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

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Abstract: The Sixth Circuit Court of Appeals’ recent decision in *International Dairy Foods Association v. Boggs*, while ultimately resulting in regulation pertaining to milk labeling that is similar to regulations in other states, provides a useful framework for challenging the Food and Drug Administration (FDA)’s contention that it lacks the authority to mandate labeling of milk from cattle that have been treated with the hormone rBST. The court in *Boggs* found that a compositional difference exists between milk from cows treated with the hormone and those that were not, which could be considered a material fact mandating labeling under the Food, Drug, and Cosmetic Act. This Article discusses the history of the FDA’s statutory authority to regulate food products, as well as considers the Act’s purposes with respect to labeling, and the agency’s interpretation of that grant of authority. The Article then discusses the FDA’s controversial approval of rBST and the resulting challenge to that decision. The article concludes by discussing how the decision in *Boggs* can be instrumental in requiring 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.
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Introduction:

The United States is currently in the throes of a large scale, social movement that many commentators deem a “food revolution,” 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. Moreover, consumers are thirsting for access to increased information about the life cycles of the food they consume. The reasons for this re-evolution are many: rational fears about future and, in many instances, yet unknown, effects of biotechnology coexist with, and are often compounded by, concerns over animal health, safety, and welfare, and the resulting impacts on the 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. 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.

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. Last September, 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 treated with rBST and milk from cows that were not. 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. Given the recognized composition difference in the two types of milk, the agency’s failure

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2 This term can be attributed, in part, to Jamie Oliver, the activist chef attempting to improve the health of our youth.

to do so makes any label without such disclosures misleading under the Food, Drug and Cosmetic Act.

Part I of this article will provide 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 consider the agency’s interpretation of that grant of authority. Part II of the article will discuss the FDA’s approval of rBST and the resulting challenge to that decision. In Part III, the article will provide 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 of this article demonstrates how the recent decision in *International Dairy Foods Association v. Boggs* can be instrumental in requiring 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.” Initially, the agency was formed as part of the Bureau of Chemistry, but first came into existence in its modern day incarnation with the passage of the Federal Foods and Drugs Act, as the law created the agency’s regulatory functions. After many unsuccessful attempts at passage of 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. With regard to drugs, the law both created and defined very specific standards, which were not also outlined for food products, but the Act 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.”

In the early years, the agency’s main emphasis was the regulation of food rather than drugs because Harvey W. Wiley, the agency’s chief administrator, a chemist, and longtime champion of pure foods, found that foods posed a greater risk to human health than drugs as he determined that most chemical additives were “unnecessary adulterants.” To test his theories about the dangers of specific food additives and preservatives frequently used in the early 1900s, Wiley received government funding to conduct a series of experiments. He assembled a group of young men, given the nomenclature the “Poison Squad” by journalists covering the trials, and fed them meals composed of the best quality ingredients prepared “in the most appetizing and

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5 Food and Drug Administration, History, <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> (last visited September 1, 2011).
[http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm](http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm) (last visited September 1, 2011).
7 Id.
8 Id.
9 Id.
hygienic fashion"¹⁰ that were also laced with measured amounts of suspect preservatives and additives customarily used by domestic and foreign food producers.

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 on the system was…mildly injurious or deadly, according to the amount and character of the preservatives absorbed.”¹¹ The Poison Squad experiments greatly influenced Wiley’s opinions about the need for strict regulation of chemical additives and preservatives in food products, hence his heavy emphasis on this issue during his tenure as the chief administrator. 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. This difference of opinion between Wiley and the Administration ultimately led to Wiley’s resignation from the agency in 1912.¹²

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,¹³ 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.¹⁴ In response to the argument that the agency was overstepping its statutory grant of authority and creating greater requirements under the law than those provided by Congress, 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 [sic] it.”¹⁵ 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 are fully aware of the ingredients included in their products, and greater disclosure was in the best interest of the public health.¹⁶

