RBST, It Does a Body Good: RBST Labeling and the Federal Denial of Consumers' Right to Know

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II. INTRODUCTION

For more than a decade, a cloud of skepticism has loomed over the Food and Drug Administration’s (FDA) approval of Recombinant Bovine Growth Hormone\(^1\) (rBGH) for use on dairy cattle. The Monsanto Corporation is the sole producer of rBGH.\(^2\) Studies, wholly sponsored by Monsanto, were the basis of the FDA’s decision to approve the commercial use of rBGH, despite mounting evidence of serious adverse effects in humans.\(^3\) The FDA found it did not have authority under the Food, Drug, and Cosmetic Act (FDCA) to require labeling of milk derived from treated cows.\(^4\) However, the FDA did

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\(^1\) Recombinant Bovine Somatotropin (rBST) and Recombinant Bovine Growth hormone (rBGH) refer to the same hormone and will be used interchangeably throughout this comment.


\(^3\) SAMUEL S. EPSTEIN, WHAT’S IN YOUR MILK?: AN EXPOSE OF INDUSTRY AND GOVERNMENT COVER-UP ON THE DANGERS OF THE GENETICALLY ENGINEEREED (rBGH) MILK YOU’RE DRINKING 5 (Trafford Publishing 2006).

release suggested guidelines for states to follow when enacting and interpreting statutes related to labeling of milk and milk related products.5

Currently, states maintain their traditional role as regulators of milk within their jurisdiction,6 but with some Monsanto-imposed limitations.7 State attempts to implement mandatory labeling schemes have come under constitutional attack and have been largely unsuccessful.8 State voluntary labeling laws have been upheld in the courts, although several state-approved labels have been modified after aggressive attacks on their legality by Monsanto.9 The FDA suggested that states permitting farmers to voluntarily label milk as “rBST-free” also disclose that the FDA concluded there are no detectable differences between milk from treated and untreated cows.10 Monsanto has successfully lobbied for the mandatory inclusion of this tag line.11

The current labeling structure of milk and milk products derived from rBST treated cows is inadequate and misleading. The FDA has ignored evidence of health risks associated with the use of this synthetic growth hormone12 and consumers are unknowingly forced to do the same. For a decade, mandatory labeling has been prohibited because Monsanto’s scientific reports, which did not include long-term testing,13 indicated no substantial difference between milk

5. See id. at 6280.
6. See id.
10. See Interim Guidance, supra note 4, at 6280.
11. See infra Part IV.B.
from treated and untreated cows.\textsuperscript{14} Like many FDA approved drugs,\textsuperscript{15} studies show serious risks associated with the use of rBST.\textsuperscript{16} Short of recalling the drug altogether, the Federal Government should amend the FDCA\textsuperscript{17} to mandate labeling of rBST milk, to protect the health and safety of our nation.

This comment challenges the federal government’s refusal to require labels on products that alert the consumer that cows treated with synthetic bovine growth hormones are the source of the product. Part II of this comment begins with an explanation of rBST and how rBST affects humans that consume milk from cows treated with rBST. A look into the FDA’s approval of rBST and the role that the sole manufacturer of rBST played in its approval is also discussed. Part II concludes with a look at the current Federal law, and the challenges brought to courts by farmers, consumers, and the manufacturer of rBST.

Part III identifies the problem as the federal government’s refusal to find that is has authority under the FDCA and the United States Constitution, to mandate farmers’ use of truthful labels on all milk from cows treated with rBST. Lastly, in Part V this comment discusses three possible alternatives to permit manufacturers and producers to inform consumers of the risks associated with rBST.

II. BACKGROUND

In order to understand the gravity of the rBST-labeling dilemma, four foundational elements must first be explored. First, the development of rBST, what it is, and why dairy farmer’s use it. Next, the effects that rBST has on both treated cows and humans that consume products originating from cows treated with rBST. Third, information about corporate giant Monsanto and its ties to the FDA as well as other powerful politicians. Finally, the FDA’s purported reasons for its decision not to require labels on those products

\textsuperscript{14} Id. at 1186.


\textsuperscript{16} See infra Part II.B.1-2.

originating from cows treated with rBST and consumer's reaction to the FDA's choice.

A. What is rBGH?

Bovine growth hormone (BGH), also known as bovine somatotropin (BST), is a naturally occurring protein hormone produced in the pituitary gland that supports the growth and lactation of dairy cows. In the 1980's, through recombinant DNA biotechnology, scientists developed rBST, a synthetic version of the naturally occurring BST hormone. Simply put, the BST gene is first isolated, and then inserted into the genomes of bacteria, which rapidly reproduce the hormone. The hormones are then harvested and administered intravenously to cows. Similar to insulin, rBST is a protein hormone, meaning it has no effect if taken orally; therefore, it must be injected directly into the cow’s bloodstream. Once injected, rBST is carried to the cow's liver where it stimulates production of Insulin-like Growth Factor (IGF-1), which then stimulates milk production.

In November 1993, the FDA approved the commercial sale and distribution of rBGH to begin in 1994. Although four major United States corporations were developing the artificial hormone throughout the 1980s, Monsanto's product was the only version approved. To this day, Monsanto maintains a monopoly as the sole producer of

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19. Id.
23. Id.
24. Id.
25. Id.
27. Emily Marden, Comment, In Search of Justice, 46 DRAKE L. REV. 617, 621 (1998). The four corporations vying for a marketable version of rBST were Monsanto, American Cyanamid, Upjohn and Eli Lilly. Id.
28. Id.
rBGH.  

When dairy farmers supplement the amount of naturally occurring BST with Monsanto’s rBST, distributed under the name “Posilac,” the result is a ten to twenty percent increase in milk production.  rBGH is administered to approximately one-third of dairy herds in the United States.  Dean Foods, the largest milk producer in the United States, reported that only ten percent of its milk processing plants offers milk from untreated cows, although it is gradually moving in the direction of being hormone free.  While Monsanto and the FDA continue to deny any adverse affects associated with use of rBST, consumers and researchers persist in challenging the truth of rBST proponents’ claims.

B. Effects of rBST

There are over twenty toxic effects to cows caused by the use of rBST.  Two, mastitis and increased levels of IGF-1,  

30. Executive Branch Study, supra note 18.
32. Id.
33. Id.
34. See Monsanto, Focus on Posilac, http://www.monsanto.com/posilac/default.asp. Monsanto’s website claims rBST “safely enhances milk production . . . . Milk from cows receiving supplemental bST [rBST] is unchanged and just as wholesome and nutritious as always . . . . levels of bST in milk remain the same.”  Id. The FDA claimed it “found no pertinent information” on risks associated with rBST. EPSTEIN, supra note 3, at 214.

Meanwhile, farmers only seem to care about their bottomline. Monsanto, See What Farmers are Saying About Posilac®, http://www.monsantodairy.com/farmer/index.html (providing examples of farmers’ thoughts on Posilac, such as “If Posilac wasn’t profitable, we wouldn’t be using it;” “I use Posilac because it makes me money;” and “We’ve kept cows in our herd making money that would have been sold without Posilac.”).

