

Fordham Environmental Law Review

Volume 23, Number 1

2011

Article 1

Milking It: Reconsidering The FDA's Refusal to Require Labeling of Dairy Products Produced From RBST Treated Cows in Light of International Dairy Foods Association V. Boggs

Laurie J. Beyranevand*

*Vermont Law School

Copyright ©2011 by the authors. *Fordham Environmental Law Review* is produced by The Berkeley Electronic Press (bepress). <http://ir.lawnet.fordham.edu/elr>

**MILKING IT: RECONSIDERING THE FDA'S REFUSAL TO
REQUIRE LABELING OF DAIRY PRODUCTS PRODUCED
FROM RBST TREATED COWS IN LIGHT OF
INTERNATIONAL DAIRY FOODS ASSOCIATION V.
BOGGS**

*Laurie J. Beyranevand**

INTRODUCTION

The United States is currently in the throes of a large scale, social movement that many commentators deem a “food revolution,”² but might more aptly be termed a food re-evolution. Open any current food magazine or watch any television show pertaining to food and, odds are, it is brimming with dozens of references to the allure of the farmer’s market, the benefits of buying locally sourced foods, ideas about how to create a menu centered around seasonal fruits and vegetables, reasons to use fewer ingredients and emphasize whole, organically grown foods – the list goes on and on. Rather than encouraging advances in the field of biotechnology for food production, consumers are consistently, and adamantly, demanding a return to the days when food was simple and unprocessed, grown in their communities by farmers they know, and not altered, chemically or otherwise.³ Moreover, consumers are thirsting for access to

* Associate Professor of Law at Vermont Law School in South Royalton, Vermont. She is beyond thankful to her partner and soon to be husband, Ben Jervey, for his never wavering support, guidance, and patience.

2. *Why We Need a Food Revolution*, JAMIE OLIVER’S FOOD REVOLUTION, <http://www.jamieoliver.com/us/foundation/jamies-food-revolution/why> (last visited Nov. 13, 2011) (The term “food revolution” can be attributed, in part, to Jamie Oliver, the activist chef attempting to improve the health of our youth.).

3. See e.g., *Good, Clean, Fair*, SLOW FOOD USA, http://www.slowfoodusa.org/index.php/slow_food/good_clean_fair/ (last visited Nov. 13, 2011) (“Slow Food USA advocates for food and farming policy that is good for the public, good for farmers and workers, and good for the planet.”); Mary Burros, *Obamas to Plant Vegetable Garden at White House*, N.Y. Times, March

increased information about the life cycles of the food they consume. The reasons for this re-evolution are many: rational fears about future and yet unknown effects of biotechnology coexist with concerns over animal health, safety, and welfare, creating a justifiable concern that policy decisions about our food supply will soon result in serious, perhaps irreversible, harm to the natural and human environment.

These issues are increasingly brought to bear in the public eye as advocacy groups, food producers, doctors, and others challenge both the use of biotechnology in food production, and the Food and Drug Administration (FDA)'s unwillingness to require any special labeling thereof.⁴ In the realm of milk and dairy products, the fight over the use of the artificial growth hormone, recombinant Bovine Somatotropin ("rBST") has raged publicly since the early 1990s when the FDA approved Monsanto's controversial application for Posilac©, their version of rBST, finding there was no significant compositional difference between milk from cows treated with the drug and those that were not.⁵

Since that time, the courts have considered numerous challenges to both the approval of rBST, and the labeling of products from cows treated with it. In September 2010, the Sixth Circuit Court of Appeals upheld the constitutionality under the First Amendment of a dairy producer's right to include a label stating the milk was "rBST free," finding the language was not misleading due to evidence proving the real, compositional difference between milk from cows

19, 2009, at A1, available at <http://www.nytimes.com/2009/03/20/dining/20garden.html> (discussing the Obamas' organic vegetable garden at the White House to symbolize "that growing more food locally, and organically, can lead to more healthful eating and reduce reliance on huge industrial farms that use more oil for transportation and chemicals for fertilizer"); Nestle, Marion, *What to Eat* (2007); Pollan, Michael, *In Defense of Food* (2008).

4. See *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) ("[T]he agency found that there was no significant difference between milk from treated and untreated cows and, therefore, concluded that under the Federal Food, Drug, and Cosmetic Act (the act), the agency did not have the authority in this situation to require special labeling for milk from rBST-treated cows").

5. See *id.*

treated with rBST and milk from cows that were not.⁶ This article proposes that the *Boggs* decision provides a framework for the argument that, despite its position to the contrary, the FDA can and should require mandatory disclosures on milk that comes from cows treated with rBST as the first step in returning to a time when consumers were provided with greater access to information about the foods they consume. Given the recognized compositional difference in the two types of milk, the agency's failure to do so makes any label without such disclosures misleading under the Food, Drug and Cosmetic Act.

Part I of this article provides a brief history of the FDA's authority under the Food, Drug, and Cosmetic Act, as well as the Act's purposes with respect to labeling, and briefly considers the agency's interpretation of that grant of authority. Part II of the article discusses the FDA's approval of rBST and the resulting challenge to that decision. In Part III, the article provides an overview of the First Amendment litigation challenging dairy producers' and manufacturers' ability to include statements about rBST on the labels of their products. Finally, Part IV demonstrates how the recent decision in *International Dairy Foods Association v. Boggs*⁷ may be instrumental in requiring the FDA to mandate labeling of milk from cows treated with rBST due to the court's acknowledgement of the compositional difference between conventional and rBST-free milk.

I. HISTORY OF THE STATUTORY GRANT OF AUTHORITY TO REGULATE FOOD PRODUCTS

A. *The Pure Foods and Drugs Act of 1906*

The Food and Drug Administration is the self-proclaimed "oldest comprehensive consumer protection agency in the U. S. federal government."⁸ Initially, the agency was formed as part of the Bureau of Chemistry,⁹ but first came into existence in its modern day

6. *International Dairy Foods Association v. Boggs*, 622 F.3d 628 (6th Cir. 2010).

7. *Id.*

8. *Food and Drug Administration History*, FDA.GOV, <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> (last visited Nov. 13, 2011).

9. *See Records of the Bureau of Agricultural and Industrial Chemistry*, NATIONAL ARCHIVES, <http://www.archives.gov/research/guide-fed-records/groups/>

incarnation with the passage of the Federal Foods and Drugs Act, which created the agency's regulatory functions.¹⁰ After many unsuccessful attempts¹¹ at passing uniform federal legislation directed at addressing the increasingly disconcerting issues of food safety and adulteration in the late 1800s, President Theodore Roosevelt finally signed the law into effect in 1906.¹² The major purpose of the law was to prevent the adulteration of food, leading many representatives from agricultural states to lend tremendous support to its passage.¹³ The law created and defined very specific standards with regard to drugs. However, the law did not create corresponding requirements for food products, though it did "prohibit the addition of any ingredients that would substitute for the food, conceal damage, pose a health hazard, or constitute a filthy or decomposed substance."¹⁴

In the early years, the agency's main emphasis was the regulation of food rather than drugs. Harvey W. Wiley, the agency's chief administrator, appointed in 1883, was a chemist and longtime champion of pure foods, and found that foods posed a greater risk to human health than drugs as most chemical additives were

097.html (last visited Nov. 13, 2011) (outlining the bureau's administrative history as established in the Agricultural Research Administration (ARA), February 14, 1943, by ARA Memorandum 5, February 13, 1943, pursuant to EO 9069, February 23, 1942, and Secretary of Agriculture's Memorandums 960, December 14, 1941, and 986, February 25, 1942).

10. John P. Swann, Ph.D., *FDA's Origin*, FDA.GOV, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (last visited Sept. 1, 2011) (adapted from A HISTORICAL GUIDE TO THE U.S. GOVERNMENT, (George Kurian, ed., Oxford University Press 1998)).

11. See Charles Wesley Dunn, *Original Federal Food, and Drugs Act of 1906, As Amended: Its Legislative History*, 1 FOOD DRUG COSM. L.Q. 297 (1946) (prior to the passage of the Act, 103 bills were introduced to Congress).

12. John P. Swann, *FDA History – Part I*, FDA.GOV, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (last visited Nov. 12, 2011) (adapted from A HISTORICAL GUIDE TO THE U.S. GOVERNMENT, (George Kurian, ed., Oxford University Press 1998)).

13. Wesley, *supra* note 10 at 303 ("These leaders in Congress for a national food and drug law . . . principally came from agricultural states; and to record the fact that representatives of agriculture were foremost advocates of this law, because they were deeply concerned that agricultural products sold to the consuming public should be pure, wholesome and honest.").