A decade later, the Court considered a misbranding case involving a product labeled and marketed as apple cider vinegar that was made from dehydrated apples which, during the manufacturing process, were rehydrated with water in substantially the same amount as that removed in the dehydration process.¹⁷ While the resulting product contained very small amounts of barium, resulting from the manufacturing process, no claims were made that this substance was injurious to or presented a threat to public health.¹⁸ Additionally, none of the parties suggested that the cider produced was of inferior quality or taste, although the district judge did

¹¹ Id.
¹² Id.
¹⁴ Id.
¹⁵ Id.
¹⁶ Id.
¹⁸ Id. at 441.
note a slight difference in both taste and appearance. Ultimately, the Court found that even though the resulting product was similar, if not virtually identical, to apple cider vinegar made from fresh apples, the addition of the water created a different product entirely, which caused the product to be misbranded as it was not “the identical thing that the brand indicates it to be.” Therefore, while the statements on the label were technically correct, the Court found them misleading to consumers. 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 disclosures regarding those processes were not required under the law. Rather, the 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 the compositional difference in substance and ingredients.

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 failed to include full disclosures regarding the specific ingredients. As the cases note, 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 products they were purchasing. Part of the reasoning 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. However, these laudable goals to protect and inform consumers coexisted with increasing public and governmental support for advances in science and technology to increase the life cycles of food and prevent spoilage and enhance flavor.

The support for scientific and technological advances in food production and the limits on the agency’s power under the statute in this respect was evidenced in cases decided by the Court during the same period as the misbranding cases. In contrast to the broader authority held by the agency in the misbranding cases, when considering the provision of the statute pertaining to adulterated foods, 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.” Relying again on the plain language of the statute, the Court opined that Congress was clear in its directive regarding chemical additives, and specifically included language that intended to allow

19 Id. at 443.
20 Id. at 444.
21 Id. at 445.
22 Id.
23 Pure Food and Drugs Act § 8 (1906) (current version at 21 U.S.C. § 431(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.).
24 Id. at § 7.
25 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 purport ed 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 injury by adding to articles of food consumption poisonous and deleterious substances which might render such articles injurious to the health of consumers.”).
producers and manufacturers to include “poisonous or other added deleterious ingredient[s]” to their products so long as they were not injurious to the public health.\(^{26}\) 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.\(^{27}\) The *Lexington Mill* decision left room for the argument that the additive may have some injurious effect rather than requiring a showing that the additive actually did cause some sort of injury to health. However, the legislative support for making this claim in all instances where a producer or manufacturer used what the agency deemed a poison in the manufacturing process did not exist. 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 what were then considered advances in food production, which has endured for many decades.

**B. The Federal Food, Drug and Cosmetic Act of 1938\(^ {28}\)**

While the Food and Drugs Act of 1906 persisted for many years, mounting concerns over the limited authority of the agency, as well as the inability of the Act to address unregulated and emerging risks with respect to food and drug safety, in addition to the expanding field of cosmetics led to the drafting of the Food, Drug and Cosmetic Act of 1938. The proposed Act was much stronger in the sense that it gave the agency greater enforcement authority and the ability to set standards for the identity and quality of food products. This was a critical addition as it created enforceable, legal standards that the government could use in misbranding and adulteration cases. Additionally, the FDCA did not appear to interfere with the states’ ability to continue to regulate food products within their borders even where the states’ laws might have affected interstate commerce except for those situations where the laws conflicted or where Congress created a system of “thorough regulation”\(^ {29}\) for a specific product.

The specific provisions within the Act regarding misbranding have not been amended since passage of the 1938 Act and largely reflect the same principles, if not similar language, to the provisions included in the 1906 Act. Following the reasoning from the Court’s decision in the *Ninety-Five Barrels* case, the courts considering misbranding cases under the new Act held that labels including disclaimers regarding misleading statements did not cure the misbranding,\(^ {30}\) as courts would consider the permissibility of the language in light of “the probable inference a

\(^{26}\) *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.”).

\(^{27}\) *Id.* at 411-412 ("although 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.'").

\(^{28}\) 21 U.S.C. § 301 et al.