35. EPSTEIN, supra note 3, at 213-14 (“A scientific publication by Dr. [Dale] Bauman [Professor of Animal Sciences at Cornell University] falsely claimed that ‘no adverse health effects were observed (in a herd of rBST injected cows) . . . . animals were in good health throughout the study.’ In fact, Bauman suppressed evidence of a high incidence of mastitis in the treated herd.”).

36. See Stauber v. Shalala, 895 F. Supp. 1178, 1183 (W.D. Wis. 1995) ("Posilac increases the risks of reduced pregnancy rates, ovarian cysts and uterine disorders, decreased lengths of gestation periods, lower birth weight of calves, retained placentas and twinning rates, may cause increased bovine body temperatures, indigestion, bloating, diarrhea, enlarged hocks, enlarged lesions, and injection site swellings."); see also EPSTEIN, supra note 3, at 185 (noting the
have a direct effect on human health and safety.37

1. Mastitis and Antibiotics

The FDA concluded that clinical and subclinical mastitis, a bacterial infection of the udder, “increased moderately” in cows treated with rBST.38 The United States Government Accountability Office (GAO)39 voiced concerns about the increased incidence of mastitis.40 Specifically, the GAO reported that rBST results in higher rates of mastitis in cows.41 Mastitis is treated with antibiotics, and the GAO voiced concern that increased infections in cows would lead to increased use of antibiotics by farmers, which in turn would increase the amount of drug residue in milk.42 Furthermore, a study conducted by veterinarians showed Posilac caused mastitis in up to twenty-five percent of cases.43 Other studies show a seventy-nine percent increase.44 However, the FDA considered the increased risk negligible,45 and approved the

package insert for Posilac lists over twenty toxic effects).

37. See infra Part II.B.1-2.
39. The Government Accountability Office (GAO) is frequently referred to as “the investigative arm of Congress” and “the congressional watchdog.” General Accounting Office, Welcome to GAO, http://www.gao.gov/ (last visited Feb. 15, 2008) (describing the functions of the GAO: “GAO supports the Congress in meeting its constitutional responsibilities and helps improve the performance and ensure the accountability of the federal government for the benefit of the American people. GAO’s work includes . . . insight into ways to make the government more efficient, effective, ethical and equitable . . . . GAO’s reports, testimonies, legal decisions and opinions make a difference for Congress and the Nation.”).
40. Executive Branch Study, supra note 18, at 7.
44. Rose Marie Williams, Bovine Growth Hormone Cover-Up (Health Risks and Environmental Issues), TOWNSEND LETTER FOR DOCTORS AND PATIENTS, Nov. 1, 2006, available at WLNR 19904469 [hereinafter TOWNSEND].
Once cows are afflicted with mastitis, farmers give the cows antibiotics to cure the disease.\textsuperscript{47} Mastitis may lead to high levels of antibiotic residue in milk, as well as, an increase in pus content.\textsuperscript{48} Despite assertions from the FDA and Monsanto that the milk is safe,\textsuperscript{49} both consumers and members of the scientific community have voiced concerns about adverse allergic reactions to the antibiotics in humans\textsuperscript{50} as well as the decreased potency of antibiotics, such as penicillin, due to an acquired resistance from exposure.\textsuperscript{51}

Currently, there are regulations in place that require inspection of milk for antibiotic residue.\textsuperscript{52} These regulations instruct farmers to discard milk that contains residue in excess of standard levels.\textsuperscript{53} According to the FDA and Monsanto, these inspection practices protect consumers,\textsuperscript{54} which they claim make mastitis a “manageable” problem.\textsuperscript{55} However, while farmers use over fifty different drugs to cure the disease, these tests only assess levels of the four antibiotics most commonly used to treat mastitis.\textsuperscript{56}

\textsuperscript{46} Id. at 1184 ("The FDA has never applied a zero risk standard when assessing the safety of new animal drugs."). In 1986, the House Committee on Government Operations concluded that the “FDA has consistently disregarded its responsibility, . . . has repeatedly put what it perceives are interests of veterinarians and the livestock industry ahead of its legal obligations to protect consumers . . . jeopardizing the health and safety consumers of meat, milk, and poultry." SAMUEL S. EPSTEIN, CANCER-GATE: HOW TO WIN THE LOSING CANCER WAR 190 (2005) (citing H. COMM. GOV. OPERATIONS, HUMAN FOOD SAFETY AND REGULATION OF ANIMAL DRUGS (1986)).

\textsuperscript{47} Letter to Congress, supra note 42, at 13-14; Marden, supra note 27, at 624.

\textsuperscript{48} Marden, supra note 27, at 624.

\textsuperscript{49} See Interim Guidance, supra note 4; Press Release, supra note 7; see also supra text accompanying note 32.

\textsuperscript{50} See EPSTEIN, supra note 3; see also David Phillips, Will rBST RIP?, DIARY FOODS, Oct. 1, 2006 at 8; Staubet, 895 F. Supp. at 1192.


\textsuperscript{52} Staubet v. Shalala, 895 F. Supp. 1178, 1184 (W.D. Wis. 1995) (discussing the Grade A Pasteurized Milk Ordinance established by the FDA, the Public Health Service, state and local regulatory agencies and members of the milk industry).

\textsuperscript{53} Id.

\textsuperscript{54} See id. at 1184-85.

\textsuperscript{55} Id. at 1184.

\textsuperscript{56} Id.
Contamination by these other drugs goes undetected according to the GAO.\(^5\)

Regardless of whether or not Monsanto acknowledges the evidence that shows a correlation between rBST and increased incidents of mastitis, or the insufficient safeguards to protect consumers to antibiotic exposure, a great number of citizens recognize, and are concerned that the first toxic effect, mastitis, has a direct effect on human health and safety.\(^5\)

2. Increased Levels of IGF-1

The second serious effect is the increased level of Insulin-like Growth Factor-1 (IGF-1) discovered in treated cows.\(^6\) Monsanto has failed to conduct any long term studies on the effects of increased levels of IGF-1 on human health.\(^6\) Still, Monsanto justifies its claim that the increased levels of IGF-1 are safe for human consumption because the amount of IGF-1 present in treated cows is less than the amount found in human breast milk.\(^6\) Although the factual assertion by Monsanto is true, it is irrelevant to the issue of safety.\(^6\) The typical child, whose development is assisted by IGF-1,\(^6\) consumes mother's milk for less than a year, while human consumption of cow's milk may last a lifetime.\(^6\) Eli Lilly\(^6\) admitted that the blood of cows treated with rBST contains levels of IGF-1 ten times greater than that of untreated

\(^5\) Id. ("The General Accounting Office has concluded that there is currently no means of assessing the degree to which current milk supplies are contaminated by these other drugs . . . . To date there have been no long term studies of the impact on human health of increased antibiotics in milk.").


\(^7\) Id. at 1185.

\(^8\) Toronto, supra note 51, at 46.

\(^9\) Id. at 47.

\(^10\) Id. IGF-1 assists in the development of a newborn's gut; assistance that is not generally needed past infancy. Id.

\(^11\) Id.