14. *Id.*

“unnecessary adulterants.”¹⁵ Moreover, Wiley placed great emphasis on the truthfulness of food labeling, even when the wholesomeness of the product was not at issue.¹⁶ Under the auspices of the agency, Wiley conducted a series of experiments to test his theories about the dangers of specific food additives and preservatives frequently used in the early 1900s.¹⁷ He assembled a group of young men, whom journalists covering the trials called the “Poison Squad,” and fed them meals composed of the best quality ingredients prepared “in the most appetizing and hygienic fashion”¹⁸ that were also laced with measured amounts of common preservatives and additives.¹⁹

All of the men in the study demonstrated ill effects as a result of their participation, which led Wiley to conclude that “the effect of food preservatives upon on the system was...mildly injurious or deadly, according to the amount and character of the preservatives absorbed.”²⁰ The Poison Squad experiments greatly influenced Wiley’s opinions about the need for strict regulation of chemical additives and preservatives in food products, and led to his heavy emphasis on this issue during his tenure as the chief administrator.²¹

15. *Id.*

16. Anderson, Oscar E. Jr., *Pure-Food Issue: A Republican Dilemma, 1906-1912*, Food, Drug, Cosmetic Law Journal, Vol. 12, Issue 1, 34 (January 1957) (Upon Wiley’s urging, Wilson signed Food Inspection Decision 45, which ruled that “mixtures of bourbon whisky and blended spirits (ethyl alcohol) were not to be labeled “blended whisky” because blends were to be a mixture of like spirits. In Wiley’s opinion, the addition of neutral spirits created an imitation. The issue was not about the “wholesomeness” of the resulting product, but rather “a matter of honesty.”).

17. Janssen, Wallace F., *The Story of the Laws Behind the Labels*, FDA.GOV, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm> (last visited October 13, 2011); Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 Food, Drug, Cosmetic L.J. 2 (1984) (“Congress specifically appropriated funds in 1900 ‘to investigate the character of proposed food preservatives and coloring matters; to determine their relation to digestion and health; and to establish the principles which should guid their use.’”).

18. *Poison Squad Escapes Federal Food Experts*, N.Y. TIMES, May 22, 1904, <http://query.nytimes.com/mem/archive-free/pdf?res=F10714F8355F13718DDDAB0A94DD405B848CF1D3> (last visited January 1, 2012).

19. *Id.*

20. *Id.*

21. Swann, *supra* note 10.

On this point, however, Wiley's views diverged with the President and then Secretary of Agriculture, James Wilson, who favored scientific advances in the field, were sympathetic to industry, and less vehement about the purity of the country's food supply.²² This difference of opinion between Wiley and the Administration, in addition to resistance by the Administration to defend Wiley's strong positions, ultimately led to Wiley's resignation from the agency in 1912.²³

1. The Food and Drugs Act in the Courts

One of the early cases decided after the passage of the Act demonstrates both the Supreme Court's willingness to recognize a broad grant of authority to the agency, as well as the agency's aggressive approach in interpreting the requirements under the new statute with respect to misbranding. In *U.S. v. Antikamnia Chemical Company*,²⁴ the Court considered a challenge under the Federal Foods and Drug Act to the government's requirement that a drug's label include not only its ingredients, but also any derivatives.²⁵ In response to the argument that the agency was overstepping its statutory grant of authority by creating stricter requirements than those Congress had authorized under the law, the Court stated, "the purpose of the act is to secure the purity of food and drugs, and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it."²⁶ Ultimately, the Court found the agency's requirements for greater disclosures in labeling did not create a significant burden for the manufacturers or producers, as they were fully aware of the ingredients included in their products, and greater disclosure was in the best interest of the public health.²⁷

22. Hutt, *supra* note 17, at 56-57; Anderson, *supra* note 16, at 45 (Members of the Administration wanted to bring cases against producers that could actually be won and did not share Wiley's passion for "the militant, even radical, administration of the law in the interest of the consumer.").

23. *Id.*

24. *United States v. Anitikamnia Chemical Co.*, 231 U.S. 654, 665 (1914).

25. *Id.*

26. *Id.*

27. *Id.*

A decade later, the Court considered a misbranding case involving a product labeled and marketed as apple cider vinegar made from dehydrated apples that, during the manufacturing process, were rehydrated with water in substantially the same amount as that removed in the dehydration process.²⁸ While the product contained very small amounts of barium from the manufacturing process, the government did not allege that this substance was injurious to or presented a threat to public health.²⁹ Additionally, none of the parties suggested that the cider produced was of inferior quality or taste, although the district judge did note a slight difference in both taste and appearance.³⁰ The Court ultimately found that even though the resulting product was similar to apple cider vinegar made from fresh apples, the addition of water during the manufacturing process created a different product entirely, causing the product to be misbranded as it was not “the identical thing that the brand indicates it to be.”³¹ Therefore, while the statements on the label were technically correct, the Court found them misleading to consumers.³² Interestingly, the Court noted that its holding with respect to misbranding was not based on the differences in production or manufacture between the two products, as the law did not require disclosures regarding those processes.³³ Rather, its decision was based on the fact that the substance marketed and labeled as apple cider vinegar was not, in fact, apple cider vinegar because of its compositional difference in substance and ingredients.³⁴

In each of these cases, the Court demonstrated an unwillingness to permit manufacturers and producers from misleading consumers by purporting to sell a product that was not exactly what it said it was or failing to fully disclose specific ingredients. The Court based its decisions on the express language of the Federal Food and Drugs Act, as well as the clear congressional intent to both protect the purity and safety of food and fully inform consumers about the

28. *United States v. Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar*, 265 U.S. 438 (1924).

29. *Id.* at 441.

30. *Id.* at 443.

31. *Id.* at 444.

32. *Id.*

33. *Id.* at 445.

34. *Id.*

products they were purchasing.³⁵ Part of the motive behind this approach was to prevent economic harm to consumers by adopting a low tolerance for inferior food products labeled in the same manner as their superior or more “wholesome” counterparts.³⁶ However, these laudable goals to protect and inform consumers coexisted with governmental support for technological advances in increasing the life cycles of food and enhancing flavor.³⁷

The Court decided other cases during the same period that evidenced the support for scientific and technological advances in food production and the limits on the FDA’s power. In contrast to the FDA’s broader authority in the misbranding cases,³⁸ the Court held that the Act did not permit the agency to seize 625 bags of allegedly adulterated flour that had been treated with a chemical additive unless the agency could demonstrate that the additive may “render such article injurious to health.”³⁹ Relying again on the plain

35. *Id.* at 442-43.

36. *Pure Food and Drugs Act* § 8, Pub. L. No. 59-384, 34 Stat. 768 (1906) (current version at 21 U.S.C. § 341(1938)) (Language of the current statute explicitly references the Secretary’s goals of promoting “honesty and fair dealing in the interest of consumers” with respect to labeling requirements.).

37. *See* *Pure Food and Drugs Act* at § 8 (permitting manufacturers to add “poisonous” or “deleterious” ingredients). *See also* Dunn, *supra* note 11, at 305 (“In thus speaking of the need for a national food and drug law, we should go on to say that during the quarter of a century when the 1906 act was legislatively developed, our country was emerging from a rural into an industrial nation; the food and drug industries were beginning to be organized on the basis of mass production and distribution; the science of food and drug manufacture had reached the point where it could be constructively used to improve these products or destructively used to debase them; and the uncontrolled forces of competition were working for the sophistication of these products, in order to secure the commercial advantage of a lower price. All of which means that the inherent need for the law of this act was then progressively increased by the evolution in the food and drug order and a working of the forces underlying its competitive operation.”).

38. *See* *Pure Food and Drugs Act* at § 7.

39. *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409 (1914) (“The statute upon its face shows that the primary purpose of Congress was to prevent injury to the public health by the sale and transportation in interstate commerce of misbranded and adulterated foods. The legislation, as against misbranding, intended to make it possible that the consumer should know that an article purchased was what it purported to be; that it might be bought for what it really was, and not upon misrepresentations as to character and quality. As against adulteration, the statute was intended to protect the public health from possible

language of the statute, the Court found that Congress was clear in its directive regarding chemical additives, and specifically included language that intended to allow producers and manufacturers to include “poisonous or other added deleterious ingredient[s]”⁴⁰ to their products so long as they were not injurious to the public health.⁴¹ In that case, the Court cited legislative history to demonstrate that Congress did not intend to grant the agency the authority to regulate any product that might contain poison in the form of chemical additives.⁴² The *Lexington Mill* decision left room for the argument that the agency retained a broad grant of authority to regulate where it was able to demonstrate that the additive had the *potential* to result in some injurious effect rather than requiring a showing that the additive actually did cause some sort of injury to health.⁴³ However, the legislative support for making a claim that a product was adulterated due to the addition of a chemical additive in all instances where a producer or manufacturer used what the agency deemed a poison in the manufacturing process did not exist.⁴⁴ Consequently, even in these early years when the purposes of the Act were to protect human health and the purity of foods, Congress’ apparent willingness to permit chemical additives in food products where the agency sought to prevent them demonstrated the broad support for

injury by adding to articles of food consumption poisonous and deleterious substances which might render such articles injurious to the health of consumers.”).

40. *Id.* at 410.

41. *Id.* at 411 (“If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act.”).

42. *Id.* at 411-12 (“[A]lthough it may be said in passing that the meaning which we have given to the statute was well expressed by Mr. Heyburn, chairman of the committee having it in charge upon the floor of the Senate (Congressional Record, vol. 40, pt. 2, p. 1131): ‘As to the use of the term ‘poisonous,’ let me state that everything which contains poison is not poison. It depends on the quantity and the combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends upon the combination, the chemical relation which it bears to the body in which it exists, as to whether or not it is dangerous to take into the human system.”).

43. *Id.* at 411.