\(^{30}\) *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)).
consumer might draw from it.\textsuperscript{31} Moreover, the Supreme Court held that the new version of the Act was Congress’ attempt to further strengthen its ability to regulate and control harmful food and drugs in commerce.\textsuperscript{32} Specifically, the Act was meant to “touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.”\textsuperscript{33} 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.\textsuperscript{34}

1. The Agency’s Interpretations of the Act

With respect to this line of reasoning, the current FDA generally follows the same logic. In other words, the agency remains concerned about misbranding and the potential for consumer confusion or deception. However, rather than regulating 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 in the sense that it suggests a superior product. Consequently, where the agency used to require manufacturers to disclose more, it has moved away from this approach in many respects. For those producers who voluntarily choose to disclose that they have not used certain processes or included certain additives that might be considered harmful, the agency now attempts to regulate those statements under the guise of consumer deception. 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” labeling.\textsuperscript{35} 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.”\textsuperscript{36} In other words, the FDA’s interpretation of the FDCA is that it 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 currently approaches these requirements very differently than it did in the early years of regulation. Specifically, the agency appears to have adopted a position

\textsuperscript{31} Id. (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).

\textsuperscript{32} United States v. Dotterweich, 320 U.S. 277 (1943).

\textsuperscript{33} Id. at 280.


\textsuperscript{35} 21 U.S.C. §343(a)(1).

\textsuperscript{36} 21 U.S.C. §321(n).
that tends to favor industry rather than full disclosure aimed at consumer protection and access to information. Despite mounting public concern over genetically engineered food, and consumer requests for greater efforts on the part of the FDA to require mandatory disclosure labeling, the agency consistently states it lacks authority under the FDCA to require specific labeling of food products based on consumer interest alone. Moreover, with regard to voluntary labeling, in its guidance, the agency suggests that producers and manufacturers should be careful in their statements about the production of food so that they do not mislead or confuse consumers into thinking the product is superior to a similar or identical product that has been processed differently. 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” and one that can “effectively reduce the environmental impact of dairy operations,” rBST has been the subject of intense scrutiny since Monsanto’s application for FDA approval of the supplement in 1987. Posilac®, or Monsanto’s commercial version of recombinant bovine somatotropin (rBST) is a genetically engineered “supplement of the naturally occurring cow hormone BST, that when administered to cows allows them to produce more milk.” Its natural counterpart, bovine somatotropin (BST) is produced in the pituitary glands of mature cows to control their lactation cycles.

Since the 1930s, scientists have been aware that the injection of BST had the potential to result in increased milk production after British scientists injected BST taken from deceased cows into living ones. On a commercial scale, this process is largely inefficient due to the inadequacy of the small quantities that can reasonably be extracted from each carcass to meet the massive demand. However, the introduction of recombinant DNA techniques in the 1980s allowed for a procedure that could mimic that attempted in the 1930s due to the development of rBST, which was able to be produced inexpensively on a large scale.

37 Food and Drug Administration, Background Document: Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon Food and Drug Administration, August 2010, at 6.
39 Id.
44 Id.; Burk, supra note 35, at 231.
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” pending completion of its full investigative process, but allowed milk and beef products from cows treated with the hormone to be sold and consumed pending approval. 46 Following this preliminary approval, the General Accounting Office was asked to take a look at the agency’s investigational review of Monsanto’s application to determine whether the agency had, in fact, conducted a thorough investigation. 47 As part of its review process, the FDA required Monsanto to perform studies assessing whether rBST was biologically absorbed into the body, which could have required additional studies to determine its potential impact of bodily organs, and, specifically, the liver. 48 To complete this study, Monsanto administered the hormone orally to rats over a twenty-eight (28) day period at 100 times the dose approved for administration to dairy cows. 49 Based on the results of this limited study, the FDA determined that the findings did not demonstrate absorption of biologically active rBST. 50 This finding was later substantiated by the expert panel retained for the preparation of the GAO Report. 51

In most respects, the GAO’s expert panel supported the findings of the FDA with one critical exception. Specifically, the GAO 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. 52 In making this conclusion, the GAO focused on the increased risk for cattle treated with rBST to develop mastitis, an infection of the udder, often treated by antibiotics that can remain in milk in trace amounts. 53 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. 54