\(^12\) Eli Lilly is a global pharmaceutical company and one of the world's largest corporations. See Eli Lilly, http://www.lilly.com/. Eli Lilly employs 42,000 people worldwide and markets its medicines in 143 countries. See Eli Lilly, About, http://www.lilly.com/about/index.html (last visited Feb. 15, 2008).
cows. Furthermore, researchers observed increases of IGF-1 up to 700 percent in cow's blood during an injection period.

Elevated levels of IGF-1 in humans could possibly induce premature growth in infants. Further, there is a positive correlation between levels of IGF-1 and both breast and gastrointestinal cancer. One study analyzing the relationship between IGF-1 concentration and breast cancer risk found no relation between IGF-1 and breast cancer risk among postmenopausal women. However, the study did find that pre-menopausal women with higher levels of IGF-1 are up to seven times more likely to develop breast cancer than women with lower levels.

To assess human toxicity, Monsanto conducted a two week study in which rats were given IGF-1. The tests showed no negative health impact on the esophagus, stomach, or intestines, but the rats' body and liver weights along with bone length significantly increased. A ninety-day study

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67. Toronto, supra note 51, at 47; see also Epstein, supra note 3, at 149-50.


69. EPSTEIN, supra note 3, at 78; see also J.R. Harris et al., supra note 68, at 473-80; V. Pappa et al., supra note 68, at 3736-40.


71. Id.


73. Id.

conducted by the Health Protection Branch (HPB) of Health Canada revealed significant absorption of rBST and toxicity to the rats.  

Prior to the study conducted by HPB, Dr. Richard Burroughs, the lead veterinary scientist for the FDA's Center for Veterinary Medicine (CVM), recommended further assessment of rBST out of serious concern for the veterinary toxicology. Not long after, in 1989, the CVM fired Dr. Burroughs for alleged incompetence. Dr. Guest, the director of CVM stated Burroughs was "slowing down his approval process." Similarly, the FDA's Director of Toxicology, Alexander Apostolou, spoke out against the FDA's failure to adequately evaluate the human food safety of veterinary drugs such as rBST, after which, the FDA pressured him to resign.

Despite several independent scientists and congressmen urging further testing to discover the long-term effects of increased levels of IGF-1 on humans, Monsanto has not conducted any such studies. The longest toxicology study acknowledged by the FDA was a ninety-day study performed on adult rats submitted by Monsanto.

Canada, New Zealand, Europe, and Japan have banned the use of rBST. The European Union's current ban is an extension of a moratorium placed on rBST, when the FDA first approved it in 1993, for socioeconomic reasons, which

75. U.S. Food & Drug Administration, Center for Veterinary Medicine, Update on Human Food Safety of BST, (Feb. 5, 1999), http://www.fda.gov/cvm/CVM_Updates/BSTSAFUP.html.
76. EPSTEIN, supra note 3, at 78.
77. Id. at 137.
78. Id.
79. TOWNSEND, supra note 44, at 1.
80. See Letter to Congress, supra note 42.
82. Morris, supra note 81, at 306.
83. EPSTEIN, supra note 3, at 48.
was to last until 1999.\textsuperscript{84} Canada’s ban came after a 1998 report by HPB found rBST to be unsafe for cows.\textsuperscript{85}

C. Monsanto Corporation

Monsanto is a major agricultural corporation, reporting a gross profit of 4.2 billion dollars in 2007.\textsuperscript{86} In addition to Posilac, Monsanto’s production endeavors include: (1) Agent Orange, a toxic chemical known to cause cancer, neurological disorders, birth defects, and death, and is now banned;\textsuperscript{87} (2) PCBs, industrial coolants, now known global pollutants,\textsuperscript{88} which have also been banned but only after forty years of damage was done;\textsuperscript{89} (3) a plethora of genetically modified crops, including cotton and soy,\textsuperscript{90} equipped with the patented “terminator gene” that prevents replanting of seeds from harvested crops;\textsuperscript{91} and (4) Roundup herbicide, composed of the highly toxic chemical glyphosate, to which only Monsanto’s genetically modified crops are tolerant.\textsuperscript{92}

It is no secret that large corporations are dominating forces in today’s world. Lobbyist efforts, campaign contributions, and the fluidity with which corporate directors and officers move in and out of government positions enable a system of corporate influence. Monsanto’s tactics in the approval of rBST are highly suspect, as demonstrated through its ties to government agencies and officials.

\begin{footnotesize}
\begin{enumerate}
\item Morris, \textit{supra} note 81, at 306.
\item Toronto, \textit{supra} note 51, at 49.
\item \textit{Id.} (“Monsanto routinely discharged toxic waste into a west Anniston creek and dumped millions of pounds of PCBs into oozing open pit landfills.”).
\end{enumerate}
\end{footnotesize}
1. Former Monsanto Employees Work for the FDA

The FDA’s Office of Chief Counsel hired Michael Taylor in 1976 where he remained as a legal advisor until 1980.93 Mr. Taylor left the FDA in 1981 to work for the law firm of King & Spalding.94 As the supervisor of the food and drug group, Mr. Taylor acted as chief counsel for Monsanto.95 In 1991, Mr. Taylor returned to the FDA, this time as Commissioner for Policy.96 Mr. Taylor was still Commissioner when the FDA approved Posilac.97 Although Mr. Taylor attempted to avoid involvement in Monsanto’s application,98 he later wrote the FDA regulations banning the labeling of milk.99

Dr. Margaret Miller served as a chemical laboratory supervisor for Monsanto from 1985 through 1989.100 Dr. Miller was responsible for validating tests that measured levels of IGF-1 and bST in cows.101 Finally, Dr. Miller performed all analytical work102 and wrote the scientific report for Posilac that was submitted to the FDA.103 Dr. Miller left Monsanto in 1989 to become a reviewer in the Antimicrobials and Antiparasitic Branch of the Division of Toxicology and Environmental Sciences.104 In this position, Dr. Miller assisted the FDA to draft an answer to a citizen petition seeking to halt all sales of milk from cows treated with rBST.105 In 1992, Dr. Miller became the Branch Chief of Hormones and Pharmacological Agents in the Division of Toxicology and Environmental sciences, the branch responsible for reviewing human safety aspects of Posilac.106

93. Letter to Congress, supra note 42, at 18.
94. Id.
95. Id.; EPSTEIN, supra note 3, at 260.
96. Letter to Congress, supra note 42, at 18-19.
97. EPSTEIN, supra note 3, at 260; see Letter to Congress, supra note 42, at 18-19.
98. See Letter to Congress, supra note 42, at 20. FDA officials verified Mr. Taylor’s lack of involvement in the approval of Posilac. Id.
100. Letter to Congress, supra note 42, at 7-8; see also EPSTEIN, supra note 3, at 244, 248.
102. Id. at 8.
103. EPSTEIN, supra note 3, at 244, 248.
104. Letter to Congress, supra note 42, at 7-8.
105. Id. at 9-10.
106. Id. at 8-9.
Basically, the FDA assigned Dr. Miller to the approval of Monsanto’s rBST.\(^{107}\)