44. *Id.* at 410-11.

what were then considered advances in food production, which has endured for many decades.⁴⁵

*B. The Federal Food, Drug and Cosmetic Act of 1938*⁴⁶

While the Food and Drugs Act of 1906 persisted for many years, mounting concerns over the limited authority of the agency, the Act's inability to address unregulated and emerging risks with respect to food and drug safety, and the expanding field of cosmetics led to the drafting of the Food, Drug and Cosmetic Act of 1938.⁴⁷ The 1938 Act was much stronger in the sense that it gave the agency greater enforcement authority as well as the ability to set standards for the identity and quality of food products.⁴⁸ This was a critical addition because it created enforceable, legal standards that the government could use in misbranding and adulteration cases.⁴⁹ Additionally, the FDCA did not appear to interfere with the states' continued ability to regulate food products within their borders, even where those laws might have affected interstate commerce except for those situations where the laws conflicted or where Congress created a system of "thorough regulation"⁵⁰ for a specific product.⁵¹

Congress has not amended the 1906 Act's misbranding provisions since passage of the 1938 Act, and they largely reflect the same principles, if not similar language, of the provisions included in the 1906 Act.⁵² The courts considering misbranding cases under the revised Act followed the Court's reasoning in the *Ninety-Five Barrels* case, holding that labels including disclaimers regarding misleading statements did not cure the misbranding,⁵³ as the court's review would consider the permissibility of the language in light of

45. *Id.*

46. 21 U.S.C. § 301 et seq.

47. 1917 REPORT OF THE USDA. BUREAU OF CHEMISTRY, reprinted in MERRIL ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 11-12 (3d ed. 2007).

48. See *Developments in the Law: The Federal, Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 636 (1954).

49. See *id.*

50. *Id.*

51. *Id.*

52. *Pure Food and Drugs Act* § 8, Pub. L. No. 59-384, 34 Stat. 768 (1906) (current version at 21 U.S.C. § 341(1938)).

53. *Id.* at 653 (citing *Pasadena Research Laboratories, Inc. v. United States*, 169 F.2d 375, 383 (9th Cir.), cert. denied, 335 U.S. 853 (1948)).

“the probable inference a consumer might draw from it.”⁵⁴ Moreover, the Supreme Court held that the amended Act was Congress’ attempt to further strengthen its ability to regulate and control harmful food and drugs in commerce.⁵⁵ The Court found that Congress specifically intended that the Act “touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.”⁵⁶ Commentators have opined that these cases set the tone for an era of deference to proactive agency decisions intended to further the goals of the statute.⁵⁷

1. The Agency’s Interpretations of the Act

The current FDA generally follows the same logic in the sense that the agency remains concerned about product misbranding and the potential for consumer confusion.⁵⁸ However, rather than regulating food products to increase the availability of information for consumers, the FDA now takes the approach that information regarding the absence of certain additives or indicating a different process that does not include drugs or additives is misleading to consumers because it suggests a superior product.⁵⁹ Consequently,

54. *Developments in the Law*, *supra* note 47, at 653 (citing *see, e.g., United States v. 11/4 Dozen Packages of Mrs. Moffat’s Shoo Fly Powders for Drunkenness*, 40 F. Supp. 208 (W.D.N.Y. 1941)) (stating on its label that an article was “for drunkenness” was held tantamount to advertising it as a cure or treatment for drunkenness).

55. *United States v. Dotterweich*, 320 U.S. 277 (1943).

56. *Id.* at 280.

57. Edward M. Basile & Melanie Gross, *The First Amendment and Federal Court Deference to the Food and Drug Administration: The Times They Are A-Changin’*, 59 *FOOD & DRUG L.J.* 31, 34 (2004).

58. *See, e.g., Interim Guidance on the Voluntary Labeling of Milk*, *supra* note 4, at 6280.

59. *See id.* at 6280 (“ However, even such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading.”); *See Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering: Draft Guidance*, FDA.gov, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabel>

where the agency used to require manufacturers to disclose more, it has moved away from this approach in many respects.⁶⁰ Under the guise of consumer confusion, the agency now attempts, through voluntary guidance, to influence the actions of producers who voluntarily disclose that they have not used certain processes or additives that might be considered harmful.⁶¹ This represents what appears to be a significant departure from the agency's position in its infancy.

Currently, the FDA maintains its authority under the FDCA is limited to requiring the labeling of products that are misbranded because of "false or misleading"⁶² labeling. To determine whether a product's labeling is false or misleading, the agency must consider "the extent to which the labeling or advertising fails to reveal facts material...with respect to the consequences which may result from the use of the article to which the labeling or advertising relates...under such conditions of use as are customary or usual."⁶³ The FDA's interpretation of the FDCA authorizes them to require mandatory labeling of foods that have the potential to be misbranded only when the labeled feature involves facts material to possible consequences of the use of the food product due to some material chemical difference in what the food actually is versus what it purports to be on the label. Unfortunately, the Act provides no guidance as to what might be considered a "material fact" and this is determined by the agency on a case by case basis.

While the provisions of the current Act closely resemble the language included in the 1906 Act, in practice, the FDA approaches them very differently than it did in the early years of regulation. Specifically, the agency appears to have adopted a position that tends

ingNutrition/ucm059098.htm, (last visited October 13, 2011) ("A statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies that the labeled food is superior to foods that are not so labeled. FDA has concluded that the use or absence of use of bioengineering in the production of a food or ingredient does not, in and of itself, mean that there is a material difference in the food.").

60. See *Interim Guidance on the Voluntary Labeling of Milk*, *supra* note 4, at 6280. See also *Guidance for Industry*, *supra* note 58.

61. See *Interim Guidance on the Voluntary Labeling of Milk*, *supra* note 4, at 6280. See also *Guidance for Industry*, *supra* note 58.

62. 21 U.S.C. §343(a)(1).

63. *Id.* at § 321(n).

to favor industry rather than full disclosure aimed at consumer protection and access to information.⁶⁴ Despite mounting public concern over genetically engineered food⁶⁵ and consumer requests for the FDA to require more mandatory disclosure labeling,⁶⁶ the agency consistently states it lacks authority under the FDCA to require specific labeling of food products based on consumer interest alone.⁶⁷ Moreover, with regard to voluntary labeling, the agency's guidance cautions producers and manufacturers to be careful in their statements about the production of food, recommending that they avoid misleading consumers into believing a product is superior to a similar or identical product that has been processed differently.⁶⁸ These issues regarding both mandatory and voluntary food labeling have been central to the debate over milk from cows treated with rBST.

II. FDA'S APPROVAL OF rBST AND RESULTING CHALLENGES

A. *Introduction of rBST to the Market*

Marketed "as an important tool to help dairy producers improve the efficiency of their operations and produce more milk more sustainably"⁶⁹ and one that can "effectively reduce the environmental impact of dairy operations,"⁷⁰ rBST has been the subject of intense scrutiny since Monsanto's application for FDA approval of the supplement in 1987.⁷¹ Posilac©, or Monsanto's commercial version of rBST is a genetically engineered "supplement of the naturally

64. See Basile & Gross, *supra* note 56, at 31.

65. See *Id.*

66. See *Id.*

67. *Background Document: Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon Food and Drug Administration*, FDA, 6 (Aug. 2010), <http://www.fda.gov/downloads/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/UCM223913.pdf>.

68. *Id.* at 3.

69. *Monsanto to Pursue Divestiture of POSILAC*, MONSANTO (Aug. 6, 2008, 10:17AM), <http://monsanto.mediaroom.com/index.php?s=43&item=626>.

70. *Id.*

71. Margaret Sova McCabe, *Got Controversy? Milk Does*, 13 *DRAKE J. AGRIC. L.* 475, 478 (2008) (citing Robert Collier, *Regulation of rBST in the U.S.*, 3 *AGBIOFORUM* 156 (2000)).

occurring cow hormone BST, that when administered to cows allows them to produce more milk.”⁷² Its natural counterpart, bovine somatotropin (BST), is produced in the pituitary glands of mature cows to control their lactation cycles.⁷³

In the 1930s, British scientists injected BST taken from deceased cows into living ones and discovered that it had the potential to result in increased milk production.⁷⁴ This process is largely inefficient on a commercial scale due to the very small quantities that can reasonably be extracted from each carcass.⁷⁵ However, the introduction of recombinant DNA techniques in the 1980s allowed for the development of rBST, which mimics BST and can be produced inexpensively on a large scale.⁷⁶

B. *Early Safety Concerns about the Use of rBST*

Prior to its final approval for the use of rBST for animals, the FDA approved the drug for “research purposes only”⁷⁷ pending completion of its full investigative process, but permitted milk and beef products from cows treated with the hormone to be sold and consumed pending approval.⁷⁸ The General Accounting Office examined the agency’s investigational review of Monsanto’s application, following the preliminary approval, to determine whether the agency had

72. *Milk Labeling – Is Monsanto Opposed to Truth in Labeling?*, MONSANTO, <http://www.monsanto.com/newsviews/Pages/milk-labeling.aspx> (last updated July 16, 2009).

73. Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant BST*, 22 COLUM. J. ENVTL. L. 227, 230 (1997) (citing William H. Daughaday & David M. Barbano, *Bovine Somatotropin Supplementation of Dairy Cows: Is the Milk Safe?*, 264 JAMA 1003 (1990)).

74. Emily Marden, *Recombinant Growth Hormone in the Courts: In Search of Justice*, 46 DRAKE L. REV. 617, 621 (1998) (citing SHELDON KRIMSKY & ROGER P. WRUBEL, *AGRICULTURAL BIOTECHNOLOGY AND THE ENVIRONMENT: SCIENCE, POLICY AND SOCIAL ISSUES*, 167-68 (1996)).

