry rBST use and highlight its "dangers." However, there are no widely publicized consumer studies that indicate what consumers know or believe about rBST. *See id*. at 4-5.

22. *See, e.g.*, Caren Wilcox, *Growth and Challenges Await Organic Dairy*, 109 DAIRY FOODS 114 (2008).

23. *See* Collier, *supra* note 8, at 156. *See also* 21 U.S.C. § 360b (2006) (mandating new animal drugs must be approved by the FDA).

24. The history of consumer reaction to genetically modified foods is beyond the scope of this article, though I believe that the FDA's early presumption that genetically engineered foods are "Generally Regarded As Safe" (GRAS) under the Food, Drug, and Cosmetics Act, 21 U.S.C. §

duction, even though rBST is indistinguishable in the lab from its natural counterpart, BST.[25] Today, consumers' concerns about rBST include increased use of antibiotics in dairy herds to reduce rBST side effects and animal welfare issues. Analysts in the area also often note that the United States is one of the few nations to approve rBST use, with Canada, New Zealand, and Australia banning it, and the European Union continuing to restrict its use.[26]

A. *1987 – 1994: FDA Approval*

BST is a naturally occurring hormone.[27] Scientists discovered that injections of BST increased milk production as early as the 1930s, though BST production was impractical.[28] This changed through the 1970s and early 80s, when Genentech and Monsanto developed genetically engineered BST – rBST – commercially known as Posilac.[29] In 1987, Monsanto applied to the FDA for Posilac approval.[30] Although there were some side effects for cows, such as increased incidence of twins, injection site infections, and a slight increase of mastitis, the FDA ruled the "risks to animal health were not significant" and approved Posilac's use in cows.[31] Because of that decision, today farmers inject cows with rBST to increase their milk production.[32]

321(s) (2006), and subsequent premarket clearance procedure is linked to continued consumer concerns about rBST. For further reading on the topic, see generally Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 166 (D.D.C. 2000); Statement of Policy: Foods Derived from Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 2001); Mario Teisel et al., *Focus Group Reactions to Genetically Modified Food Labels*, 5 AGBIOFORUM 6 (2002); Nocenzi, et al., *supra* note 10; KIMBRELL, *supra* note 10.

25. John F. Murphy, *Mandatory Labeling of Food Made from Cloned Animals: Grappling with Moral Objections to the Production of Safe Products*, 63 FOOD & DRUG L.J. 131, 140-41 (2008) (analogizing consumer concerns about cloned meat to rBST controversy and noting the rBST controversy "is another poignant example that American consumers have come to care about not just merely what is on their plate (or in their glasses), but also how it got there."). *See also* Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?* 11 VA. J.L. & TECH. 4, 40 n.144 (2006) (reviewing history of rBST approval).

26. *See* Dirk Brinkman, *The Regulation of rBST: The European Case*, 3 AGBIOFORUM 164 (2000); Kevin Jones, *Constructing rBST in Canada: Biotechnology, Instability and the Management of Nature*, 25 CAN. J. SOC., 311, 311-41 (2000).

27. Collier, *supra* note 8, at 157 (noting that until Monsanto and Genentech discovered how to genetically engineer BST, its commercial production was impractical).

28. *Id.* at 156.

29. *Id.*

30. *Id.*

31. Stauber v. Shalala, 895 F.Supp. 1178, 1184 (W.D. Wis. 1995).

32. Barham & Foltz, *supra* note 7, at 15.

FDA approval of Posilac was politically and legally controversial.[33] Before the approval was issued, Senator Patrick Leahy of Vermont requested and obtained a General Accounting Office (GAO) investigation of FDA actions.[34] The GAO recommended that the FDA withhold approval of Posilac pending further research of its "potential negative impact on human health."[35] Next, Congress delayed the sale of the drug for 90 days while "an inter-agency task force supervised by the Office of the President reviewed the data upon which the FDA based its decision.[36] By January 1994, that task force concluded the "FDA's. . . [decision] was adequately supported," by evidence, and that Monsanto could begin marketing Posilac to dairy farmers.[37]

B. *1995, Challenging the Science:* Stauber v. Shalala

The FDA's rBST approval methodology and the science behind it survived judicial review in 1995.[38] Consumers brought the action seeking declaratory and injunctive relief against the FDA and seeking to prevent rBST from entering the human food supply.[39] Specifically, the consumer-plaintiffs made claims under the Food, Drug, and Cosmetic Act, the Environmental Protection Act, and the Administrative Procedure Act.[40] The government prevailed at summary judgment, primarily because the plaintiffs had no admissible, relevant evidence to support their claims because they relied on material never presented to the FDA during the Posilac approval process.[41]

The consumer claims echoed those raised by the political process and GAO investigation: the FDA did not adequately consider health and safety claims, mandatory warning labels should have been required on Posilac packaging to highlight its negative side effects on the animals, and the government

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33. *See* Nocenzi et al., *supra* note 10. *See also* KIMBRELL, *supra* note 10. The history of the controversy is beyond the scope of this article, though it is very interesting. rBST is considered the "first" genetically modified substance allowed for human consumption under the FDA's policy of presumptive safety. Since milk is a cornerstone of American nutrition, especially for children, there was likely no worse choice than milk to forge the way for genetically engineered foods.