47 Id.
48 Id.
49 Food and Drug Administration, Report on the Food and Drug Administration’s Review of the Safety of Recombinant Bovine Somatotropin, http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm130321.htm (last visited September 1, 2011) (the FDA updated this study in response to the report issued by Health Canada, the Canadian counterpart to the FDA, which was prepared by the Royal College of Physicians and Surgeons of Canada).
49 Id.
50 Id.
51 GAO, supra note 43, at 6.
52 Id. at 6.
53 Id. at 9.
54 Id. (citing General Accounting Office, Food Safety and Quality: FDA Surveys Not Adequate to Demonstrate Safety of Milk Supply, November 1, 1990). The GAO panel’s concerns with regard to the agency’s inadequate surveys were not unfounded. See Philip James Kijak, FDA Validates Rapid Screening Tests for Antibiotics in Milk, FDA Veterinarian Newsletter July/August 2004 Volume XIX, No IV, available at http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm093812.htm (“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
Interestingly, the GAO report also raised concerns about the FDA’s unwillingness to label food products derived from animals treated with investigational drugs. 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. The agency largely agreed with the findings of the GAO report, however, 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.”

C. FDA Approval of rBST and the Resulting Challenges

Despite concerns over the safety of rBST for both animals and humans, in 1993, the FDA approved the use of the artificial hormone, finding 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.” Moreover, the agency determined “there was no significant difference between milk from treated and untreated cows.” Consequently, the agency issued guidance to the industry stating that because it did not find a compositional difference existed in the two types of milk, it was unable to require mandatory labeling of milk from cows treated with rBST.

Moreover, with regard to statements about the absence of hormones, or the absence of rBST in particular, the FDA issued guidance advising 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. In other words, the FDA encouraged manufacturers and producers to ensure their statements did not imply or lead consumers to draw the inference that milk from cows not treated with rBST was not of a superior quality given their findings.

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, as a Canadian report prepared for Health Canada (the Canadian counterpart to the FDA) 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.
In the Canadian report, the panel made several findings that were also addressed by the GAO panel and continue to spark debate in the battle over the safety of rBST. Specifically, that panel found that Monsanto’s ninety (90) day rat study demonstrated an antibody response to rBST leaving open the question of a hypersensitivity response in humans. Additionally, as noted by both the FDA and the GAO report, the concentration of Insulin-like Growth Factor 1 (“IGF-1”) is increased in milk from cows treated with rBST, the complete effects of which were then unclear, but in the panel’s opinion, could potentially result in an increased risk of cancer for specific individuals. The Canadian panel also expressed consternation over the increased risk for cattle treated with rBST to develop mastitis for the same reasons cited in the GAO report. Based on its findings, the panel concluded that Health Canada had enough information to make a decision about whether it should 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.” Ultimately, Health Canada chose not to approve Monsanto’s application.

1. **Stauber v. Shalala**

The case the FDA uses 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 warrants some discussion, as the FDA continues to publicly rely on the holding as a limit to its authority in this context. In *Stauber v.*

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64 Report of the Royal College of Physicians and Surgeons of Canada – Expert Panel on Human Safety of rBST, January 1999, available at http://www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/rbst-stbr/rep_rcpsc-rapcrmcc_final-a-eng.php#hebfp (last visited September 1, 2011) (“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.”)
65 Id.
66 Id.
67 Id.; see also Food and Drug Administration, Evaluation and Use of Antimicrobial Drug Screening Tests, http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/CodedMemoranda/MemorandaofInformation/ucm082165.htm (last visited September 1, 2011) (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.).
68 Id.
70 Food and Drug Administration, Background Document: Public Hearing on the Labeling of Food Made from the AquaAdvantage Salmon (August 2010), available at http://www.fda.gov/downloads/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/UCM223913.pdf (“Fifth, FDA cannot require additional labeling about production methods unless it is necessary to ensure that the labeling 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.”) (citing 72 Fed. Reg. 16291,
Shalala, 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, M.D., then Commissioner of the Food and Drug Administration. 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, who were 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” about the differences in the milk.