75. *Id.*; Burk, *supra* note 72, at 231.

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

77. U.S. GENERAL ACCOUNTING OFFICE, B-248450, RECOMBINANT BOVINE GROWTH HORMONE: FDA APPROVAL SHOULD BE WITHHELD UNTIL MASTITIS ISSUE IS RESOLVED 2 (1992).

78. *Id.*

conducted a thorough investigation.⁷⁹ As part of its review process, the FDA required Monsanto to perform studies assessing whether rBST was biologically absorbed into the body, and could have required Monsanto to perform additional studies to determine its potential impact of bodily organs, in particular the liver.⁸⁰ Monsanto administered the hormone orally to rats over a 28- day period at 100 times the dose approved for administration to dairy cows.⁸¹ The study found, and the FDA concurred, the rats did not demonstrate absorption of biologically active rBST.⁸² The expert panel retained for the preparation of the GAO Report later substantiated this finding and determined that rBST was safe for use.⁸³

The GAO's expert panel supported the FDA's findings in most respects with one critical exception. The panel noted that while the FDA's investigation largely considered the direct risks of rBST on human health and food safety, the agency had failed to consider the indirect human food safety risks that could result from negative health impacts to animals injected with the drug.⁸⁴ In reaching this conclusion, the GAO focused on the increased risk of cattle treated with rBST to develop mastitis, an infection of the udder, which producers often treat with antibiotics that can remain in milk in trace amounts.⁸⁵ The GAO expressed concern that antibiotic residue levels in milk were already at unsafe levels due to the FDA's inadequate survey system, which made the agency's failure to assess whether the use of rBST would further increase the levels of antibiotics in milk even more problematic.⁸⁶

79. *Id.*

80. *Report on the Food and Drug Administration's Review of the Safety of Recombinant Bovine Somatotropin*, FDA.GOV, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm130321.htm> (last visited September 1, 2011) [hereinafter *Report on the Food and Drug Administration's Review*] (the FDA updated this study in response to the report issued by Health Canada, the Canadian counterpart to the FDA).

81. *Id.*

82. *Id.*

83. U.S. GENERAL ACCOUNTING OFFICE, *supra* note 76, at 6.

84. *Id.*

85. *Id.* at 9.

86. *Id.* (citing U.S. GENERAL ACCOUNTING OFFICE, GAO/RCED-91-26, *FOOD SAFETY AND QUALITY: FDA SURVEYS NOT ADEQUATE TO DEMONSTRATE SAFETY OF MILK SUPPLY* (1990) . The GAO panel's concerns with regard to the agency's inadequate surveys were not unfounded. See Philip James Kijak, *FDA Validates*

Interestingly, the GAO report also raised concerns about the FDA's unwillingness to label food products derived from animals treated with investigational drugs.⁸⁷ While the agency agreed in principle that this was an issue that needed to be addressed in the future, it felt this was the wrong situation to require such labeling, as it had determined rBST presented no risk to human health.⁸⁸ The FDA largely agreed with the GAO report's findings, but on this point the two diverged: as the GAO report stated, "we believe the public should have the right to know which food products have been produced from animals being tested with investigational drugs."⁸⁹

C. FDA Approval of rBST and the Resulting Challenges

Despite concerns over the safety of rBST for both animals and humans, the FDA approved the use of the artificial hormone in 1993, asserting it was "safe and effective for dairy cows, that milk from rBST treated cows [was] safe for human consumption, and that production and use of the product [did] not have a significant impact on the environment."⁹⁰ The agency determined "there was no significant difference between milk from treated and untreated cows."⁹¹ Consequently, the agency issued guidance to the industry stating that because it did not find a compositional difference existed

Rapid Screening Tests for Antibiotics in Milk, FDA.GOV, <http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm093812.htm> (last updated Oct. 28, 2009) ("The screening tests are meant to be fast and accurate. They are not meant to supply complete information about the potential of antibiotics in milk. For instance, most kits will not test for all six beta-lactam drugs. And, in most cases, the tests do not provide information on what drug caused the positive result. Still, the screening tests fulfill their principal duty—keeping the milk supply in the United States safe—while not slowing down delivery of fresh milk to consumers.").

87. U.S. GENERAL ACCOUNTING OFFICE, *supra* note 76, at 11.

88. *Id.*

89. *Id.*

90. *Interim Guidance on the Voluntary Labeling of Milk* *supra* note 4, at 6280; see also *Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension*, 58 Fed. Reg. 59,946 (Nov. 12, 1993) (to be codified at 21 C.F.R. pts. 510, 522) (approving the use of rBST).

91. *Interim Guidance on the Voluntary Labeling of Milk*, *supra* note 4, at 6280.

in the two types of milk, it was unable to require mandatory labeling of milk from cows treated with rBST.⁹²

The FDA went a step further and addressed what types of statements would pass scrutiny under the FDCA for producers who wished to include information about milk produced from cattle not treated with the hormone. In its guidance, the agency advised producers to tailor the statements on their labels to focus on process rather than composition, and include an appropriate disclaimer noting that the FDA found no significant difference between the two types of milk.⁹³ In other words, the FDA encouraged manufacturers and producers who did not use rBST to ensure their statements did not lead consumers to infer that their milk was of a superior quality.⁹⁴

The FDA's findings regarding the safety of rBST were later challenged by two advocacy groups, the Vermont Public Interest Research Group ("VPIRG") and Rural Vermont following the release of a Canadian report prepared for Health Canada (the Canadian counterpart to the FDA). This report, completed in 1999, noted a number of potential risks to humans based on a ninety (90) day study submitted by Monsanto for approval in the European Union ("EU"), which was allegedly also submitted to the FDA during its approval process.⁹⁵

The Canadian report made several findings that the GAO panel had also addressed and that continue to fuel debate over the safety of rBST.⁹⁶ Specifically, the Canadian panel found that Monsanto's 90-day rat study demonstrated an antibody response to rBST, leaving

92. *Id.*

93. *Id.*

94. *See id.*

95. *Report on the Food and Drug Administration's Review*, *supra* note 79.

96. *Report of the Royal College of Physicians and Surgeons of Canada – Expert Panel on Human Safety of rBST*, HEALTH CANADA, http://www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/rbst-stbr/rep_rcpsc-rap_crmcc_final-a-eng.php#hebfp (last visited September 1, 2011) [hereinafter *Royal College of Physicians and Surgeons of Canada*] ("bST does cause increased production of IGF-1 and may, on the basis of rat studies, cause an antibody response in some recipients of oral dosing. The latter response warrants further study in order to determine the likelihood of human hypersensitivity reactions. The implications of human exposure to slightly increased IGF-1 production (1% increment over normal exposure) would be impossible to study in any animal or human model.").

open the question of a hypersensitivity response in humans.⁹⁷ Additionally, as both the FDA and the GAO reports noted, milk from rBST-treated cows contains an increased concentration of Insulin-like Growth Factor 1 (“IGF-1”). The complete effects of IGF-1 were then unclear,⁹⁸ but in the panel’s opinion, greater concentrations of IGF-1 in humans could potentially result in an increased risk of cancer for specific individuals.⁹⁹ The Canadian panel also expressed concern over the increased possibility for cattle treated with rBST to develop mastitis.¹⁰⁰ The panel concluded that Health Canada had enough information to make a decision about whether to approve the use of rBST, however, it stated, “[t]he only definitive proof of absolute safety of milk from rBST-treated cattle would be long term follow up data in a population exposed to the resulting food products.”¹⁰¹ In response to these findings, Health Canada ultimately chose not to approve Monsanto’s application.¹⁰²

1. *Stauber v. Shalala*

The case the FDA relies upon to support its claims regarding its inability to require mandatory labeling of milk products from cows injected with rBST was filed in immediate response to the agency’s approval of the artificial growth hormone and provides the basis for the agency’s continued refusal to mandate labeling in this context.¹⁰³

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*; see also *Evaluation and Use of Antimicrobial Drug Screening Tests*, U.S. Department of Health & Human Services, <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/CodedMemoranda/MemorandaofInformation/ucm082165.htm> (last updated June 18, 2009) (Stating that five of the eleven approved drugs to treat mastitis can cause hypersensitivity in certain individuals and that there is no ideal test, as it cannot identify the specific drug residue nor its concentration.) (stating that five of the eleven approved drugs to treat mastitis can cause hypersensitivity in certain individuals and that there is no ideal test, as it cannot identify the specific drug residue nor its concentration.)

101. *Royal College of Physicians and Surgeons of Canada*, *supra* note 95.

102. *Drugs and Health Products*, HEALTH CANADA, <http://www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/rbst-stbr/index-eng.php> (last modified Oct. 1, 2004).