2. **Monsanto Infiltrates the System**

Former Secretary of Defense Donald Rumsfeld was president of Monsanto’s subsidiary, Searle Pharmaceuticals.\(^{108}\) Lidia Watrud, former Monsanto biotech researcher, is currently the senior scientist at the EPA Environmental Effects Laboratory.\(^{109}\) Former Secretary of Agriculture, Anne Veneman, was on the board of directors for a Monsanto subsidiary.\(^{110}\) Former Health and Human Services Secretary, Tommy Thompson, while acting governor of Wisconsin, used state funds to set up a $317 million dollar biotech zone for the use of Posilac in Wisconsin\(^{111}\) after receiving $50,000 in campaign contributions from biotech companies.\(^{112}\) Monsanto also contributed to other political campaigns, including those of Attorney General John Ashcroft and Richard Pombo, chairman of the Agriculture Subcommittee on Dairy, Livestock, and Poultry.\(^{113}\)

3. **Monsanto Comes Under Investigation**

At the request of three Members of Congress,\(^{114}\) the GAO investigated the conflicts of interested on the part of Michael Taylor, Dr. Margret Miller, and Dr. Suzanne Sechen.\(^{115}\) Further, Congress asked the GAO to determine whether “any FDA employees involved in the approval of Posilac had an appearance of the loss of impartiality because of a prior

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108. Editorial, supra note 91.
110. Idaho Observer, supra note 91.
112. Idaho Observer, supra note 91.
113. Id.
114. Letter to Congress, supra note 42, at 1. The requesting members were: The Honorable George E. Brown, Jr., Chairman, Comm. on Sci., Space and Tech., H.R.; The Honorable David Obey, H.R.; and The Honorable Bernard Sanders, H.R. Id. at 1.
115. Letter to Congress, supra note 42, at 1, 3. The FDA hired Dr. Sechen in 1988 as an animal scientist. Id. at 16. Prior to her employment at the FDA, Dr. Sechen conducted research on investigational rBST formulas at Cornell University for Monsanto. Id.
relationship with Monsanto.” The GAO concluded that “there were no conflicting financial interests with respect to the drug’s approval or the voluntary milk labeling guidance.”

Despite the GAO’s conclusion, foreclosing conflicts of interest between three former employees of Monsanto and their role in the FDA, Posilac’s approval remains suspect. Numerous potential conflicts exist that the GAO left unexamined. Monsanto has been the subject of criminal investigations for fraud, including falsified studies in its past endeavors. Monsanto’s political influence and poor track record, at the very least, demonstrate the dubious nature of Posilac’s approval.

D. Labels Become a Battlefield

After Posilac was approved, the FDA declined to mandate labeling of products originating from cows treated with rBST. Those dairy farmers not using rBST on their herds showed their disapproval by indicating on the labels that their dairy products came from cows not treated with rBST. As discussed below, battles ensued between Monsanto and those dairy farmers who distinguished their milk on labels.

116. Id at 1.
117. Id. The GAO based its conclusion on an investigation that consisted of: reviewing more than 40,000 pages of documents; conducting fifty-four interviews with current and former FDA and DHHS employees, attorneys, Monsanto officials, and editors of scientific journals; reviewing the financial disclosure and conflict-of-interest statements of all CVM employees who played a significant role in Posilac’s approval; and reviewing the relevant ethical standards. Id.
118. Internal Memorandum of the EPA from William Sanjour, Policy Analyst to David Bussard, Dir., Characterization and Assessment Div. (July 20, 1994), available at http://pwp.linacs.net/sanjour/monsanto.htm. In 1990, the EPA Office of Criminal Investigation recommended “a full field criminal investigation” of Monsanto for potential criminal violations of three laws: (1) 15 U.S.C. 2615(b), the Toxic Substances Control Act (TSCA), requiring persons to report any substantial risk of their products to the EPA and providing criminal penalties for knowing violations; (2) 18 U.S.C. 371, conspiracy to defraud the United States; and (3) 18 U.S.C. 1001, making a false statement on a matter within the jurisdiction of any agency in the United states. Id.
119. Interim Guidance, supra note 4.
120. See infra Part III.D.2-3.
121. See infra Part III.D.2-3.
1. The Food, Drug, and Cosmetic Act of 1938

The FDA, a federal agency currently organized under the Department of Health and Human Services, is primarily responsible for administering the Food Drug & Cosmetic Act of 1938 (FDCA).\footnote{122. 21 U.S.C. §§ 301-94 (2006); see FDA, Laws Enforced by the FDA and Related Statutes., http://www.fda.gov/opacom/laws/default.htm (last visited Feb. 15, 2008).} As mentioned in the previous section,\footnote{123. See supra Part I.} the FDA did not require farmers to provide labels on milk that would identify a product as originating from cows treated with rBST.\footnote{124. See supra Part I.} The FDA made the decision not to require labeling based on its interpretation of the FDCA and after a joint meeting of the Veterinary Medicine and Food Advisory Committees in May 1993.\footnote{125. Executive Branch Study, supra note 18.} At the meeting, the committees heard testimony from several members of the medical and scientific communities as well as dairy farmers, dairy organizations, and farm and agricultural groups.\footnote{126. Stauber v. Shalala, 895 F. Supp. 1178, 1186 (W.D. Wis. 1995).} Despite several committee members concluding there were possible health consequences associated with the use of rBST,\footnote{127. Executive Branch Study, supra note 18.} the FDA concluded that there are no significant differences in milk from rBST treated cows and milk from untreated cows.\footnote{128. Id.; see also Stauber, 895 F. Supp. at 1186 ("[T]he FDA concluded that there is no significant difference between milk from cows treated with Posilac and milk from untreated cows.").}

The FDCA specifically addresses the issue of food labeling,\footnote{129. See The Food, Drug, and Cosmetic Act (FDCA) § 403(a), 21 U.S.C. § 343(a) (2006); FDCA § 201(n), 21 U.S.C. § 321(n).} but the use of subjective terms has ignited heated debate over whether the FDA should mandate that genetically modified foods be labeled. Under the FDCA section 403(a), 21 U.S.C. section 343(a), a food is misbranded in violation of the Act if “its labeling is false or misleading in any particular.”\footnote{130. FDCA § 403(a), 21 U.S.C. § 343(a).} Section 201(n) of the Act defines the term “misleading” as it is used in section 403(a):

In determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by
statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.131

Courts have provided further clarification into the standards for what is misleading. When considering how a label may be interpreted by a consumer, courts generally do not use the objective "reasonable person" standard. Instead, courts have imputed a lower standard by evaluating the labels as a consuming public would, which they characterize as "ignorant," "unthinking," and "credulous."132 All statements that may mislead or deceive are prohibited; they are not confined to those claims that omit material information and include "the use of statements not technically false or which may be literally true."133

The FDA uses the second part of section 201(n), regarding "material" facts and consequences, to require labeling for safety reasons.134 Such warning statements may be placed on food labels only where there is scientifically-based evidence of a potential health hazard.135 Monsanto submitted scientific reports that disregard possible health consequences associated with consumption of foods from rBST-treated cows voiced by members of the advisory committee.136 The FDA subsequently concluded no adverse health consequences would result.137 Therefore, the FDA found it did not have the authority under the FDCA to