The plaintiffs advanced two theories to support their argument that the FDA was mandated by law to require labeling of milk from cows treated with rBST. First, milk produced from cows that have been treated with rBST is “organoleptically” different from milk produced from non-rBST treated cows. Second, the “widespread consumer desire for mandatory labeling of rBST-derived milk” evidenced a degree of demand which, in turn, amounted to a material fact triggering the labeling requirements under the FDCA. Under section 201(n) of the FDCA, “[i]nformation disclosing differences in performance characteristics (e.g., physical properties, flavor characteristics, functional properties 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.” 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).

The evidence submitted by the plaintiffs to substantiate their claims that rBST has a negative impact on human health was presented 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 in this proceeding as they were outside the record before the agency. The court noted that the plaintiffs also relied on an affidavit from Dr. Richard Burroughs, who was a


71Stauber 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.).

72Id. at 1182.
73Id. at 1193.
74Id.
75Id.
76Id. Section 403(a) provides: “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).”
77Id. 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 also Marden, supra note 40, at 634 (Marden suggests 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).

78Burroughs 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
veterinary medical officer for the FDA that participated in the review process for Posilac®. In the court’s opinion, because the plaintiffs relied on this affidavit only to support the proposition that rBST can have serious negative health consequences for cows, the court considered it only in that regard and accepted those facts as undisputed. However, Dr. Burroughs’ affidavit also cited several critical flaws in the agency’s review of the drug, in addition to concerns about Monsanto’s testing processes. While this information could have been useful to clarify the record before the agency or to illuminate the agency’s decisionmaking process and help the court determine whether the resulting decision was arbitrary and capricious, the court stated it could not consider the affidavit in that light, as it was not proffered for that purpose.

While sympathetic to the issues raised by the plaintiffs, the court deferred to the findings of the agency regarding the safety of rBST, holding its decision to approve the hormone was not arbitrary and capricious. The court then went on to analyze the issue of mandatory labeling under the FDCA. Addressing plaintiff’s arguments that the milk from cows injected with rBST differs organoleptically from that of cows not treated with rBST, the court found that plaintiffs failed to point to evidence in the record proving that the two types of milk differ in terms of performance characteristics or organoleptic properties. Specifically, the plaintiffs did not demonstrate that the administration of rBST has an impact on the composition of milk.

The plaintiffs also argued that widespread consumer demand for labeling information about milk from cows treated with rBST necessitates mandatory labeling under the Act. However, the FDA only considers consumer demand when making a determination about disclosures of material facts on labels when it has determined that the product is different than what it says it is and that difference is something about which consumers would want to know. Therefore, even if consumers viewed the product as different, the FDA could not require labeling unless a material difference exists between the two products or it would risk running afoul of the FDCA. In Stauber, the 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,” therefore, a label stating the milk was derived from cows treated with rBST would constitute misbranding under the Act.

In some respects, the Stauber decision does not seem to reflect a departure from the original cases interpreting the misbranding provisions of the Act. The court deferred to the agency’s decision not to require labeling, based on its finding that no material difference existed.

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80 **Stauber, supra** note 76, at 1190.
81 *Id.*
82 *Id.*
83 *Id.* (citing *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420-421 (1971)).
84 *Id.* at 1192.
85 *Id.* at 1193.
86 *Id.*
87 *Id.*
88 *Id.*
89 *Id.*
between milk from cows treated with rBST and those that were not. 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 offered for sale within the State that were derived from cattle treated with rBST. The legislature cited “strong consumer interest” and the “public’s ‘right to know’” as the bases for the law. The plaintiffs, 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. Ultimately, the Second Circuit Court of Appeals decided the case on First Amendment grounds and did not reach the Commerce Clause issues.

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.

The court also determined that plaintiffs successfully demonstrated they would likely be successful on the merits. Using the four part test articulated in Central Hudson, 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

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90 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, supra note 76, at 1193).

91 6 V.S.A. § 6754 (“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.”)


94 Id.

95 Id. at 72 (citing International Dairy, supra note 96, at 251-252; Paulsen v. County of Nassau, 925 F.2d 65, 68 (2d Cir.1991)).