103. See *Background Document*, *supra* note 66 (citing 72 Fed. Reg. 16291, 16294 (Apr. 4, 2007); 59 Fed. Reg. 6279 (Feb. 10, 1994); *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995)) (“Fifth, FDA cannot require additional labeling about production methods unless it is necessary to ensure that the labeling

In *Stauber v. Shalala*,¹⁰⁴ the United States District Court of Wisconsin considered the issues on the parties' cross motions for summary judgment, finding in favor of the defendants, Donna Shalala, then Secretary of Health and Human Services, and David Kessler, then Commissioner of the FDA.¹⁰⁵ In addition to arguing that the FDA's decision to approve the drug was arbitrary and capricious because of the agency's failure to consider the health and safety effects of rBST, the plaintiffs, consumers of commercial dairy products, argued that the FDCA required the agency to mandate labeling of any products derived from cows treated with rBST due to "material facts"¹⁰⁶ about the differences in the milk.¹⁰⁷

The plaintiffs advanced two theories to support their argument regarding labeling. First, milk from rBST-treated cows is organoleptically¹⁰⁸ different from milk from untreated rBST cows.¹⁰⁹ Second, the "widespread consumer desire for mandatory labeling of rBST-derived milk"¹¹⁰ evidenced a degree of demand which, in turn, amounted to a material fact triggering the labeling requirements under the FDCA.¹¹¹ Under section 201(n) of the FDCA, "[i]nformation disclosing differences in performance characteristics (e.g., physical properties, flavor characteristics, functional properties

is not false or misleading. Another way of stating this point is that FDA cannot require labeling based solely on differences in the production process if the resulting products are not materially different due solely to the production process. For example, recombinant Bovine Somatotropin ("rBST") is a synthetic growth hormone that increases milk production in dairy cows. Because FDA found that there was no material difference between milk from rBST-treated cows and milk from non-rBST-treated cows, FDA did not have the authority to require additional labeling of milk from rBST-treated cows.").

104. *Stauber v. Shalala*, 895 F. Supp. 1178 (W.D. Wis. 1995) (*Stauber* was originally commenced with forty-one (41) plaintiffs as *Barnes v. Shalala*, 865 F. Supp. 550 (W.D. Wis. 1994). The court in *Barnes* granted the defendant's motion to dismiss based on a lack of standing for all those plaintiffs that were not consumers. The remaining five (5) consumers were the plaintiffs in *Stauber*.)

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

106. *Id.* at 1182.

107. *Id.*

108. The FDA defines organoleptic properties as "those that stimulate the sensory organs, such as texture or aroma." *Background Document*, *supra* note 66.

109. *Stauber*, 895 F. Supp. at 1193.

110. *Id.*

111. *Id.*

and shelf life) is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article.”¹¹² Consequently, any failure to disclose this information to the consumer on the label was misleading, causing the product to be misbranded under section 403(a).¹¹³

The plaintiffs submitted evidence to substantiate their claims that rBST has a negative impact on human health largely in the form of affidavits, which the court noted were not given to the FDA during the approval process, and therefore, could not be considered.¹¹⁴ The court found that the plaintiffs also relied on an affidavit from Dr. Richard Burroughs,¹¹⁵ a veterinary medical officer for the FDA who had participated in the Posilac© review process.¹¹⁶ Because the plaintiffs presented this affidavit to support the proposition that rBST can have serious negative health consequences for cows, the court considered it solely in that regard, and accepted the facts regarding negative health consequences to cattle as undisputed.¹¹⁷ Dr. Burroughs’ affidavit also cited several critical flaws in the agency’s review of the drug, as well as concerns about Monsanto’s testing

112. *Id.*

113. *Id.* 21 U.S.C. § 403(a) (current version at 21 U.S.C. § 343(a)(1) (2010)) (“A food shall be deemed to be misbranded—(a) If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of sec. 411(b)(2).”).

114. *Stauber*, 895 F. Supp at 1190 (“Plaintiffs cannot ask this court to rely on opinions within the medical community regarding health risks posed by rbST without first establishing that those opinions were presented to the FDA before it granted approval of Posilac.”); *see Marden, supra* note 40, at 634 (suggesting that the court unnecessarily expanded the scope of the rule barring judicial review of an agency’s findings to prohibit review of “nonagency” data outside the record).

115. Burroughs was terminated from the FDA in 1988, allegedly for incompetence. Upon his firing, Burroughs made public statements about the FDA’s review of rBGH alleging that the agency was ignoring problems with the drug while Monsanto was manipulating the data. Burroughs was reinstated after it was determined he was improperly fired. However, his allegations were taken seriously enough that the GAO was asked to investigate the issue leading to the report mentioned above. FOOD AND WATER WATCH, *RBGH: HOW ARTIFICIAL HORMONES DAMAGE THE DAIRY INDUSTRY AND ENDANGER HUMAN HEALTH*, 2 (June 2009).

116. *Stauber*, 895 F. Supp. at 1190.

117. *Id.*

processes.¹¹⁸ While this information could have been useful to clarify the record before the agency or to illuminate the alleged capriciousness of the agency's decision-making process, the court would not consider the affidavit in that light, as it was not proffered for that purpose.¹¹⁹

The *Stauber* court was sympathetic to the issues raised by the plaintiffs, but ultimately deferred to the findings of the agency regarding the safety of rBST, holding that the decision to approve the hormone was not arbitrary and capricious.¹²⁰ The court then analyzed the issue of mandatory labeling under the FDCA. With regard to this issue, the court found that plaintiffs failed to point to evidence in the record proving that milk from rBST-treated and untreated rBST cows differ in terms of performance characteristics or organoleptic properties.¹²¹ Specifically, the plaintiffs failed to demonstrate that the administration of rBST has an impact on the composition of milk.¹²²

The plaintiffs also argued that widespread consumer demand for labeling information about milk from cows treated with rBST necessitated mandatory labeling under the FDCA.¹²³ However, when deciding which facts to require on labels, the FDA may only consider consumer demand when it has first determined that the product is different than what it claims to be, and that then determined that the difference is one about which consumers would want to know.¹²⁴ In other words, even if consumers viewed the product as different, the FDA could not require labeling unless a material difference exists between the two products.¹²⁵ The *Stauber* court held that the "plaintiffs [did] not present[] any evidence demonstrating organoleptic differences between regular and rbST-derived milk or of any harmful effects of rbST on consumers,"¹²⁶ therefore, a label

118. *Id.*

119. *Id.* (citing *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420-21 (1971)).

120. *Stauber*, 895 F. Supp. at 1192.

121. *Id.* at 1193.

122. *Id.*

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.*

stating the milk was derived from cows treated with rBST would constitute misbranding under the Act.¹²⁷

In some respects, the *Stauber* decision does not seem to reflect a departure from the original cases interpreting the FCDA's misbranding provisions. The court deferred to the agency's decision not to require labeling based on its finding that no material difference existed between milk from cows treated with rBST and those that were not. This holding has been upheld in cases following the *Stauber* decision.¹²⁸ However, what is striking about the *Stauber* case is the agency's departure from its previous role of preventing consumer fraud by erring on the side of caution and giving consumers more, rather than less, information about the products they are purchasing.

III. STATE LEGISLATIVE RESPONSE AND FIRST AMENDMENT CHALLENGES

A. *International Foods v. Amestoy*

In response to the FDA's unwillingness to require labeling of products from cattle treated with rBST, the Vermont legislature enacted a statute mandating the labeling of milk and milk products

127. *Id.*

128. This holding has been upheld in cases following the *Stauber* decision. Specifically, in *Alliance for Bio-Integrity v. Shalala*, the plaintiffs challenged the FDA's decision to recognize foods altered through recombinant DNA technology as safe and not require mandatory labeling. The court in *Alliance for Bio-Integrity* cited *Stauber* finding "Plaintiffs fail to understand the limitation on the FDA's power to consider consumer demand when making labeling decisions because they fail to recognize that the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling. Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact. Thus, 'if there is a [material] difference, and consumers would likely want to know about the difference, then labeling is appropriate. If, however, the product does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceived the product as different.'" *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 179 (D.D.C. 2000) (citing *Stauber*, 895 F. Supp. at 1193).

sold within the State that were derived from rBST-treated cows.¹²⁹ The legislature cited “strong consumer interest” and the “public’s ‘right to know’” as the bases for the law.¹³⁰ In response, a group of dairy manufacturers challenged the constitutionality of the law under the First Amendment and the Commerce Clause, and requested injunctive relief to prevent its enforcement.¹³¹ The Second Circuit Court of Appeals ultimately decided the case on First Amendment grounds and did not reach the Commerce Clause issues.¹³² With regard to a showing of irreparable harm, the court reversed the lower court’s decision, holding that because the statute required the dairy manufacturers to speak when they desired to remain silent, it “‘contravene[d] core First Amendment values,’” which resulted in irreparable harm to the plaintiffs.¹³³

The court also determined that the plaintiffs successfully demonstrated they would likely be successful on the merits.¹³⁴ Using the four part test articulated in *Central Hudson*,¹³⁵ which pertains to commercial speech, the court considered: “(1) whether the expression concerns lawful activity and is not misleading; (2) whether the government’s interest is substantial; (3) whether the labeling law directly serves the asserted interest; and (4) whether the labeling law is no more extensive than necessary.”¹³⁶ Regarding the second prong, the court found that the State failed to demonstrate it had a substantial interest in requiring labeling of milk products from cattle treated with rBST because it did not “‘claim that health or safety concerns prompted the passage of the Vermont Labeling Law,’”¹³⁷

129. *Int’l Dairy Foods Assn. v. Amestoy*, 92 F.3d 67, 69 (2d Cir. 1996) (citing 6 V.S.A. § 6754 (1995)) (“If rBST [a recombinant bovine growth hormone] has been used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such.”).

130. *Int’l Dairy Foods Assn. v. Amestoy*, 898 F. Supp 246, 249 (D. Vt. 1995) (*rev’d* 92 F.3d 67 (2d Cir. 1996)).