34. Collier, *supra* note 8, at 158.

35. *Stauber*, 895 F. Supp. at 1183.

36. *Id.*

37. *Id*. *See also* Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946 (Nov. 12, 1993) (codified at 21 C.F.R. pts. 510 and 522). The actual approval date was 1993, but the Congressional moratorium on rBST's sale did not expire until Feb. 3, 1994.

38. *See Stauber*, 895 F. Supp. at 1178.

39. *Id*. at 1182-83.

40. *Id*. at 1182.

41. *Id*. at 1183.

should have conducted an environmental impact statement before approving Posilac.[42] The government's position was simply that it complied with the relevant law and rules when approving rBST.[43]

The *Stauber* decision revealed some unpleasant realities about milk production to the public. The first concern, which remains one of the biggest today, is that use of rBST also increases the use of antibiotics. Cows then secrete those antibiotics into milk sent to market. Increased human consumption of antibiotics does lead to increased antibiotic resistance in humans.[44] For example, in 2005, the FDA withdrew the use of the antibiotic Baytril in poultry destined for human consumption out of concern that humans would develop resistance to one of the few drugs effective against biological terrorism materials.[45] Consumers avoid rBST milk for similar reasons – they are concerned that they are drinking antibiotics with their milk, and they may be right.

rBST-treated cows are often treated with antibiotics to prevent or treat the mastitis that can be more frequent in treated cows. In *Stauber*, the plaintiffs asserted this was a valid safety concern, but the court was not swayed.[46] Instead, it ruled that the FDA did not rely arbitrarily or capriciously on the USDA milk grade testing process to screen out milk that had excessive antibiotic residue.[47] However, the court also acknowledged that, at the time, there were limitations on the testing.[48] Though the Grade A pasteurized milk standard was rigorous, testing at the time was only for the four most common antibiotics used in dairy herds.[49] The court acknowledged that over fifty drugs were used to treat cow infections, some of them not even approved for use in cows.[50] Therefore, unless a farmer treating with rBST and antibiotics used one of the four antibiotics tested for, consumers could unwittingly drink antibiotic residue from one of the other forty-six drugs used but not tested for.

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42. *Id.* at 1182.
43. *Id.*
44. *See* FDA, FINAL DECISION OF THE COMMISSIONER, NO. 2000N-1571, WITHDRAWAL OF APPROVAL OF THE NEW ANIMAL DRUG FOR ENROFLOXACIN IN POULTRY 53 (2005), *available at* http://www.fda.gov/oc/antimicrobial/baytril.html. (Baytril is the trade name for Enrofloxacin, a fluoroquinolone. Humans are treated with a similar drug named Cipro). *See also* Enrofloxacin for Poultry; Final Decision on Withdrawal of New Animal Drug Application Following Formal Evidentiary Public Hearing; Availability, 70 Fed. Reg. 44,105 (Aug. 1, 2005).
45. *See id*; Ellen K. Sibergeld & Polly Walker, *What if Cipro Stopped Working,* N.Y. TIMES, Nov. 3, 2001, at A23.
46. *Stauber*, 895 F. Supp. at 1192.
47. *Id.*
48. *Id.*
49. *Id.*
50. *Id.* at 1184.

Indeed the court acknowledged "[b]ecause the current regulatory scheme does not detect the presence of all drug residues in dairy products, there is a risk that greater amounts of antibiotic drug residue will be ingested by human dairy consumers."[51] This is not exactly reassuring for the dairy consuming public, yet it illustrates the weakness of the consumers' case: they could not produce evidence to support their health and safety concerns. Even more damaging to consumers' claims was the fact that there was no long-term study of whether antibiotics in milk affected human health at all.[52]

The court also touched on other specific differences in rBST milk that consumers claimed were significant, yet the FDA ruled immaterial.[53] Specific consumer concerns were: higher somatic cell (white blood cell) counts in milk and higher insulin growth factor (IGF-1) levels.[54] In both cases, the court found no evidence to support the consumers' claims.[55] Since the FDA had reviewed Monsanto's studies on somatic cell count that showed no significant increase in the rBST milk, the Court ruled the FDA had done its job.[56] As for IGF-1, since Monsanto had not done any studies on human health but could present evidence that there was no impact on the digestive tract in a two-week rat study, the court found the FDA had also acted reasonably on this issue.[57]

Stauber upheld the FDA's approval of Posilac, though it is reasonable to conclude that the court could do little more given the standard of review and the fact that the plaintiffs' evidence had not been reviewed during the FDA approval process. The court considered only whether the FDA had acted arbitrarily or capriciously, abused its discretion, or otherwise acted outside the law.[58] Given the close scrutiny that the rBST approval process had already survived, including the GAO review, it is difficult to imagine any other ruling. In fact, the true issue was science – or more accurately stated, the lack thereof. This is especially so because the FDA has scientific expertise, entitling its evaluation of the science to great deference by the court.[59]

The plaintiffs did submit scientific evidence to the *Stauber* court.[60] The problem was that the same evidence had not been presented to the FDA during

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51. *Id*. at 1185.
52. *Id*.
53. *Id*.
54. *Id*. at 1185, 1193.
55. *Id*.
56. *Id*.
57. *Id*. at 1185.
58. *Id*. at 1189 (*citing* Upjohn Mfg. v. Schweiker, 681 F.2d 480, 483 (6th Cir. 1982)).
59. *See id.* (discussing deference afforded agency decisions).
60. *Id*. at 1190.

the drug review and thus could not be considered by the court.[61] As a result, the Court found that the FDA's process was sound, even when it decided to rely on testing process for grading milk to make sure antibiotic residue was kept out of the milk supply.[62] The *Stauber* case raises many unsettling points about what was truly known about rBST and its effect on humans when it was approved.