96 Id.

extensive than necessary. 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 the State did not "claim that health or safety concerns prompted the passage of the Vermont Labeling Law," rather, it cited consumer interest and the public right to know. In the court’s opinion, these interests were not sufficient to deprive the plaintiffs of their First Amendment rights.

Following the same reasoning as Stauber, 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 they have no discernable impact on the final product. Specifically, because the FDA determined rBST has no "appreciable effect on the composition of milk produced by treated cows," the requirement that manufacturers disclose whether their cattle have been treated with the drug has no discernable connection to public health, safety, and welfare. Even where the statement on a label is factually accurate and truthful, unless the State can demonstrate the warning is necessary to prevent harm, deception, or confusion, it cannot be sustained under the First Amendment.

While the State of Vermont attempted to provide more information to consumers by mandating labeling where the FDA failed to, other states enacted labeling laws addressing voluntary labeling standards according to the guidance set forth by the agency. One state went so far as prohibiting any labeling including terms such as “rBST free,” or “rBGH-free,” due to the potential for confusion among consumers.

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. The Governor, Ted Strickland, responded to these measures by issuing an executive order directing the Ohio Department of Agriculture (“ODA”) to “define

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98 Int'l Dairy Foods, supra note 97 (citing Central Hudson, supra note 99).
99 Id.
100 Id. at 73.
101 Stauber, supra note 76
102 Int'l Dairy Foods, supra note 97.
103 Id.
104 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)).
what constitutes false and misleading labels on milk and milk products.”

Following this directive, the ODA issued a proposed rule that aimed to restrict the types of comments dairy processors could include on their products. 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. 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 proposed rule.” Despite the tremendously negative public response, ODA Director, Robert Boggs, adopted the rule in May 2008.

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. The plaintiffs moved for a preliminary injunction; thereafter, both parties sought summary judgment on all issues with the exception of an equal protection claim. In response, the district court granted summary judgment in favor of the State on virtually every claim except that pertaining to the rule’s restrictions on production claims, on which it granted partial summary judgment. Because of those rulings, the court found the plaintiffs could not demonstrate that they were likely to prevail on the merits and denied the motion requesting a preliminary injunction. The plaintiffs then took an interlocutory appeal of only the First Amendment and Commerce Clause claims.

1. First Amendment Challenge to Restriction on Composition Claims

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 Food and Drug Administration 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.

1 Boggs, supra note 4 at 634 (citing Ohio Governor Executive Order 2008-03S (Feb. 7 2008)).
10 Id.
109 Id.
110 Id.
111 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.”

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12 Boggs, supra note 4 at 634.
13 Id.
14 Id. at 635.
15 Id.
16 Id.
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. 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, the court held the rule was more extensive than necessary to meet the State’s interest in preventing consumer confusion or deception.\(^{117}\)

### a. Inherently Misleading

When considering the argument that the composition claims were inherently misleading, the court noted that “where speech is only potentially misleading….the preferred remedy is more disclosure rather than less.”\(^{118}\) While 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 appeals found the record told a different story.\(^{119}\) 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.’)\(^{120}\)

To make this finding, the appellate court considered additional scientific information outside the scope of the FDA’s record, which was a different approach than that taken by the district court.\(^{121}\) In its opinion, the district court noted that it held a conference on the preliminary injunction request at the start of the case.\(^{122}\) During the conference, the court asked the parties what evidence they intended to present in support of their claims.\(^{123}\) According to the district court, the Director of ODA suggested they might need an expert witness to testify about the science behind rBST and the plaintiffs disagreed, claiming the issues were “largely legal,” leading the court to the conclusion that the parties did not dispute the FDA’s findings regarding rBST.\(^{124}\) Rather than strictly relying on the FDA’s findings regarding the science of rBST, the appellate court reviewed the evidence submitted by the amici curiae to make several findings relevant to the First Amendment challenge.\(^{125}\)

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.\(^{126}\) Second, cattle treated with rBST are induced to produce milk during their “negative energy phase” when they would not normally produce milk, which causes that milk to be of lower quality due to “increased fat

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\(^{117}\) *Id.* at 639 (citing *Central Hudson, supra* note 102).