131. FDCA § 201(n), 21 U.S.C. § 321(n).
134. Executive Branch Study, supra note 18.
135. Id.
136. Id.
137. See Interim Guidance, supra note 4; Letter to Congress, supra note 42 at 1-4; Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995).
require labeling of milk.\textsuperscript{138}

In February 1994, Michael Taylor issued the FDA's \textit{Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin}.\textsuperscript{139} These guidelines warn of potential violations of section 201(n) and 403(a) of the FDCA through the use of misleading statements that imply that milk originating from cows not treated with rBST is somehow better than or compositionally different than milk from treated cows.\textsuperscript{140} The guidelines suggest that to avoid consumers being misled, any voluntary statements made by producers or retailers should be followed by further information such as "no significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows."\textsuperscript{141}

\textbf{2. The People Speak Out}

The FDA guidelines are intended to function as a reference for states when interpreting their own statutes. However, complying with the FDA's suggested terminology does not automatically protect producers and retailers from litigation. Nevertheless, milk production traditionally has been regulated by the states. Therefore, state statutes on the subject of labeling are controlling because there are currently no federal laws on the subject to preempt state law.\textsuperscript{142}

In \textit{Stauber v. Shalala},\textsuperscript{143} consumers of dairy products sought declaratory and injunctive relief pursuant to the FDCA. Plaintiffs alleged, among other things, that the FDA should require mandatory labeling of milk from treated cows in order to comply with 21 U.S.C. section 343(a)(1) and section 321(n).\textsuperscript{144} Plaintiffs argued that differences exist between milk from treated and untreated cows and that these

\begin{thebibliography}{99}
\bibitem{138} Executive Branch Study, \textit{supra} note 18.
\bibitem{139} Interim Guidance, \textit{supra} note 4.
\bibitem{140} Id. The guidelines suggest that milk labeled as "rBST free" may imply a compositional difference that would be misleading in violation of the Act and that the more appropriate phrase is, "from cows not treated with rBST." However, even this preferred phrasing "has the potential to be misunderstood by consumers . . . such statements could be misleading." \textit{Id.}
\bibitem{141} Id.
\bibitem{142} Id.; see also U.S. CONST. art. I, § 8, cl. 3.
\bibitem{143} Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995).
\bibitem{144} Id. at 1192.
\end{thebibliography}
differences are "material facts" under the Act, which require labeling.\textsuperscript{145} In addition, plaintiffs argued that consumer demand for labeling is also a "material fact" that requires labeling.\textsuperscript{146}

Courts give great deference to the decisions made by the FDA as a federal agency. Federal court review is limited and employs the highly deferential "arbitrary and capricious" standard of review.\textsuperscript{147} This means that even if a court were to disagree with the FDA's decision, as long as there is a discernable rational basis for the FDA's action, the court will uphold it as valid.\textsuperscript{148}

As a result of this great deference, the Wisconsin District Court in \textit{Stauber} subsequently upheld the FDA's decision to decline mandatory labeling because it was based on scientific evidence in Monsanto's reports, which found that rbST posed no significant risk to consumers, and that there was no significant difference in milk from treated and untreated cows.\textsuperscript{149} The District Court refused to admit evidence submitted by the plaintiffs that demonstrated negative human health consequences caused by rbST.\textsuperscript{150} Chief Judge Crabb, writing for the majority of the court stated, "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."\textsuperscript{151} Despite the fact that the FDA approves drugs with sometimes deadly side effects that are not discovered until after approval,\textsuperscript{152} Judge Crabb, acknowledging that no long-term studies were

\textsuperscript{145} Id. at 1193.
\textsuperscript{146} Id.
\textsuperscript{147} Id. at 1189.
\textsuperscript{148} Id.
\textsuperscript{149} Stauber v. Shalala, 895 F. Supp. 1178, 1183 (W.D. Wis. 1995).
\textsuperscript{150} Id. at 1190.
\textsuperscript{151} Id. (emphasis added).
\textsuperscript{152} See Dissertation, supra note 15. Some examples include Vioxx, Rezulin and Aspartame. Vioxx remained on the market for four years and was the cause of over 10,000 deaths; Rezulin was on the market for three years despite evidence of its deadly liver toxicity. Dissertation, supra note 15. Additionally Aspartame, which is still currently available in over 7,000 products, has been attributed to over ninety toxic adverse reactions including Alzheimer's disease and death. Betty Martini & Don Harkins, The Legacy of Donald Rumsfeld: Diseases Bearing His Name, Millions of People Sick and Dying From Them – And Diane Fleming, \textsc{The Idaho Observer}, Nov. 2006, available at http://proliberty.com/observer/200611115.htm.
conducted, would not accept scientific evidence of potential harm to humans if such studies were performed subsequent to the FDA's approval. The District Court's refusal to admit evidence simply because it was concluded after approval is illogical. Under the District Court's view no challenge to rBST could possibly be successful since the great deference afforded to the FDA's decision would require the FDA to conduct independent investigation. Despite mounting evidence of serious health risks associated with rBST, it will remain on the market.

3. Monsanto and Dairy Manufacturers Challenge Labels

Dairy manufacturers challenged the constitutionality of a Vermont statute that required mandatory labeling of milk derived from treated cows in International Dairy Foods Ass'n v. Amestoy. The Second Circuit Court of Appeals struck down a statute that required all milk and milk products originating from rBST-treated cows to disclose that information on the label or packaging on the grounds that the statute compelled speech in violation of the manufacturer plaintiffs' First Amendment rights. The court reasoned that Vermont could not justify the statute on consumers' curiosity alone. "Some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern" is needed to force manufacturers to involuntarily disclose the information.

Displeased by any statement that identified a product as coming from untreated cows, Monsanto sent out 2,000 letters threatening to sue manufacturers if they made statements similar to those of manufacturers, retailers, states, and dairies whose voluntary labeling methods Monsanto was challenging in the courts. One such label, used by

155. Id. at 69.
156. Id.
157. Id. at 74.
158. Thornley, supra note i, at 799.
159. Id. Monsanto challenged the voluntary labeling methods of Oakhurst Dairies, Swiss Valley Farms, Pure Milk and Ice Cream Company, and the State of Maine, among others. Id.
Oakhurst Dairy read: "Our Farmers' Pledge: No Artificial Growth Hormones." Monsanto filed suit seeking an injunction to prohibit the dairy from using the statement. The parties settled the suit out of court, and Oakhurst agreed to amend its pledge to include the word "used," as well as adding the phrase: "FDA states: No significant difference in milk from cows treated with artificial growth hormones." Monsanto's attempt to suppress consumer knowledge of rBST has gone beyond dairy producers and manufacturers. When Fox Television investigative reporters composed a story that revealed the adverse health effects linked to rBST, Monsanto responded with a letter to the head of Fox News threatening litigation if the story aired. The story was then rewritten several times. Monsanto required the removal of all references to the word cancer, and although European officials had banned rBST because of health concerns, the story was to report that no such concerns existed. Ultimately, the story never aired and the two reporters were subsequently fired for refusing to report lies. Although Monsanto and the courts currently hold that consumers have no right to know the milk they drink comes from cows treated with rBST, all hope is not lost. The Federal Government is the solution.