However, the fact is that rBST has been on the market for almost fifteen years without consumers returning to convince the FDA that it was wrong when it found rBST "has no significant effect on the overall composition of milk."[63] Since the FDA concluded that there was no compositional difference between milk from rBST treated cows and those that are not, there is no legal basis for the FDA to label the milk.[64] As *Stauber* recognized "the FDA does consider consumer opinion relevant when determining whether a label is required to disclose a material fact."[65] As a result, absent scientific proof that rBST milk is materially different from rBST-free milk, consumers have no right to know whether it has been used to produce milk, as Vermont found in 1996.[66]

C. *1996 Commercial Speech (Round One):* Int'l Dairy Foods Ass'n v. Amestoy

Posilac's next challenge came from Vermont's law mandating disclosure of rBST use on the milk label or on the grocery store shelf.[67] The Vermont regulation mandated a sign at the dairy case stating:

> The products in this case that contain or may contain milk from rBST-treated cows either (1) state on the package that rBST has been or may have been used, or (2) are identified by a blue shelf label like this [blue rectangle], or (3) a blue sticker on the package like this [blue dot].[68]

Dairy producers, represented by the International Dairy Foods Association, moved for a preliminary injunction against implementing the law, which the district court denied finding there was no irreparable harm to dairy producers.[69] Overruling the district court, the Second Circuit rejected the law for many of the

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61. *Id.*
62. *Id.* at 1192.
63. *Id.* at 1193.
64. *Id.*
65. *Id.*
66. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 74 (2d Cir. 1996).
67. *Id.* at 69-70.
68. *Id.* at 70.
69. *Id.*

same reasons *Stauber* upheld FDA's approval – there was simply no scientific evidence of material difference in the record, regardless of consumer concerns.[70]

Vermont's statute requiring farmers to label milk from rBST-treated cows illustrates the strength of consumer concern in Vermont,[71] but the pro-consumer statute was simply an unconstitutional restriction on commercial speech. Specifically, the Second Circuit held that consumer interest alone was insufficient to allow regulation of commercial speech under *Central Hudson.*[72] When striking down the law, the court ruled that if consumer interest alone were enough, "there is no end to the information that states could require manufacturers to disclose about their production methods."[73]

The district court originally upheld Vermont's mandatory disclosure law, reasoning that there was no irreparable harm to the producers based primarily on the economic impact of the labels.[74] The Second Circuit found fault with this economic analysis primarily because the law caused irreparable harm by requiring producers to make an involuntary statement, though true, in order to offer their products for sale (regardless of economic impact).[75] However, the most instructive part of the case is the court's ruling that the Vermont law failed the *Central Hudson* standard because the state lacked a substantial interest.[76] Despite the political controversy over rBST prior to FDA approval, the court emphasized that producers could not be required to disclose its use in cows absent "reasonable concern for human health or safety or some other sufficiently substantial government concern."[77] The court left it to "those consumers interested in such information [to] exercise the power of their purses by buying products from manufacturers who voluntarily reveal it."[78] However, when the court left consumers to

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70. *Id*. at 74.

71. *Id*. at 69.

72. *Id*. at 74; *see also* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980) ("In commercial speech cases, then, a four-part analysis has developed. At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.").

73. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 74 (2d Cir. 1996) This position may not take into account the role of preemption in manufactured food-labeling requirements under the FDCA.

74. *Id*. at 70-71.

75. *See id*. at 71.

76. *Id*. at 73.

77. *Id*. at 74.

78. *Id*.

the power of their purses, it left regulators to consider how consumers exercise that power. As the court wrote, "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement."[79] Where does this leave the consumer who is skeptical of rBST safety and curious enough to continue reading labels? It leaves her with voluntary disclosure, which remains at the heart of the controversy today.

D. *1994 to Present: Producers Safe Harbor – FDA Milk Label Guidance*

What *can* producers voluntarily reveal about rBST-free milk on labels? In 1994, the FDA labeling guidelines advised manufacturers who label milk "from cows not treated with rBST" to include the disclaimer with the statement that "'No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows.'"[80] The FDA label guidance is straightforward and intended to protect against consumers having the impression that rBST-free milk is superior or more nutritious than milk from cows treated with rBST.