\(^{118}\) *Id.* at 636 (citing *Central Hudson, supra* note 102, at 203; *Bates, supra* note 109, at 374-375 (“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’”)).

\(^{119}\) *Id.*

\(^{120}\) *Id.*

\(^{121}\) *Id.*


\(^{123}\) *Id.*

\(^{124}\) Id. (citing Case no. 2:08-cv-628, Doc. 19, p.32).

\(^{125}\) *Boggs, supra* note 4, at 636.

\(^{126}\) *Id.*
content” and “decreased levels of proteins.”

Similarly, milk from cattle treated with rBST has a higher somatic cell count, which can cause the milk to turn sour more quickly than milk from untreated cows. Additionally, “and more salient to the regulation of composition claims like ‘rBST-free,’” 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, thus far, not been able to develop a test to accurately detect its presence. The court finds the FDA’s statement that it found “no significant difference” compelling, as it suggested the agency left room for the finding that “some compositional difference between the two types of milk may exist.”

Considered collectively, the appellate court held that the evidence proved there were, in fact, “two distinct types of milk.” The first type of milk comes from cattle not treated with rBST, meaning the milk can never contain the hormone. 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 or does not. Therefore, because a compositional difference exists between these two types of milk, as 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. 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.”

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 substantial. The State’s asserted interest in drafting the rule was “to prevent the use of ‘false or misleading’ labeling.” While the plaintiffs agreed this was a substantial interest, because the rule is 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.” 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. The FDA Guidance did not provide any supporting evidence to demonstrate a real harm of consumer deception.

127 Id. at 636-637.
128 Id. at 637.
129 Id.
130 Id.
131 Id.
132 Id.
133 Id.
134 Id.
135 Id.
136 Id. at 638 (citing Ohio Admin. Code, §901:11-9-01(A).
137 Id. (citing Ibanez v. Fla. Dep’t of Bus. And Prof’l Regulation, Bd. Of Accountancy, 512 U.S. 136, 146 (1994) (citation omitted)).
138 Id.
139 Id.
Additionally, the public comments from consumers in response to the proposed rule demonstrated some consumer confusion regarding the presence of rBST in conventional milk, but the confusion was not the result of product labels, and appeared to originate from outside information. 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.”

2. First Amendment Challenge to Disclosures for Production Claims

The court next addressed the production claims such as, “this milk is from cows not supplemented with rBST.” 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. Moreover, the 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.

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, which considered disclosure requirements and did not apply the same strict standard as Central Hudson. The court was unconvinced by this argument, holding that Zauderer provided the appropriate standard, as it applied to speech that was inherently misleading, which the court concluded also controlled speech that was only potentially misleading.

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.” The plaintiffs argued that the State failed to demonstrate the production claims were deceptive or confusing to consumers. However, 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. The court found this evidence, weak as it was, provided some indication that claims about production can be confusing to consumers in Ohio, at least, who seemed unclear about the presence or absence of rBST in the milk they purchase.

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 rationally related to the State’s interest. The State was particularly concerned over the use of asterisks next to the

\[140\text{Id. at 639.}\]
\[141\text{Id.}\]
\[142\text{Id.}\]
\[143\text{Id. at 640 (citing Ohio Admin. Code § 901:11-8-01(B)(2)).}\]
\[144\text{Id.}\]
\[145\text{471 U.S. 626 (1985).}\]
\[146\text{Id.}\]
\[147\text{Id. (citing Zauderer, supra note 150, at 651).}\]
\[148\text{Id. at 642.}\]
\[149\text{Id.}\]
\[150\text{Id.}\]
\[151\text{Id.}\]
disclosure statements, as it asserted, without supporting evidence, that asterisks have caused problems in the past.\textsuperscript{152}

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.\textsuperscript{153} However, in the absence of the restrictions on composition claims and asterisks, the Ohio rule closely resembles the labeling regulations in other states.