III. IDENTIFICATION OF THE PROBLEM

Recombinant DNA techniques are relatively new and experimental. Studies conducted by members of the scientific
community independent of Monsanto's research team contradict the corporation's conclusion that rBST is safe. A two-week study of toxicity performed on lab rats is inadequate to evaluate the possible health and safety consequences from prolonged exposure to rBST. The current labeling structure is misleading in that it implies there is no difference between milk from cows treated with rBST and untreated cows, when, in fact there is. Consumers have a strong desire to know whether the milk they purchase comes from treated cows and they should be entitled to this information via labels.

IV. ANALYSIS

There are three possible solutions to the problem of mandatory labeling of milk products that originate from cows treated with rBST. These solutions are derived from three separate sources of power: the courts, the FDA, and the Federal Government. First, the courts can reevaluate whether there is a sufficient state interest to compel speech without violating the First Amendment rights of dairy producers and manufacturers. Second, the FDA may require labeling of rBST products if it finds that there is sufficient evidence that harm may result from consumption of these products. Finally, the Federal Government may mandate labels of rBST products via the Commerce Clause.

A. States' Interest Sufficient to Compel Speech

First, the logic of the Second Circuit in International Dairy should be reevaluated. However, this is not likely because every rBST label Monsanto has challenged so far has settled out of court. The high costs of litigation discourage many dairy producers from fighting the good fight, and allow Monsanto to retain control over what is printed on the packaging. Fearful of a costly battle, many states and producers adhere to the FDA's suggested guidelines. Still, if International Dairy were litigated today, a court would likely follow Judge Leval's dissent and uphold the state's compulsory labeling scheme as a valid exercise of the state's

police powers.170

The First Amendment protects speech from government regulation.171 The largest exception to this general grant of freedom is known as the “commercial speech doctrine.” The United States Supreme Court defined commercial speech as speech that merely proposes a commercial transaction.172 While non-commercial speech receives complete First Amendment protection,173 commercial speech receives a significantly lesser degree.174 The Court reasoned that full protection of commercial speech is not required to ensure that the flow of truthful and legitimate commercial information is unimpaired,175 because of the “common sense” differences that exist between commercial and non-commercial speech.176

170. Int’l Dairy, 92 F.3d at 74 (Leval, J., dissenting) (“Vermont’s regulation requiring disclosure of use of rBST in milk production was based on substantial state interests, including worries about rBST’s impact on human and cow health, fears for the survival of small dairy farms, and concerns about the manipulation of nature through biotechnology. The objective of the plaintiff milk producers is to conceal their use of rBST from consumers.”). In the dissenting opinion, Judge Leval points out the Majority’s disregard of evidence that shows Vermont’s true interests and the district court’s findings that recognized those interests. Id. at 76. Leval opines that the “interests of the citizenry that led to the passage of the law include health and safety concerns, among others.” Id. The concerns Vermonters voiced were based on their beliefs that: (1) the use of genetically-engineered hormones is unnatural; (2) small dairy farmers will be hurt by the use of rBST because the increased milk production will result in lower prices; (3) the use of rBST is harmful to cows and potentially harmful to humans; and (4) there is a lack of knowledge regarding long term effects associated with rBST. Id. at 75-76.

171. U.S. CONST. amend. I.


174. Va. State Bd. Pharmacy, 425 U.S. 748. The longstanding belief that commercial speech is less valuable than other types of speech was solidified with the Supreme Court’s decision in Central Hudson, when the court held that commercial speech is categorically worthy of less protection. Cent. Hudson, 447 U.S. at 561.

175. Va. State Bd. Pharmacy, 425 U.S. at 771 (“Untruthful speech, commercial or otherwise, has never been protected for its own sake.”).

176. Id. (stating that commercial speech is more “objective” since it is easily
In Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, the United States Supreme Court established the test for governmental regulation of speech.\textsuperscript{177} Under the Central Hudson test, if commercial speech is false, deceptive, or misleading, states are not restrained in preventing dissemination.\textsuperscript{178} However, if commercial speech is truthful,\textsuperscript{179} states cannot prevent dissemination unless there is a substantial governmental interest, the means chosen directly advances that interest, and no less burdensome alternatives exist.\textsuperscript{180}

In International Dairy, the Second Circuit Court of Appeals held that Vermont's mandatory labeling requirement was invalid as a violation of the plaintiff's First Amendment rights because it found that the interest asserted by Vermont was not substantial.\textsuperscript{181} The majority suggested that if health or safety concerns had been the motivating force for instituting the regulations rather than mere "consumer interest and the public's right to know," Vermont's interest would have qualified as substantial.\textsuperscript{182} As the dissent correctly stated, the majority opinion "simply disregards the evidence of Vermont's true interests and the district court's findings recognizing those interests."\textsuperscript{183}

Vermont did not advance any scientific evidence contradicting the FDA's claims of safety. Instead, it stated that consumers believed that the use of rBST causes harm to cows and is potentially harmful to humans.\textsuperscript{184} While, as Judge Leval's dissenting opinion stated, consumer's legitimate belief of potential harm should be a substantial state interest, today, there is more than consumer's fear of potential harm. There is scientific evidence. Increased cancer risks from higher IGF-1 levels and risks of exposure to

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verifiable and that commercial speech is unlikely to be chilled because it is driven by profits).
\textsuperscript{177} Cent. Hudson, 447 U.S. at 557.
\textsuperscript{178} Id. at 566; Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 638 (1985).
\textsuperscript{179} "Truthful" in this context means that the commercial speech is not false, deceptive or misleading.
\textsuperscript{180} Cent. Hudson, 447 U.S. at 566; see also Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 77 (2d Cir. 1996).
\textsuperscript{181} Int'l Dairy, 92 F.3d at 73.
\textsuperscript{182} Id. at 72-73.
\textsuperscript{183} Id. at 76.
\textsuperscript{184} Id.
}
antibiotics due to increased incidents of mastitis have been sufficiently demonstrated to support government interest in the health and safety of its citizens.\footnote{See Epstein, supra note 3; Townsend, supra note 44; Toronto, supra note 51.}

To have a permissible statute for regulating commercial speech, the means chosen must also directly advance the substantial state interest in a way "no more intrusive than necessary to accomplish its goal."\footnote{Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980).} By compelling those who use rBGH to disclose that information to purchasers, the state is helping consumers protect themselves against these increased health risks. Although some labeling strategies will undoubtedly result in increased costs to the dairy producers and manufacturers, methods such as Vermont's "blue sticker"\footnote{See Int'l Dairy, 92 F.3d at 70. Manufacturers who used rBST had to comply with one of four options to reveal that information. One such option was to post a sign in stores selling dairy products that stated: "The products in this case that contain or may contain milk from rBST-treated cows either (1) state on the package that rBST has been or may have been used, or (2) are identified by a blue shelf label [blue rectangle] or (3) a blue sticker on the package [blue dot]. The [US FDA] has determined that there is no significant difference between milk from treated and untreated cows. It is the law of Vermont that products made from the milk of rBST-treated cows be labeled to help consumers make informed shopping decisions." Id.} would be slight and likely would be passed onto the consumer by increasing the cost a few cents per gallon, a small price to pay for what most consumers would consider valuable knowledge.