The FDA's notice clearly stated that it was not binding on the FDA or any state, nor did it create any rights for individuals.[81] The guidance was simply the FDA's interpretation of the law and it reserved the right to change its interpretation should it receive compelling comments.[82] The guidance contains relevant advice to the current label controversy when it counsels: "States should evaluate any labeling statement about rBST in the context of the complete label and all labeling for the product, as well as any advertising for the product. Available data on consumers' perceptions of the label statements could also be used to determine whether a statement is misleading."[83]

The guidance also suggested ways that states could insure that claims were valid – such as recordkeeping by producers or third party certification.[84] Today, the 1994 guidance remains the same. Its purpose also remains the same –

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79. *Id.* (citing Riley v. Nat'l Fed. of the Blind, 487 U.S. 781, 797-98 (1988)).

80. 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, 6280 (Feb. 10, 1994) (providing guidance to dairy industry with the intent to preclude "rBST-free labels" from giving consumers the impression that milk from rBST treated cows is somehow unsafe or less healthful than rBST-free).

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

to support the legally valid conclusion that there is no material difference between milk from rBST treated cows and milk from those that are not.[85]

Despite the label requirement meant to inform consumers that there is no difference between rBST-free and conventional milk, in 2007, several major dairy marketers informed producers that they would no longer accept milk from cows treated with rBST.[86] Marketers took the action because consumers were demanding "hormone free" milk, but "they will not accept any price increases for this milk."[87] This is not a small consumer movement. Large distributors such as Publix and Kroger announced that their store brand milk would be hormone-free.[88]

E. *2006 -2008, The rBST-free Market Emerges*

The market demand for rBST-free milk has consequences for farmers. In one case, a state tried to use milk price controls to protect farmers who use rBST.[89] In 2006, the New Jersey Department of Agriculture attempted to fix a milk price premium for rBST-free milk.[90] Specifically, processors were demanding rBST-free milk from farmers without agreeing to pay farmers voluntary premiums. As a result, farmers using rBST had a choice: either abandon it with reduced production or continue to use it and accept a lower price for the milk.[91] At the premium's public hearing, one farmer relied on a Monsanto produced pamphlet to testify that there was a "hypothetical loss" of $0.76 per hundredweight for rBST-free milk.[92] Based in part on that testimony, the Director made the following findings:

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85. *Id.*

86. DairyBusiness Communications, *Dairy Technology Restrictions Move Toward Deadlines*, VOICES FOR CHOICES, July 31, 2007, at 4, *available at* http://www.dairybusiness.com/voicesforchoices/pdf/vfe-newsletter-7.31.pdf.

87. *Id*.

88. *Id.; Kroger Rejects GMO Milk: The Tipping Point*, ENVIRONMENTAL NEWS NETWORK, Aug. 7, 2007, *available at* http://www. enn.com/agriculture/article/21413/print.

89. *See generally In re* Sept. 28, 2006 Order of Dir. of the Div. of Mktg. and Dev., No. A-827-06T1, 2006 WL 3783503 (N.J. Super. Ct. App. Div. Dec. 27, 2006).

90. *Id*. at *1.

91. *Id*. at *2. For example, a year after the New Jersey case, the American Farm Bureau Federation Quarterly Marketbasket Survey for the second quarter of 2007 indicated three levels of pricing for wholesale milk ½ gallons: regular whole, $2.22; rBST-free $3.01; organic $3.65. DairyBusiness Communications, *'Niche Market' Milk Drawing Premium Price*, VOICES FOR CHOICES, July 31, 2007, at 1, *available at* http://www.dairybusiness.com/voicesforchoices/pdf/VfC-newsletter-7.31.pdf.

92. *In re* Sept. 28, 2006 Order of Dir. Of the Div. of Mktg. and Dev., No. A-827-06T1, at *3.

> Posilac results in increased milk production; the processors demand "rBST-free" milk; negotiations over premiums for "rBST-free milk" were difficult; and "rBST-free" milk is a value added product. . . .[A] processor demanding "rBST-free" milk should be obligated to cover at least the costs of production.[93]

Based on these findings, the Director did impose a $0.76 per hundredweight premium for rBST free milk.[94] On appeal, the court vacated the premium because the Director's decision rested on hypothetical, not actual, data.[95] However, the Court did not preclude the Director from conducting additional hearings on premiums for "rBST-free" milk.[96]

New Jersey did hold additional hearings. In late 2007 and early 2008, the Director held hearings on both a fuel premium and the rBST premium.[97] He concluded that there "is evidence on either side of the issue of whether an rBST premium should be imposed."[98] Since the evidence could not clearly establish whether rBST-free milk was a value added product that warranted a price premium, the Director declined to impose one.[99] Rather, because of the inadequate evidence, he decided it was not an appropriate time to interfere with the market.[100]

Despite the FDA's position on rBST's safety, consumer demand for rBST- free milk currently drives the market. There is also growing evidence that, despite the FDA's "no material difference" stance, how milk is produced plays a key role in its nutritional quality. For example, in June 2008 a published study showed that organic and low-input organic milk had higher levels of key nutrients.[101] Though the study did not specifically examine rBST use, many con-