131. *Int’l Dairy Foods*, 92 F. 3d at 70.

132. *Id.*

133. *Id.* at 72 (citing *Int’l Dairy Foods*, 898 F. Supp. at 251-52; *Paulsen v. County of Nassau*, 925 F.2d 65, 68 (2d Cir. 1991)).

134. *Id.*

135. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980).

136. *Int’l Dairy Foods*, 92 F.3d at 72 (citing *Central Hudson*, 447 U.S. at 566).

137. *Id.* at 73.

rather, it cited consumer interest and the public right to know.¹³⁸ In the court's opinion, these interests were not sufficient to deprive the plaintiffs of their First Amendment rights.¹³⁹

Following the same reasoning as *Stauber*,¹⁴⁰ the court noted it was not aware of any cases justifying a requirement that manufacturers disclose warning information about production methods on the basis of consumer interest alone, when the methods have no discernable impact on the final product.¹⁴¹ Specifically, because the FDA determined rBST has no "appreciable effect on the composition of milk produced by treated cows,"¹⁴² the requirement that manufacturers disclose whether their cattle have been treated with the drug has no discernable connection to public health, safety, or welfare.¹⁴³ Under this holding, even where a statement on a label is factually accurate and truthful, unless the State can demonstrate the warning is necessary to prevent harm, deception, or confusion, the language on the label cannot be sustained under the First Amendment.¹⁴⁴

While the State of Vermont attempted to provide more information to consumers by mandating labeling in response to the agency's failure to do so, other states approached the issue differently and enacted restrictive labeling laws to comply with the voluntary

138. *Id.*

139. *Id.*

140. *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995).

141. *Int'l Dairy Foods*, 92 F. 3d at 73. (2d Cir. 1996).'

142. *Id.* (citing *Int'l Dairy Foods Assn. v. Amestoy*, 898 F. Supp. 246, 248 (D.Vt. 1995)).

143. *Id.*

144. *See id.* at 74 (citing *United States v. Sullivan*, 332 U.S. 689, 693 (1948) (upholding federal law requiring warning labels on "harmful foods, drugs and cosmetics") (emphasis added); *see also Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985) (disclosure requirements are permissible "as long as [they] are reasonably related to the State's interest in preventing deception of consumers."); *In re R.M.J.*, 455 U.S. 191, 201 (1982) ("warning[s] or disclaimer[s] might be appropriately required ... in order to dissipate the possibility of consumer confusion or deception."); *Bates v. State Bar of Arizona*, 433 U.S. 350, 384 (1977) (state bar association could not ban advertising that was neither misleading nor deceptive); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-72 (1975) (regulation aimed at preventing deceptive or misleading commercial speech would be permissible)).

labeling standards set forth by the agency's guidance.¹⁴⁵ The State of Ohio went so far as to prohibit any labeling including terms such as "rBST free," or "rBGH-free," due to the potential for confusion among consumers, which led to the most recent legal challenge regarding milk labeling.¹⁴⁶

IV. INTERNATIONAL DAIRY ASSOCIATION V. BOGGS AND MOVING FORWARD

A. The Boggs Decision - Acknowledging a Compositional Difference

To address consumer demand for dairy products from cattle not treated with rBST, dairy processors in Ohio began including information on their labels stating that they did not use rBST in the production process.¹⁴⁷ Governor Ted Strickland responded by issuing an executive order directing the Ohio Department of Agriculture ("ODA") to "define what constitutes false and misleading labels on milk and milk products."¹⁴⁸ The ODA proposed a rule that aimed to restrict the types of comments dairy processors could include on their products.¹⁴⁹ For example, any compositional claims stating "No Hormones", "Hormone Free", "rBST free", "rBGH free", "No Artificial Hormones", or "bST Free" were deemed "false and misleading" under the rule regardless of the inclusion of any disclaimers about the FDA's findings.¹⁵⁰ The results of two public hearings and many public comments on the proposed rule suggested that, by and large, Ohioans disfavored the suggested labeling restrictions.¹⁵¹ Specifically, "[l]ess than 70 of the 2,700 emails and letters sent to the ODA during this time period were in favor of the

145. *E.g.*, Pa. Dep't. of Agric.: Milk Labeling Standards 2.0.1.17.08 (Jan. 17, 2008), S.B. 595, 2008 Sess. (Kan. 2008); H.B. 1300 115th Gen. Assemb., 2d Reg. Sess. (Ind. 2008).

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

147. *Int'l Dairy Foods Ass'n. v. Boggs*, 2009 WL 937045, 5 (S.D. Ohio).

148. *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 634 (6th Cir. 2010) (citing Ohio Governor Executive Order 2008-03S (Feb. 7, 2008)).

149. *Id.*

150. *Id.*

151. *Id.*

proposed rule.”¹⁵² Despite the tremendously negative public response, ODA Director, Robert Boggs, adopted the rule, as originally proposed, in May 2008.¹⁵³

Both the International Dairy Foods Association (“IDFA”) and the Organic Trade Association (“OTA”) filed lawsuits, which were ultimately consolidated, challenging the constitutionality of the rule.¹⁵⁴ The plaintiffs moved for a preliminary injunction; thereafter, both parties sought summary judgment on all issues with the exception of an equal protection claim.¹⁵⁵ The district court granted

152. *Id.*

153. *Id.* In pertinent part, the rule provides:

A) Pursuant to sections 917.05 and 3715.60 of the Revised Code, dairy products will be deemed to be misbranded if they contain a statement which is false or misleading.

(B) A dairy label which contains a production claim that “this milk is from cows not supplemented with rbST” (or a substantially equivalent claim) may be considered misleading on the basis of such language, unless:

(1) The labeling entity has verified that the claim is accurate, and proper documents, including, but not limited to, producer signed affidavits, farm weight tickets and plant audit trails, to support the claim, are made readily available to ODA for inspection; and

(2) The label contains, in the same label panel, in exactly the same font, style, case, and color and at least half the size (but no smaller than seven point font) 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.”

(C) Making claims regarding the composition of milk with respect to hormones, such as “No Hormones”, “Hormone Free”, “rbST Free”, “rbGH Free”, “No Artificial Hormones” and “bST Free”, is false and misleading. ODA will not permit such statements on any dairy product labels.

(D) Statements may be considered to be false or misleading if they indicate the absence of a compound not permitted by the United States [F]ood and [D]rug [A]dministration to be present in any dairy product, including, but not limited to antibiotics or pesticides. Except as otherwise provided in this rule, accurate production claims will not be deemed false or misleading.

Ohio Admin. Code §901:11-8-01 (2008).

154. *Boggs*, 622 F.3d at 634.

155. *Id.*

summary judgment in favor of the State on virtually every claim except the one pertaining to the rule's restrictions on production claims, on which it granted partial summary judgment.¹⁵⁶ Because of the rulings on summary judgment, the court found the plaintiffs could not demonstrate that they were likely to prevail on the merits, and denied the request for a preliminary injunction.¹⁵⁷ The plaintiffs then filed an interlocutory appeal of only the First Amendment and Commerce Clause claims.¹⁵⁸

1. First Amendment Challenge to Restriction on Composition Claims

The plaintiffs first argued that the rule's prophylactic ban on any composition claims such as "rBST-free," antibiotic-free," or "pesticide-free" violated the First Amendment.¹⁵⁹ Using the same four part test from *Central Hudson* applied by the *Amestoy* court to consider whether the speech, characterized as commercial, was entitled to First Amendment protection,¹⁶⁰ the court agreed with the plaintiffs, holding the rule was more extensive than necessary to meet the State's interest in preventing consumer confusion or deception.¹⁶¹

a. Inherently Misleading

The court adopted the plaintiff's reasoning, holding that "where speech is only potentially misleading....'the preferred remedy is more disclosure rather than less.'"¹⁶² Whereas the district court held the composition claims were inherently misleading because they implied a compositional difference between the two milks, contradicting the FDA's findings relative to that issue, the court of

156. *Id.*

157. *Id.* at 635.

158. *Id.*

159. *Id.*; Ohio Admin. Code §901:11-8-01(C)(2008).

160. See *Int'l Dairy Foods Ass'n. v. Amestoy*, 92 F. 3d 67, 72 (2d Cir. 1996).'

161. *Boggs*, 622 F.3d at 639 (citing *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980)).