\section*{B. FDA's Narrow Construction of Sections 343(a) and 201(n)—Misleading and Materiality}

Monsanto has used sections 343(a) and 201(n) of the FDCA as the basis for its claims against those who choose to identify their milk products as "rBGH free." Monsanto vehemently insists that the display of two simple words, "rBGH free," that are, in fact, pure unadulterated truth, on milk packaging is an attempt by those whose cows are untreated to "mislead" and "deceive" consumers into believing that milk with these labels is safer or healthier.\footnote{Press Release, supra note 7.} Monsanto argues that labels should be required to "provide consumers with the accurate scientific context about milk from cows}
supplemented with rBST so that consumers can make an informed choice." The problem with Monsanto’s position is that it considers only the scientific reports by its people, which indicate the use of rBST as safe for human consumption. Monsanto brushes aside the contradictory scientific evidence compiled by those impartial researchers outside of Monsanto’s reach, and even results of some within its grasp, as unnecessary to consumers making an “informed” decision.

Through bully tactics, Monsanto has made inclusion of the statement, “there is no significant difference between milk from cows treated with rBST and milk from untreated cows,” an unspoken law. Employing the “ignorant, unthinking, credulous” consumer standard, this disclaimer is deceptive and misleading under section 201(n). Consumers are likely to infer from this statement that adequate long-term human toxicity testing of rBST has been performed, when it has not. The FDA’s conclusions as to the safety of a drug are not a guarantee. Consumers put their trust in the hands of the FDA, unaware of the numerous drugs that passed FDA standards only to cause related adverse side-effects, such as heart-attack, sexual dysfunction, and even death post-approval.

In Stauber, the plaintiffs alleged two bases of support for their assertion that the FDA should require mandatory labeling of milk from cows treated with rBGH. First, they claimed that organoleptical differences exist between milk

189. Id.
190. Townsend, supra note 44. Dr. Burroughs, while employed for the FDA spoke, out against safety concerns from lack of research as did other members of the scientific community before the FDA in the joint committee hearing on the labeling of rBST. Id.; Stuber v. Shalala, 895 F. Supp. 1178, 1186 (W.D. Wis. 1995).
191. See supra Part II.D.3.
196. Organoleptical differences are those capable of being detected by the
from treated cows and milk from untreated cows, which are “material facts” under section 201(n). Further, plaintiffs argued that high consumer demand for the right to know is also a “material” fact. The Wisconsin district court rejected both contentions.

The FDA considers differences in performance characteristics and organoleptic differences as material facts under section 201(n), which must be disclosed to prevent misbranding under section 403(a). Since human sense organs cannot detect difference between the two milks, the district court was correct in stating there are no organoleptic differences between the two milks; thus, under current interpretation of the FDCA, the FDA cannot mandate labeling under this premise. There are also no differences in the performance characteristics of milk that comes from treated and untreated cows that would permit the FDA to require labeling. However, the FDA neglects major differences by refusing to consider the process of genetic engineering, which itself makes the two dissimilar, or the three percent difference in composition that the FDA now admits exists between the two milks, as material.

The plaintiffs’ second argument that labeling should be mandated because consumer demand is a material fact also fails to establish a sufficient legal basis. Nowhere in the FDCA is authorization given to require action due to consumer demand. As the court in Stauber stated, if “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 perceive the product as different.” The plaintiffs in Stauber did not argue health and safety reasons as justification for labeling. Even if they

198. Id.
199. Id.
200. Id.
201. Id.
202. Id. The FDA considers performance characteristics to be: physical properties (color, consistency), flavor characteristics, functional properties, and shelf life. Id.
203. EPSTEIN, supra note 3, at 2.
had, the court would have refused the evidence. Since technically increased levels of IGF-1 are not detectable by humans during consumption or inspection, the plaintiffs incorrectly focused on organoleptic differences when they should have presented safety concerns as justification under the “material fact” portion of section 201(n). Although the court in Stauber refused to consider such contrary findings, with such mounting proof of harm and unsettling consumer demand, a court today would likely permit such evidence.

Section 201(n) authorizes the FDA to require labeling to reveal facts that are material “with respect to consequences which may result from the use of the article.” There is sufficient scientific evidence in existence today about the harm associated with the ingestion of milk from treated cows to satisfy section 201’s “may result” standard. So far, the FDA has ignored findings by members of the scientific and medical communities that show the harm associated with rBST. If the FDA acknowledged studies performed by those other than Monsanto’s people, it would find it has authority under section 201(n) to mandate labeling of products from rBST-treated cows.

C. Federal Regulation via the Commerce Clause

If the FDA continues to turn a blind eye to scientific evidence that shows risks of significant harm associated with rBST, and maintains the position that it lacks authority under the FDCA to require labeling, then Congress by virtue of the Commerce Clause can explicitly mandate labeling by amending the FDCA or enacting other legislation. Currently, states are able to regulate labels intrastate because no federal laws have preempted such state statutes through complete occupation of the field. Although the FDCA authorizes the FDA to require labeling, regulating milk is traditionally the role of the states, creating a presumption that federal

206. Id. at 1192-93.
207. FDCA § 201(n); 21 U.S.C. § 321(n).
209. FDCA § 201(n); 21 U.S.C. § 321(n).
210. Letter to the Editor, supra note 12.
legislation was not meant to preempt state law.\textsuperscript{212}

However, Congress has the authority to limit the states' control by enacting legislation that requires labeling of all rBST-treated milk and milk products that travel in interstate commerce\textsuperscript{213} or that substantially affect interstate commerce.\textsuperscript{214} Article I, section 8, clause 3 of the United States Constitution, the "Commerce Clause," authorizes the federal government to regulate persons and things in interstate commerce, as well as those activities that have a substantial effect on interstate commerce.\textsuperscript{215} Congress has the authority to regulate the labeling of milk and milk products that cross state boarders under the commerce power. Under the rule established in \textit{NLRB v. Jones & Laughlin Steel Corp.},\textsuperscript{216} Congress is able to regulate the labeling practices of milk sold intrastate by producers who also sell their milk interstate.\textsuperscript{217}