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93. *Id.* at *4.
94. *Id.*
95. *Id.* at *6.
96. *Id.* at *7.
97. Letter from Alfred Murray, Dir., Div. of Mktg. & Dev., NJ Dept. of Agric. Mkts. & Dev. to Nina Mitchell Wells, Sec'y of State, at 1 (April 10, 2008).
98. *Id.*
99. *Id.* at 1-2.
100. *Id.*
101. Gillian Butler et al., *Fatty Acid and Fat-Soluble Antioxidant Concentrations in Milk from High-and Low-Input Conventional and Organic Systems: Seasonal Variation*, 88 J. SCI. FOOD AGRIC. 1431 (2008). The study compared dairy operations in the United Kingdom using either high-input or low-input organic farming methods. Low-input and organic milk had higher nutrient quality, including beneficial fatty acids. High-input methods resulted in fewer key nutrients, even in cases where the herd was supplemented with vitamins. Specifically, high-input operations supplementing with Vitamin E did not produce milk with higher levels of Vitamin than low-input operations not supplementing. It is important to note that this study does not examine rBST, but I have little doubt that it will be used to support the argument that "naturally" produced milk is superior, including arguments against rBST.

sumers will undoubtedly interpret its findings to supporting their sentiment that rBST-free milk is superior because it is more natural.

III. FALSE AND MISLEADING? FEDERAL TRADE COMMISSION ACTIONS

In 2007, several dairies' interpretation of the FDA guidance led Monsanto to complain to the Federal Trade Commission that the rBST-free labeling used in many markets misleads consumers.[102] This was not Monsanto's first effort to curb rBST-free labeling.[103] In 2003, Monsanto challenged Oakhurst Dairy over its labels claiming "No Artificial Growth Hormones" in federal court.[104] In 2007, Monsanto and various dairy producers complained to the FTC that those producers making claims such as "cows are not injected with BST (hormones)" and "The Natural Milk – No Added BST (hormones)" were misleading consumers because the labels conflicted with the FDA labeling guidance.[105] The complaint maintains that statements about hormone-free milk mislead the consumer into believing that milk from cows *not* treated with rBST is superior or more nutritious.[106]

Monsanto's FTC complaint was right in one significant way – many consumers believe that milk from rBST free cows is more desirable (or there would not be a market for the milk).[107] Whether this is a result of the marketing practices complained of by Monsanto to the FTC – or whether it is the persistence of the consumer concerns in existence since rBST was approved is unknown. However, this consumer preference should signal label regulators that consumers do not believe the FDA rBST safety ruling.

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102. Complaint, FDA Matter, No. 072-3080, *surpa* note 2 at 1.

103. Petition for Plaintiff at 1, Monsanto Co. v. Oakhurst Dairy, No. 03-11273 (D. Mass. filed July 3, 2003).

104. *Id.*

105. *See* Complaint, FDA Matter No. 072-3080, *supra* note 2, at 5.

106. *See id*. *See also* Butler, *supra* note 101, at 1435. It is significant to note that in June 2008, a study was published showing that the nutritional value of organic milk and low-input non-organic milk was higher than conventional. Certainly, this study while not specifically identifying rBST as unsafe, will add to consumer sentiment that rBST free milk is indeed superior. *But see*, DairyBusiness Communications, *A Fair Question: Who Is Asking for rBST-free Milk?*, VOICES FOR CHOICES, Sept. 25, 2007, at 4, *available at* http://www.dairybusiness.com/voicesforchoices/pdf/VfC.9.25.pdf (questioning whether consumers really care about rBST in milk).

107. *See* Dairy Business Communications, *'Niche Market' Milk Drawing Premium Price*, VOICES FOR CHOICES, July 31, 2007, at 1 *available at* http://www.dairybusiness.com/voicesforchoices/pdf/VfC-newsletter-7.31.pdf.

On August 21, 2007, the FTC responded to the Monsanto request for action against false and misleading rBST labels.[108] The FTC noted that Monsanto was aware that the milk producers had the right to inform consumers about whether the milk was produced using rBST or not.[109] Further, the FTC informed Monsanto that it had independently reviewed websites and other marketing in light of the 1994 FDA Guidance and with FDA staff.[110] The FTC concurred with the FDA policy that producers could label rBST-free, as long as "in the context of the entire label, they do not mislead consumers to believe that milk from cows not treated with rBST is safer or of higher quality."[111] The FTC's response letter also acknowledges that there may be reasons that producers want to advertise as rBST- free other than safety or quality – and that it is permissible so long as consumers are not misled. The primary example of "other reasons" is animal welfare.