B. Conclusion

Critics of the decision in \textit{Boggs} suggest that the end result is the creation of a state regulation in Ohio to address milk labeling that is not significantly different from regulations in other states. However, the decision in \textit{Boggs} arguably represents a dramatic departure from the cases addressing milk labeling up to this point. 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,”\textsuperscript{154} the court in \textit{Boggs} considered scientific evidence outside the record before the agency when it initially approved the drug.\textsuperscript{155} 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.\textsuperscript{156} Beyond the fact that no court has either looked outside the record before the agency or made the determination that a compositional difference between the two types of milk exists, what is perhaps most compelling about the court’s decision is its reliance on the agency’s language regarding its own findings, suggesting there is not a \textit{significant} difference between the two types of milk.\textsuperscript{157} 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.\textsuperscript{158} Following this line of reasoning, the court went on to suggest that because the agency currently does not have a test to determine whether milk from cows treated with rBST may contain the hormone in trace amounts, the possibility that it might is too significant to be ignored.\textsuperscript{159} Therefore, 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 agency 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.\textsuperscript{160} Arguably, the \textit{Boggs} decision provides yet another example of a federal court’s
unwillingness to simply accept, as true, the agency’s determination about the effects of a particular drug it approved almost a decade ago. The court’s findings regarding the effects of rBST on human and animal health, as well as milk quality, reflect what could be seen as a distrust of the agency’s own limited findings. Despite numerous petitions and requests 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. The most recent petition was filed on February 15, 2007, 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. According to Samuel S. Epstein, one of the authors of the opinion, the FDA did not respond to, nor did it acknowledge this petition. The petitioners resubmitted their request for suspension of approval of the drug on January 12, 2010, and the Commissioner dismissed it on procedural grounds.

While there are numerous options available to those seeking labeling of milk from cows treated with rBST that have been unsuccessful to date, the Boggs decision at least affirms producers’ rights to make claims 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 requirements are too onerous. One suggested solution from commentators is to urge the agency to ban the drug altogether. However, as seen from the example above, this does not appear to be the most viable choice at this point. Another suggestion includes encouraging the agency to allow statements such as “rBST free” without also requiring the disclosures about the FDA’s findings.

A more ambitious solution would be to compel the agency to mandate labeling of milk from cows treated with rBST. Contrary to its claims that it cannot require labeling based on consumer interest alone, the agency currently requires food that has been irradiated to be labeled as such. 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. The agency has noted that “like other forms of processing, irradiation can affect the characteristics of food.” 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

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.”.

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162 Id.

163 McCabe, supra note 40, at 495.


165 Id.

166 Id.

167 Id.
food has been irradiated.” Interestingly, the agency requires labeling in this instance despite the fact that it has deemed the process to be safe, and even though they have information to suggest that consumers have a negative view of foods that have been irradiated because of their lack of information. Using the decision in Boggs, coupled with the agency’s willingness to require labeling where the process can have a chemical impact on the food, which consumers would likely want to know, perhaps the time has come to again challenge the agency and require it mandate labeling of milk from cows treated with rBST based on material facts that demonstrate a compositional difference exists 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 one way or the other will likely make their purchase decision based on price or some other feature they find important. This attempt is supported by the holding in Boggs, as well as the agency’s requirements for labeling of other foods that are similarly processed.

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, as consumers have expressed a clear preference for products from cows that have not been treated with rBST. 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. Commentators suggested that once Wal-Mart made this decision, the balance tipped in favor of “rBST-free” milk becoming the conventional choice. In the end, it appears consumers no longer rely exclusively or even extensively on the Food and Drug Administration to protect the health and safety of their food supply, as they did in the early years of regulation since the agency is no longer viewed as the protector of consumers over industry. Ultimately, most consumers will find ways to get the information they need about the foods they feed themselves and their children, and their preferences will decide the issue whether it be through labeling or market choice.

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168 Id.
169 Id.
170 Donna M. Byrne, Cloned Meat, Voluntary Food Labeling, and Organic Oreos, 8 Pierce L. Rev. 31, 63 (2009).
171 Wal-Mart, Wal-Mart Offers Private Label Milk Produced Without Artificial Growth Hormone, http://walmartstores.com/pressroom/news/8147.aspx (“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.’”).