162. *Id.* at 636 (citing *In re R.M.J.*, 455 U.S. 191, 203 (1982); *Bates v. State Bar of Arizona*, 433 U.S. 350, 374-75 (1977) ("striking down a ban on advertising for 'routine' legal services in part because 'it seems peculiar to deny the consumer, on the ground that the information is incomplete, at least some of the relevant information needed to reach an informed decision'")).

appeals found the record told a different story.¹⁶³ Specifically, “contrary to the district court’s assertion, a compositional difference does exist between milk from untreated cows and conventional milk (‘conventional milk,’ as used throughout this opinion, refers to milk from cows treated with rBST.)”¹⁶⁴

The appellate court considered additional scientific information outside the scope of the FDA’s record to reach this finding, which signifies a different approach than that of the district court.¹⁶⁵ In the case below, the district court held a conference on the preliminary injunction request at the start of the case¹⁶⁶ and asked the parties what evidence they intended to present.¹⁶⁷ According to the district court, the Director of ODA suggested the defendants might need an expert witness to testify about the science behind rBST, and the plaintiffs disagreed, claiming the issues were “largely legal,”¹⁶⁸ which led the court to conclude that the parties did not dispute the FDA’s scientific findings regarding rBST.¹⁶⁹ On appeal, the court chose not to strictly rely on the FDA’s findings regarding the science of rBST, and also reviewed amici curiae evidence to make several findings relevant to the First Amendment challenge.¹⁷⁰

First, the appellate court determined that the use of rBST has been shown to increase IGF-1 levels, which has been linked to certain types of cancers.¹⁷¹ Second, rBST induces cattle to produce milk during their “‘negative energy phase’”¹⁷² when they would not normally produce milk, which causes that milk to be of lower quality due to “‘increased fat content’” and “‘decreased levels of proteins.’”¹⁷³ Milk from cattle treated with rBST also has a higher somatic cell count, which can cause the milk to turn sour more quickly than milk

163. *Id.*

164. *Id.*

165. *Id.*

166. *Int’l Dairy Foods Ass’n v. Boggs*, 2009 WL 937045, 5 (S.D. Ohio).

167. *Id.*

168. *Id.*

169. *Id.* (citing Case no. 2:08-cv-628, Doc. 19, p.32).

170. *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 636 (6th Cir. 2010).

171. *Id.*

172. *Id.* (citing Brief for Center for Food Safety, et al. as Amici Curiae Supporting Appellants, *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628 (6th Cir. 2010) (No. 09-3515)).

173. *Id.* at 636-37.

from untreated cows.¹⁷⁴ Additionally, “and more salient to the regulation of composition claims like ‘rBST-free,’”¹⁷⁵ the inability to determine whether rBST is present in milk from cows treated with the hormone is not because the drug is not present in the milk, but because scientists have not yet developed a test to accurately detect its presence.¹⁷⁶ The court found the FDA’s statement that it detected “no *significant* difference”¹⁷⁷ compelling, as it suggested the agency left room for the finding that “*some* compositional difference between the two types of milk may exist....”¹⁷⁸

Considering the evidence collectively, the appellate court held that there were, in fact, “two distinct types of milk.”¹⁷⁹ The first type of milk comes from cattle not treated with rBST, meaning the milk can never contain the hormone.¹⁸⁰ The second type of milk comes from cattle treated with rBST and may or may not contain rBST - but there currently exists no test to determine whether it does.¹⁸¹ Because a compositional difference exists between these two types of milk, and it is impossible to determine whether conventional milk does, in fact, contain rBST, a composition claim on a label for milk from untreated cows stating the milk is “rBST free” is not inherently misleading.¹⁸² Such a label informs consumers “of a meaningful distinction” and, “at worst potentially misleads them into believing that a compositionally distinct milk adversely affects their health.”¹⁸³

*b. Substantial State Interest Directly Related to the Regulation,
Which is Not More Extensive Than Necessary*

After making the determination that the composition claim “rBST-free” was not inherently misleading, the court went on to consider the remaining three factors under *Central Hudson*. First, the court considered whether the State’s interest in creating the rule was

174. *Id.* at 637.

175. *Id.*

176. *Id.*

177. *Id.*

178. *Id.*

179. *Id.*

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.*

substantial.¹⁸⁴ The State's asserted interest in drafting the rule was "to prevent the use of 'false or misleading' labeling."¹⁸⁵ While the plaintiffs agreed this was a substantial interest because the rule was targeted at consumer deception, the State was required to show that "the harms it recite[d] [were] real and its restriction [would] in fact alleviate them to a material degree."¹⁸⁶ Here, the State cited only the FDA Guidance and the public comments to the draft proposed rule it received from consumers to demonstrate the targeted deception.¹⁸⁷ The FDA Guidance did not provide any supporting evidence to prove a real harm of consumer deception.¹⁸⁸ Additionally, the public comments from consumers in response to the proposed rule evidenced some consumer confusion regarding the presence of rBST in conventional milk, but the confusion was not the result of product labels, and, rather, appeared to originate from outside sources.¹⁸⁹ Consequently, the court determined that the evidence simply did not prove that consumers in Ohio have been misled by the labeling on their milk and milk products, leading it to conclude that the rule did not directly advance the State's asserted interest in preventing false or misleading labeling and was "more extensive than necessary to serve that interest."¹⁹⁰

2. First Amendment Challenge to Disclosures for Production Claims

The court next addressed the production claims, stating, for example, "this milk is from cows not supplemented with rBST."¹⁹¹

184. *Id.* at 638.

185. *Id.* (citing Ohio Admin. Code, 901:11-9-01(A) (2008)).

186. *Id.* (citing *Ibanez v. Fla. Dep't of Bus. and Prof'l Regulation, Bd. Of Accountancy*, 512 U.S. 136, 146 (1994) (citation omitted)).

187. *Id.*

188. *Id.* ("The FDA suggests in the Guidance that the claim 'rBST free' 'may imply a compositional difference' between the two types of milk, 59 Fed.Reg. 6279, 6280 (emphasis added), but this statement does not establish that such a claim is necessarily misleading in every context. Furthermore, the FDA cited no evidence or studies in the Guidance to support its concerns regarding consumer confusion. The Guidance therefore does not constitute 'evidence of deception' as required under *Ibanez*.").

189. *Id.* at 639.

190. *Id.*

191. *Id.* at 640.

The Ohio rule required that these claims had to be accompanied by a disclosure statement to inform the consumer that the FDA had not found any significant difference between the two types of milk.¹⁹² Moreover, the Ohio rule required that the disclosure be included on the same panel, “in exactly the same font, style, case, and color and at least half the size (but no smaller than seven point font)” as the claim addressing production.¹⁹³

The plaintiffs argued the district court applied the wrong standard of review by focusing on *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*,¹⁹⁴ which considered disclosure requirements and did not apply the same strict standard as *Central Hudson*.¹⁹⁵ The court was unconvinced by this argument, holding that *Zauderer* provided the appropriate standard, as it applied to speech that was inherently misleading.¹⁹⁶ This standard also controlled speech that was only potentially misleading.¹⁹⁷

Under the *Zauderer* analysis, requirements pertaining to disclosures must be “‘reasonably related to the State’s interest in preventing deception of consumers’ and cannot be ‘unjustified or unduly burdensome.’”¹⁹⁸ The plaintiffs argued that the State failed to demonstrate the production claims were deceptive or confusing to consumers.¹⁹⁹ The court rejected this argument despite the fact that the FDA’s guidance and the public comments submitted in response to the draft rule provided only minimal evidence of deception or confusion.²⁰⁰ This evidence, weak as it was, provided some indication that claims about production can be confusing to consumers in Ohio, who seemed unsure about the presence of rBST in the milk they purchased.²⁰¹ Despite finding that the disclosure requirement is reasonably related to the State’s asserted interest in preventing deception, the court found the requirement that such disclosure be contiguous to the production statement was not

192. *Id.* (citing Ohio Admin. Code 901:11-8-01(B)(2)).

193. *Id.*

194. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985).

195. *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 640 (6th Cir. 2010).

196. *Id.* at 641.

197. *Id.*

198. *Id.* (citing *Zauderer*, 471 U.S. at 651).

199. *Id.* at 642.

200. *Id.*

201. *Id.*

rationally related to the State's interest.²⁰² The State was particularly concerned over the use of asterisks next to the disclosure statements, as it asserted (without supporting evidence) that asterisks have raised issues in the past.²⁰³

The plaintiffs also argued that the Ohio rule was unduly burdensome because it was significantly different from the rules in other states, which would require manufacturers and processors to make Ohio-specific labels.²⁰⁴ However, in the absence of the restrictions on composition claims and asterisks, the Ohio rule closely resembles the labeling regulations in other states.²⁰⁵

B. Conclusion

The end result of the decision in *Boggs* is the creation of a state regulation in Ohio to address milk labeling that is not significantly different from regulations in other states. However, this reading fails to consider how the *Boggs* decision represents a dramatic departure from prior cases addressing milk labeling. While the previous cases deferred to the findings of the agency, reiterating its conclusion that there is “no significant difference between milk from treated and untreated cows,”²⁰⁷ the *Boggs* court considered new scientific evidence that was outside the agency's record when it initially approved the drug.²⁰⁸ Moreover, the court relied in part on this evidence to make the determination that a compositional difference exists between milk from treated and untreated cows.²⁰⁹ Beyond the fact that no court has looked outside the agency's record or made a determination that a compositional difference between the two types of milk exists, what is most compelling about the court's decision is

202. *Id.* at 643.

203. *Id.*

204. *Id.*

205. *See, e.g.*, Wis. Admin. Code, ATCP § 83.02 (2004); Alaska Stat. § 17.20.013 (2011); Minn. Stat. § 32.75 (2004); New Jersey Dep't of Agric. and Dep't of Health and Senior Service's Joint Guideline for “NON-rBST” Claims (2007); Title 61, Legislative Rule, West Virginia Dep't of Agric, Series 4D, “Labeling of Dairy Products for rBST or rBGH” (1995).

207. *Guidance for Industry, supra* note 58.

208. *Boggs*, 622 F.3d at 636-37.