Ultimately, the FTC ruled that its staff "did not find any examples of national or significant regional advertising campaigns that made express or implied claims linking rBST to human health or safety."[112] While the FTC did note some unfounded rBST claims, it advised companies engaging in such claims to revise their marketing.[113] Given that the companies appeared cooperative and there was no evidence of widespread consumer confusion, the FTC declined action.[114]

In order to understand better the FTC's decision, a slight digression is appropriate. In 2008, Sanderson Farms sued Tyson Foods for misleading consumers with its "Raised without Antibiotics Claim" used on Tyson's chicken.[115] That claim carried the qualifying language "that impact antibiotic resistance in humans."[116] The marketing claim was a phenomenal success, with two problems – it was not USDA approved, nor was it accurate.[117] While the Tyson's farmers may have "raised" chicks without antibiotics, Tyson's label did not disclose the fact that while in their shells chicks were injected with antibiotics and later fed a type of antibiotic known as ionophores.[118] Additionally, the no antibiotics claim's qualifying language "that impact antibiotic resistance in humans" had no

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108. *See* Letter from Mary K. Engle, Assoc. Dir., Div. of Adver. Practices, FTC, to Jodie Z. Bernstein, Esq., Dana B. Rosenfeld, Esq., Bryan Cave L.L.P. (Aug. 21, 2007), *available at* http://www.ftc.gov/os/closings/staff/070821monsanto.pdf.

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*

114. *See id*.

115. Sanderson Farms v. Tyson Foods, Inc., 547 F. Supp. 2d 491, 492 (D. Md. 2008).

116. *Id*.

117. *Id*. at 494.

118. *Id*. at 492.

significant meaning to consumers.[119] As a result, the court ruled that the label claims were literally false.[120]

To prove their case, Sanderson and its co-plaintiff Perdue presented significant evidence of consumer confusion to the court.[121] Specifically, the court relied on the various consumer survey methodologies employed by the plaintiffs' experts when ruling the labels were misleading.[122] Experts found 63.4% of survey respondents thought the label claim meant no antibiotics had been used (when they had), and that 54.9% of consumers disregarded the qualifying language "that impact antibiotic resistance in humans."[123] These statistics, and the testimony of Tyson's own expert that "these figures far exceed the level of consumer survey evidence usually required by courts" to establish a Lanham Act violation, lead the court to rule in favor of the plaintiffs.[124]

When issuing the injunction and putting an end to the labels, the court wrote:

> Having heard testimony for four days and having reviewed hundreds of exhibits, this Court is convinced by a preponderance of the evidence that a substantial percentage of consumers are misled by Defendant's advertisements carrying the message "Raised Without Antibiotics that impact antibiotic resistance in humans." The qualifying language does not appear to serve its intended purpose-the consumer is still led to believe that Defendant does not use antibiotics, when in fact Defendant uses ionophores in its chicken feed and injects its chicken eggs with antibiotics. Indeed, the qualification may only serve to reinforce that Defendant's chicken is "Raised Without Antibiotics," a claim that is literally false.[125]

This digression is relevant to rBST because, throughout the years of claims of consumer confusion on both sides, no proceeding has produced the type of survey evidence that was so compelling in the Tyson case. In order to resolve the rBST controversy, such data will be not only helpful, but essential.

IV. SAFE OR NOT? FOOD AND DRUG ADMINISTRATION PETITION

Just 12 days before Monsanto and producers complained to the FTC about the unfair marketing practices, the FDA received a petition seeking the withdrawal of Posilac's approval or action requiring a cancer risk-warning label

119. *Id*. at 505.
120. *Id*.
121. *Id*. at 499-502.
122. *Id*. at 502-03.
123. *Id*. at 504.
124. *Id*.
125. *Id*. at 505.

on milk from rBST treated cows.[126] The petitioners are the Cancer Prevention Coalition, Organic Consumers Association, and Family Farm Defenders.[127]

Citing scientific literature, the petitioners claim that rBST milk is, in fact, abnormal.[128] The petitioners claim rBST milk has: 1) reduced casein,[129] 2) different fatty acid composition, 3) higher thyroid hormones, 4) antibiotic residue from treatment of mastitis,[130] and 5) more frequent pus cells due to mastitis.[131] Additionally, the petition's greatest emphasis is on insulin growth factor (IGF-1). IGF-1 is a protein hormone that is statistically higher in rBST-treated milk.[132] When the FDA approved Posilac, "not much was known about the hormone."[133] However, petitioners assert that now, some fourteen years later, "[i]ncreased levels of IGF-1 have been shown to increase risks of breast cancer by up-to seven fold in 22 publications. . .risks of colon cancer in 16 publications. . .and prostate cancer in 10 publications. . . ."[134] Many of the publications cited were published after 1994, though the petition does not specifically claim that they link rBST in milk and human cancer rates.[135]

To date, the FDA has taken no action on the petition. When and if it does, as *Amestoy* and *Stauber* held years ago, action must be based on scientific evidence, not consumer preferences. In the absence of scientific evidence of material differences in rBST-free and conventional milk attributable to Posilac, it is unlikely that the law would permit revocation of Posilac or require cancer-risk warnings. Rather than waiting for the FDA outcome and relying on FTC to counsel wayward dairies, the rBST controversy has moved to the states.

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126. Petition for Labeling of Products Produced with Posilac, *supra* note 3, at 1.

127. *Id*.

128. *See generally id*.

129. *Id.* at 2. Casein is a protein that comes from milk's reaction with rennet (Enzymes used to digest milk) resulting in the milk separating into cords and whey. Casein is used in cheese, paint, and plastic.

130. *See* Stauber v. Shalala, 895 F. Supp. 1178, 1184-85 (W.D. Wis. 1995) One way a consumer can avoid most antibiotic residue is to purchase USDA organic milk.