The parameters of activities such as milk production, which traditionally have been regulated by the states and are conducted wholly intrastate, are still unclear and may be outside the scope of the commerce power. Nevertheless, the aggregation principle established in \textit{Wickard v. Filburn}\textsuperscript{218} arguably allows regulation of labeling even on wholly intrastate milk producers. The aggregation principle applies only to economic activities,\textsuperscript{219} and the commercial sale of milk is an economic activity. If intrastate producers are not subject to the same mandatory labeling scheme as interstate

\begin{itemize}
\item \textsuperscript{212} Interim Guidance, \textit{supra} note 4.
\item \textsuperscript{213} U.S. v. Darby, 312 U.S. 100 (1941).
\item \textsuperscript{214} Wickard v. Filburn, 317 U.S. 111 (1942).
\item \textsuperscript{216} \textit{NLRB}, 301 U.S. 1.
\item \textsuperscript{217} \textit{See id.} The Court held the federal government has the power to regulate local employment practices in companies whose business effects interstate commerce. \textit{Id.}
\item \textsuperscript{218} \textit{Wickard}, 317 U.S. 111. The defendant farmer was penalized for growing wheat in excess of his allotment under the federal Agricultural Act. The Supreme Court found the purpose of the Act was to restrict the supply of wheat in order to maintain prices, and although the amount grown by the defendant for consumption on his farm was trivial, when taken in the aggregate it could have an effect on interstate prices. \textit{Id.; see also} Gonzales v. Raich, 545 U.S. 1 (2005); Perez v. United States, 402 U.S. 146 (1971).
\item \textsuperscript{219} United States v. Morrison, 529 U.S. 598 (2000) (holding Congress cannot use the Commerce Clause to regulate a local non-economic activity, even if the national aggregate of the activity substantially affects interstate commerce).
\end{itemize}
producers, this would have a substantial effect on the price of milk nationwide.

Milk derived from rBST-treated cows sells at an average of forty cents less per gallon than milk labeled “rBGH-free.” If intrastate producers were not required to label milk produced from cows treated with rBST, they would be able to charge a higher price than rBST-treated milk from out-of-state producers packaged with identifying labels. Consumers might be misled to believe that an unlabeled carton of milk comes from cows not treated with rBST, since most producers would not label their product as coming from treated cows if they were not required to do so. Such deception in the marketplace would have a substantial effect on the price of milk nationwide. Therefore, because of the aggregate effect on milk prices nationwide, and in the interest of uniformity, Congress should regulate the labeling of wholly intrastate milk production under the commerce power.

V. PROPOSAL

There are three possible paths that all lead to the solution to the rBST-treated labeling issue. First, the federal government can act pursuant to the Commerce Clause to create a law that requires all producers of milk and milk products derived from rBST-treated cows to disclose this information on the product packaging or label. Second, under existing law, the FDA can require a compulsory labeling scheme in the interest of the health and safety of United States citizens. Finally, the Federal Government could allow producers and manufacturers of milk not treated with rBST to state possible health risks associated with rBST to consumers on the milk packaging or label.

A. Federal Government Should Regulate

The most effective option is for the federal government to enact legislation requiring all milk and milk products derived from rBST-treated cows be labeled as such. In addition, such “qualifying” statements as “the FDA finds no significant difference” should be banned as misleading.

The FDCA was enacted for the protection of consumers. Thus, the FDA has an obligation to uphold this duty and act in the best interests of the health and safety of the general public. Corporate influence has penetrated today’s society, and numerous conflicts of interest bind Monsanto to the FDA. There is something seriously wrong with the FDA when researchers present glaring scientific evidence, warning of the possible risks associated with the continued use of rBST, and it chooses to ignore the facts. Monsanto’s lack of credibility has been shown time and time again. The people of the United States need protection. Congress is in the best position to provide effective defense.

B. FDA Can Require Mandatory Labeling Under Section 201

The second, and less likely, alternative is for the FDA to acknowledge that it has authority under the FDCA to require producers and manufacturers of cows treated with rBST to identify this on their product label or packaging. The FDA need only look to evidence other than that supplied by studies funded and controlled by Monsanto to see that there are serious health and safety concerns at issue. Under section 201(n), health risks to consumers such as increased risk of cancer, allergic reactions, and increased resistance to antibiotics qualify as “material with respect to consequences which may result from the use of the article.” If the FDA considered such health risks to be a scientifically proven possibility, it would have authority under the FDCA to require labeling of rBST-treated products. If the FDA believed such health and safety issues “may result,” its failure to require disclosure of the use of rBST would be “misbranding” in violation of section 343(a).

C. Labels Should Reveal Contradictory Studies

The third option is to permit dairy manufacturers and producers who do not use rBST to state findings of adverse health effects on consumers or, at least, lack of long-term studies conducted by the FDA. The following are two

222. See Epstein, supra note 3, at 260; Cohen, supra note 107.
examples of statements that are truthful and should be allowed:

1) “From cows not treated with rBST. The FDA has concluded that no significant difference in milk from rBST treated cows and milk from untreated cows exists. No long term studies on the effect of rBST milk on humans have been conducted.”

2) “From cows not treated with rBST. The FDA has concluded that no significant difference in milk from rBST treated cows and milk from untreated cows exists. Milk from cows treated with rBST may contain increased levels of IGF-1. Independent scientific research has shown a link between increased IGF-1 levels and cancer.”

Using labels that include facts other than those permitted by the FDA, gives consumers greater decision-making power. Although Monsanto will surely claim such labels are misleading and bring charges against those who choose to place such statements on their packaging, a judge could find against Monsanto. If a court accepted scientific findings other than those contained in Monsanto’s reports, proponents of such labels would have sufficient scientific evidence to support the above statements. If backed by evidence, the above statements could not be considered misleading in violation of section 343.

VI. CONCLUSION

The arrival of genetic engineering was greeted with mixed reactions. While some farmers and producers benefit by the increased product yield and lower production costs, consumers remain wary and demand to know the synthetic processes by which their foods are made.225 Despite reports by independent scientists and researchers that demonstrate negative health consequences,226 the FDA has not yet acknowledged the dangers related to human consumption of milk and milk products from rBST-treated cows.

The FDA has the authority under sections 403(a) and 201(n) of the FDCA to order all rBST products provide full

226. See supra Part II.B.1-2.
disclosure on their labels.\textsuperscript{227} Although the court in \textit{Stauber} held that consumer demand to know is insufficient to require labeling, the FDA has required labels for non-health related issues that are important to consumers such as "dolphin safe" tuna\textsuperscript{228} and farm raised salmon.\textsuperscript{229} The FDA could require labeling, but chooses not to.

The FDA's reluctance to appease consumers may be attributed to corporate influence and the fact that powerful corporations such as Monsanto, which pay the FDA's salaries,\textsuperscript{230} speak in a louder voice than the average consumer. After denying consumers the right to know for over a decade, it is unlikely that the FDA will alter its interpretation of the FDCA and require labeling in the near future. Therefore, the burden must fall on Congress to protect consumers by enacting a new law that requires products derived from rBST-treated cows to bear identifying labels.

\begin{itemize}
\item\textsuperscript{227} See supra Part VI.B.
\item\textsuperscript{228} 16 U.S.C. § 1385 (1999).
\item\textsuperscript{229} 68 Fed. Reg. 61944 (proposed Oct. 30, 2003). Effective April 4, 2005, the USDA requires mandatory labeling of fish and shellfish products for country of origin and method of production (i.e., wild or farm-raised). \textit{Id.}
\item\textsuperscript{230} Dissertation, supra note 15.
\end{itemize}