209. *Id.*

its reliance on the agency's language regarding its own findings.²¹⁰ The agency's findings state there is not a *significant* difference between the two types of milk.²¹¹ The slightly ambiguous nature of this statement led the court to posit that the agency's language does not preclude the possibility that a difference in the two types of milk may, in fact, exist.²¹² The court followed this line of reasoning to suggest that because the agency currently does not have a test to determine whether milk from rBST-treated cows may contain the hormone in trace amounts, the possibility that the milk might contain hormones is too significant to be ignored.²¹³ Taking this particular finding a step further and applying it to the language of the statute itself, advocates may have a good argument to compel the FDA to mandate labeling of milk from cows treated with rBST.

Commentators suggest that the age of deference to the FDA is coming to an end, as the federal courts are more willing to strike down agency decisions that ban or restrict commercial speech.²¹⁴ Arguably, the *Boggs* decision provides another significant example of a federal court's unwillingness to simply accept the agency's determinations about the effects of a particular drug it approved almost a decade prior. The court's findings regarding the effects of rBST on human and animal health, as well as milk quality, reflect what could be viewed as a distrust of the agency's own limited findings signaled by its willingness to depart from the traditional deference accorded to agency findings. Despite numerous requests in the form of lawsuits and petitions to the agency to revisit its conclusions about the safety of rBST, the agency has remained steadfast in its approach and continues to maintain the drug is safe for both animals and humans, as evidenced by the agency's continued approval for use in dairy cattle. On February 15, 2007, a group of

210. *See id.* at 637.

211. *Id.*

212. *Id.*

213. *Id.*

214. *See* Basile & Gross, *supra* note 56, at 43 (analyzing the decision in *Thompson v. Whitaker*, 248 F. Supp. 2d 1 (D.D.C. 2002) where the "the court went beyond its typical judicial practice and conducted its own analysis of the scientific data, ultimately substituting its interpretation of the data for the agency's. The *Whitaker* court's approach not only stretched the limits under *Chevron*, and arguably a departed from legal precedent, but its decision also has the potential to undermine FDA's credibility in future decisions.").

individuals filed the most recent petition, and requested the Secretary of the FDA to “immediately suspend approval” of the drug based on “imminent hazard” due to the scientific evidence showing increased risks of cancer for individuals consuming treated milk.²¹⁷ According to Samuel S. Epstein, one of the authors of the petition, the FDA did not even acknowledge their filing.²¹⁸ The petitioners resubmitted their request for suspension of approval of the drug on January 12, 2010, and the Commissioner dismissed it on procedural grounds.²¹⁹

While advocates seeking labeling of milk from rBST-treated cows have been unsuccessful to date, the *Boggs* decision at least affirms producers’ rights to claim that their untreated milk is “rBST-free,” allowing consumers access to this desired information. However, in many states, milk producers do not include this statement on their labels for fear of legal challenges, or simply because the particular state’s requirements are too onerous.²²⁰ One suggestion is to ban the drug altogether. However, the above example demonstrates that this may not currently be the most viable choice.²²² Another suggestion includes encouraging the agency to allow statements such as “rBST-free” without also requiring the disclosures about the FDA’s findings.²²³

A more ambitious solution would be to compel the agency to mandate labeling of milk from cows treated with rBST. Given the uncertainty for producers and manufacturers in the absence of uniform regulation addressing the issue, mandatory labeling could be less controversial than regulators fear. Contrary to its claims that it cannot require labeling based on consumer interest alone, the agency

217. Citizen Petition from Samuel S. Epstein, et al. to Mike Leavitt, Secretary of Health and Human Services (February 15, 2007), available at http://www.preventcancer.com/publications/pdf/FINAL_PET_withsig_may177.pdf (last visited September 1, 2011) (seeking the withdrawal of the new animal drug application approval for Posilac – Recombinant Bovine Growth Hormone).

218. Samuel S. Epstein, *The Dangers of Genetically Engineered Milk*, HUFFPOST (July 30, 2010, 8:00 AM), http://www.huffingtonpost.com/samuel-s-epstein/the-dangers-of-geneticall_b_633955.html.

219. *Id.*

220. See e.g., West Virginia Dep’t of Agric., *supra* note 204 (West Virginia’s requirement that any claims regarding the absence of rBST have to be verified through documentation and herd tracking.).

222. See Epstein, *supra* note 214, at 495.

223. McCabe, *supra* note 70, at 495.

currently requires food that has been irradiated to be labeled as such.²²⁴ While individuals have questioned the safety of ionizing radiation due to the chemical changes that can result from the process, the agency has determined the process is safe and helps to extend the shelf life of certain foods, while killing certain infestations.²²⁵ The agency notes that “like other forms of processing, irradiation can affect the characteristics of food.”²²⁶ Therefore, “[c]onsumer choice mandates that irradiated food be adequately labeled and under the general labeling requirements, it is necessary that the food processor inform the consumer that food has been irradiated.”²²⁷ Interestingly, the agency requires labeling in this instance despite the fact that it has deemed the process to be safe, and possesses information to suggest that consumers have a negative view of foods that have been irradiated due to their lack of information about the safety of the process.²²⁸

The decision in *Boggs*, coupled with the agency’s willingness to require labeling disclosing a process that can have a chemical impact on food, suggests the issue of mandatory milk labeling may again be ripe for review. The *Boggs* decision provides a framework by which advocates can petition the agency to stop milking their justification for failing to institute rulemaking, and demand the agency develop rules to mandate the labeling of milk from cows treated with rBST, based on the proven compositional difference between the two types of milk. Such a label could state, “this milk comes from cows that have been treated with rBST.” As a practical matter, requiring this label might not have an ill effect on the sale of conventional milk, as consumers who have no preference will likely make their purchase decision based on other factors.²²⁹ The *Boggs* decision provides support for this proposed label, as do as the agency’s requirements for labeling of irradiated foods.

224. Kim M. Morehouse & Vaneek Komolprasert, *Irradiation of Food and Packaging*, FDA.GOV, <http://www.fda.gov/Food/FoodIngredientsPackaging/IrradiatedFoodPackaging/ucm081050.htm> (last update May 4, 2009).

225. *Id.*

226. *Id.*

227. *Id.*

228. *Id.*

229. Donna M. Byrne, *Cloned Meat, Voluntary Food Labeling, and Organic Oreos*, 8 PIERCE L. REV. 31, 63 (2009).

If such an effort is unsuccessful, advocates can take some solace in the fact that, in the realm of milk and milk products, the market has already begun to respond even where the law has failed. Consumers have expressed a clear preference for products from cows that have not been treated with rBST, and suppliers are listening. For example, Wal-Mart recently issued a press release stating that the Great Value milk offered in its stores comes from cows that have not been treated with rBST because of the strong consumer desire for that option.²³¹ Commentators suggested that once Wal-Mart made this decision, the balance tipped in favor of “rBST-free” milk becoming the conventional choice.²³² Kroger food stores, along with many others nationwide, quickly followed suit by transitioning to certified rBST-free milk supplies citing consumer demand as the reason for the change.²³³ Ultimately, these examples suggest consumers tend to find ways to get the information they need about the foods they feed themselves and their children, and the increasing availability of rBST free products at conventional grocery and retail chains demonstrates their preferences may decide the issue if not by government regulation, than by market choice. Some suggest that one hundred

231. *Wal-Mart Offers Private Label Milk Produced Without Artificial Growth Hormone*, WAL-MART, <http://walmartstores.com/pressroom/news/8147.aspx> (last visited December 18, 2011) (“While the FDA has stated that milk from cows treated with rbST poses no risk to human health, many Wal-Mart customers have expressed a desire for milk choices. Today’s announcement is evidence that Wal-Mart is committed to keeping its product selection in line with what customers expect to find when shopping its stores. ‘We value our customers’ opinions and understand how important variety is in all aspects of the business,’ said Pam Kohn, senior vice president, general merchandise manager, Wal-Mart Stores, Inc. ‘We’ve listened to customers and are pleased that our suppliers are helping us offer Great Value milk from cows that are not treated with rbST.’”).

232. Janet MacFarland, *Wal-Mart Move Tipping Point for Driving Monsanto’s Bovine Growth Hormone Off the Market*, TORONTO GLOBE AND MAIL, Mar. 22, 2008, available at http://www.organicconsumers.org/articles/article_11050.cfm.

233. Kroger, *Kroger to Complete Transition to Certified rBST Free Milk By Early 2008*, THE KROGERCO.COM (Aug. 1, 2011) (“http://www.thekrogerco.com/corpnnews/corpnnewsinfo_pressreleases_08012007.htm (last visited September 30, 2011) (“For the past 10 years, Kroger has informed its raw milk suppliers that the Company prefers milk from cows that have not been given rBST, based on consumer preference.”); see e.g., Rick North, *Consumer Demand for rGBH-(rBST-) Free Dairy Products*, November 12, 2007, <http://www.responsibletechnology.org/docs/154.pdf> (citing a number of business leaders who began supplying rBST free dairy products because of increasing consumer demand).

years ago, the pure foods issue was an important one in the election of 1912.²³⁴ One hundred years later, the controversy surrounding the Obamas' decision to plant an organic garden at the White House suggests that perhaps it will be an issue that helps shape our nation's politics and policies going forward.²³⁶

234. Anderson, *supra* note 16, at 31.

236. See e.g., Crop Life, *Call to Action: A Letter Writing Campaign*, <http://www.croplife.com/article/601> (last visited January 1, 2012) (Urging citizens to write a letter to Michelle Obama to encourage her to use "crop protection products" keeping in mind the importance of conventional agriculture to our national economy).