131. Petition for Labeling of Products Produced with Posilac, *supra* note 3, at 3.

132. *See id.*

133. *See Stauber*, 895 F. Supp. at 1185 (noting that "defendants have done no long term studies on the effects of increased levels of IGF-1 on human health.").

134. Petition for Labeling of Products Produced with Posilac, *supra* note 3, at 3.

135. *Id*. at 3-8.

V. COMMERCIAL SPEECH, ROUND TWO: CURRENT LEGISLATION AND RULEMAKING

Four states considered further specific guidance on rBST-free milk labels in 2008: Indiana,[136] Ohio,[137] Kansas,[138] and Pennsylvania.[139] All four state actions are similar. Indiana and Kansas would ban any dairy product claim related to composition that lab analysis could not confirm or claims supported only by affidavits or testimonials.[140] Pennsylvania bases its rBST mislabeling review on "the entirety of the particular label under review."[141] Ohio goes one step further by specifically barring compositional claims such as "No Hormone," "Hormone Free," "rBST-free," "rbGH-free," and "bST Free" and classifying such claims as "false and misleading."[142] While these initiatives are largely consistent with the 1994 FDA compliance guidelines for rBST, one is much more specific (and restrictive).

The Ohio rule is a radical enough departure from the 1994 FDA Guidance, that the International Dairy Foods Association is seeking an injunction against it.[143] Specifically, the regulation only permits the words "this milk is from cows not supplemented with rBST."[144] It then goes on to require a contiguous disclaimer, rather than use of an asterisk to make the disclaimer elsewhere on the packaging (as is the current prevalent practice).[145] Finally, the Ohio rule also mandates font size, color, and type to match the permitted statement.[146] The rule

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136. *See* H.B. 1300, 115th Gen. Assem., 2d Reg. Sess. (Ind. 2008).

137. Ohio Emergency Rule, Dairy Labeling, 901:11-8-01 (May 22, 2008).

138. *See* S.B. 595, 2008 Sess. (Kan. 2008).

139. Pa. Dep't. of Agric., Milk Labeling Standards 2.0.1.17.08 (proposed Jan. 17, 2008) The proposed standard was postponed by Pennsylvania Governor Rendell due to consumer demands for continued rBST-free labels.

140. *See* S.B. 595, 2008 Sess. (Kan. 2008); H.B. 1300 115th Gen. Assem., 2d Reg. Sess. (Ind. 2008).

141. Pa. Dep't. of Agric., Milk Labeling Standards 2.0.1.17.08 (Proposed Jan. 17, 2008).

142. Ohio Emergency Rule, Dairy Labeling, 901:11-8-01 (May 22, 2008).

143. Complaint at 1, Int'l Dairy Foods Ass'n v. Boggs, No. 08-cv-00628-JLG-NMK, *supra* note 6.

144. Ohio Emergency Rule, Dairy Labeling, § 901:11-8-01 (B) (May 12, 2008) (stating "A dairy label which contains a production claim that 'this milk is from cows not supplemented with rbST' (or a substantially equivalent claim) will be considered misleading on the basis of such language, unless. . ." and the rule goes on to require documentation *and* is accompanied "in the same label panel, in exactly the same font, style, case, size and color as the foregoing representation, the following contiguous additional statement (or a substantially equivalent statement): 'The FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows.'").

145. *Id*.

146. *Id*.

is more restrictive than any other state or federal rBST-free label guidance. Ohio argues that its labels are necessary to avoid consumer confusion.

Boggs is the mirror image of *Amestoy* the − Vermont case finding mandatory disclosure of rBST use an unconstitutional commercial speech restriction. While in *Amestoy* farmers fought for their right to remain silent about production methods,[147] today farmers are fighting for their right to announce production methods. Unlike Vermont's desire to make sure consumers knew if milk contained rBST, Ohio wants consumers to know that rBST milk is no different from conventional. However, the IFDA argues that the Ohio rule cannot survive its challenge because there is no evidence that the current labels, compliant with the 1994 FDA Guidance, are false and misleading.[148] IFDA's argument is a good one because absent consumer surveys showing confusion or an FTC finding (which we already know was not forthcoming) of false and misleading, Ohio has little evidence to support its position.

Consumer confusion is not a substantial state interest in the commercial speech context.[149] Thus, even if the Court is persuaded that the current labels are false and misleading, Ohio's rule will still have to survive *Central Hudson* analysis. This will be difficult without more compelling disclosure of the government's motives. As the litigation currently stands, the IFDA rests on the press releases from the Ohio Department of Agriculture (ODA) that point to consumer confusion as the "substantial interest" that justifies the new rule. Absent better evidence of consumer confusion, this is unlikely to constitute a "substantial interest" – even if it did, *Amestoy* calls into question whether any regulation solely based on consumer concern can survive *Central Hudson* analysis.[150]

Obviously, Ohio has an additional concern – one that it should not be afraid to herald – the dairy industry. The interests here are two-fold: allowing farmers to maximize their production and indirectly, promoting the acceptance of Posilac, which is after all, an FDA-approved drug. It is safe for animals (though it is not a zero tolerance standard) and safe for human consumption – or at least that is what the science showed in 1994. Since conventional milk is also cheaper, Ohio's rule could also be viewed as protecting the consumer by supporting those farmers who choose to use rBST, and thus produce cheaper milk. In this time of rising food costs such a goal is substantial.

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147. *Compare* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 67 (2d Cir. 1996), *with* Complaint at 22, Int'l Dairy Foods Ass'n v. Boggs, No. 2:08-cv-00628-JLG-NMK, *supra* note 6.

148. *See* Complaint at 22, Int'l Dairy Foods Ass'n v. Boggs, No. 2:08-cv-00628-JLG-NMK, *supra* note 6.

149. *Int'l Diary Foods Ass'n*, 92 F.3d at 74 (citing Riley v. Nat'l Fed. of the Blind, 487 U.S. 781, 797-98 (1988)).

150. *See Int'l Diary Foods Ass'n*, 92 F.3d at 74.

Boggs also raises commerce clause issues as well as administrative law concerns relating to the enactment of an emergency rule. The court has scheduled the parties to submit summary judgment arguments in August 2008. Those filings will determine whether Ohio can be more restrictive than the FDA guidance, but it will not resolve the underlying labeling issue.

The convergence of the FTC labeling complaint, FDA petition to withdraw Posilac approval, and state action against rBST-free labels is troubling. This type of consumer-driven controversy is not supposed to happen. Consumers are supposed to accept the FDA's rBST safety ruling as clear proof that it is safe for human consumption and that its risk to animal welfare is acceptable.[151] Consumers are supposed to buy organic milk if they want milk free of genetically engineered materials – not demand that conventional milk come clean. Further, industry – whether producers or manufacturers of products that support producers – is supposed to respond to market forces by changing the product offered, not seeking legislation against the consumer. The activity surrounding rBST in all parts of the milk market should indicate to government regulators either that consumers are truly misinformed or that government approval of rBST was a mistake.

VI. GOT SOLUTIONS? REGULATORS AND INDUSTRY SHOULD

The history of rBST, and the fact that it is repeating itself, should prompt lawmakers, regulators, and industry to move beyond the current regulatory schemes. Specifically, there should be an effort to understand consumers' perceptions of rBST, similar to the evidence presented in the *Tyson* case.[152] Next, there should be study of what label design is most effective for consumers and producers. Once these two steps are taken, lawmakers can determine how to modify the FDA guidance and similar state provisions. One method might be a federal decision to abandon the guidelines and rely on the USDA organic symbol to help consumers find rBST-free milk. Another solution is to devise an rBST-free symbol similar to the USDA organic logo.

Altering milk labels will not be an easy task and will face opposition. Unless the FDA takes the bold step of reviewing rBST safety, consumer concerns about rBST milk will remain. In the FDA's defense, without compelling scientific evidence that rBST approval was a mistake there is little that they can do to remove it from the milk supply. As state regulators and producers rigidly adhere to rBST's safety determination, consumers seem to have grown more distrustful

151. *See* Stauber v. Shalala, 895 F. Supp. 11178, 1184 (W.D. Wis. 1995) (stating that the standard is acceptable risk, not zero tolerance).

152. *See generally* Sanderson Farms v. Tyson, 547 F. Supp. 2d 491, 491 (D. Md. 2008).

of rBST. Since the market for rBST milk has rapidly decreased, wholesalers and retailers alike demand farmers discontinue rBST use. The existence of a market for "rBST-free milk," − that is not organic milk, but not conventional milk − should tell regulators that milk labels are not providing the best information to consumers. A potential middle ground exists in the creation of an rBST-free symbol that is not accompanied by text.

The activity surrounding rBST in all parts of the milk market should indicate to government regulators that there is a significant information imbalance that affects both producers and consumers.[153] To resolve the controversy, all parties need to understand exactly what consumers want and what they understand about rBST. While generalizations can be made and interest groups can advocate for the generic "consumer," the parties should understand that consumer survey data is the most reliable way to design rBST-free labels. Unless there is better understanding of how consumers perceive the information on milk labels, the controversy will continue.

153. *Cf.* Press Release, Tyson Foods, Tyson to Withdraw Qualified Raised Without Antibiotics Chicken Label; Company Calls for Public Process to Address Regulatory Confusion (June 2, 2008), http://www.tyson.com/corporate/press room/viewarticle.aspx?id=2955&print=true. Tyson stood to make millions on its "raised without antibiotics" poultry label claim. Rather than spend millions fighting about the labels in court or with the USDA, on June 3, 2008, Tyson foods announced that it was withdrawing its qualified "Raised without Antibiotics Label." The company's press release declared:

> We still support the idea of marketing chicken raised without antibiotics because we know it's what most consumers want. . . .[h]owever,. . . to preserve the integrity of our label and our reputation as a premier company in the food industry, we believe there needs to be more specific labeling and advertising protocols developed to ensure the rules are clear and application of the rules is equitable.

While the Tyson antibiotic label litigation undoubtedly carried costly legal expenses and negative press that Tyson chose to withhold production information was in hopes of clearer regulation is not an optimal outcome for consumers (or producers).