This paper is not meant as a determination that there are significant differences between rbST and non-rbST milk: The Controversy Over rbST Milk and Absence Labeling

Megan Green, Spring 2011

Introduction: milk production, rbST, and the role of the label

Milk is an essential part of our diets from birth through adulthood, making milk production of special concern to all kinds of consumers. So when biotechnology made its premier appearance in a living animal as a means of food production when it entered our milk supply, it did not happen quietly. From the time that the genetically engineered version (recombinant bovine Somatotropin (rbST)) of the naturally occurring hormone (bovine Somatotropin (bST)) began its early stages of testing, right up until the present, the topic has been hot among consumers, regulatory agencies, and producers alike.

The naturally occurring form of the hormone is found in dairy cows and plays a role in the natural process of production of milk. When extra amounts of the synthetic hormone are injected into dairy cows the level of milk production in that cow is increased beyond its natural level. On its face, this increased milk production seems like it would benefit the producer and consumer similarly. But there remain questions of whether or not this synthetic hormone is safe for the cow, and furthermore whether milk from cows treated with the synthetic hormone is safe for human consumption. Furthermore, there are questions over whether labeling, which is not currently required on milk that comes from cows treated with rbST, is permissible for milk that comes from cows that are not treated with rbST. And if it is permissible, to what extent may producers label their milk as such, and what requirements must be met to do so.

This paper will introduce the development of the synthetic hormone, discuss the regulation of its use and labeling requirements that are issued at the federal level, give insight into consumers' standpoints on the controversial topic, and explain how labeling regulations at the state level were assessed when challenged in federal court. Finally the

paper will touch on what all of those factors may indicate about the future of rbST's use in milk production, and possible implications for the future of product labeling.

The Facts of rbST and Milk Production

Background.

Before we can understand what recombinant bovine Somatotropin is, and the role it plays in milk production in dairy cows, we must first start with a little background on the process of milk production. Cows normally lactate in a two phase cycle; for about 12 weeks they break down tissues to build energy and nutrients to contribute to milk production. This is followed by a period during which the tissues are built back up through anabolic processes.[1]

Bovine Somatotropin is a hormone that occurs naturally in cows. This hormone is produced by the cow's pituitary gland and is crucial for "growth, muscle development, and milk production."[2] Specifically relevant to this topic, in lactating dairy cows, bST is a regulator of the production of milk.[3] The hormone works to coordinate the metabolism

[1] David S. Kronfeld, Recombinant Bovine Growth Hormone: Cow Responses Delay Drug Approval and Impact Public Health, 65-112 at 70, in *The Dairy Debate: Consequences of Bovine Growth Hormone and Rotational Grazing Technologies* (William C. Liebhardt ed., University of California Sustainable Agriculture Research and Education Program, 1993) .

[2] Stephen Nottingham, Eat Your Genes: How genetically modified food is entering our diet, 27 (Zed Books Ltd. 2d ed. 2003)

[3] Richard Raymond, et al. Recombinant Bovine Somatotropin (rbST): A Safety Assessment 2010. Initially presented at the Joint Annual Meeting of the American Dairy Science Association®,Canadian Society of Animal Science, and American Society of Animal Science. Available at http://www.elanco.us/products/pdfs/posilac/Recombinant_Bovine_Somatotropin_rbST_-_A_Safety_Assessment.pdf

of body tissues, and calls for the allocation of more nutrients to milk synthesis than to other processes in the body.[4]

Before the development of current technology farmers found that injecting cows with pituitary extracts, which contain the hormone bST, increased their milk yields. More bST in a cows system means more milk production. This affects the normal two phase cycle of lactation by stimulating extra milk production during the initial break down phase where more milk is made from the catabolic break down of tissues. This phase is then, similar to the normal lactation cycle, followed by a period during which the tissues that were broken down for milk production are built back up.[5]

However, the limited supply and poor quality of this additional hormone through pituitary extract limited its use and effect on milk production operations. Efforts to purify the hormone from the pituitary extracts in order to increase its quality proved similarly fruitless. This led to the research and development of the artificial version of this hormone, rbST. Initially there were four different companies who produced similar, but slightly different genetic variants of bovine Somatotropin.[6] It took Monsanto, the leading manufacturer over 6 years to bring the product to market.[7]

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[4] *Id*. at 2.

[5] Dairy Debate, *supra* note 1 at 70.

[6] *See Id*. at 69.

[7] Libby Moulton, Labeling Milk from Cows Not Treated with rbST: Legal in all 50 States as of September 29th, 2010. The Columbia Science and Law Technology Law Review, Volume XII. Available at http://www.stlr.org/2010/10/labeling-milk-from-cows-not-treated-with-rbst-legal-in-all-50-states-as-of-september-29th-2010/

The recombinant form of this naturally occurring bovine hormone is produced with the help of modified micro-organisms, and then the resulting concoction is injected into the cow. In order to make this a possibility it was first necessary for scientists to isolate the hormone from the pituitary gland of cows, and identify the DNA coding sequence of the protein that coded for the hormone. These sequenced bST genes were then placed into vectors[8] where they were cloned by the *Escherichia coli* bacterium. The techniques for this procedure were adapted from those that scientists were familiar with from the development of procedures to produce insulin or other medicinal hormones in bacterial vectors.[9] After the cloning procedure is complete the bacterial vectors are killed and the hormone that was produced is extracted from the bacteria and purified.[10]

During this period of technique and product development several different companies were synthesizing slightly different forms of rbST. Slight changes were made to the amino acid sequence of the recombinant hormone for either functional purposes such as ease in synthesis, or for practical reasons such as ease in patenting. Post production the hormone is stored in sterile vials from which it can be directly injected into the cows to increase milk production. With injections every 14 or every 28 days milk production can be increased between 15 and 25 per cent.[11] The hormone injections work by allowing the continuation of milk production at the part in the lactation cycle where

[8] Nottingham, *supra* note 2 at 28.

[9] *Id.*

[10] *Id.*

[11] R. Deakin, 'BST: the first commercial product for agriculture from biotechnology', 64-73 in P. Wheale and R. McNally (eds), *The Bio-Revolution* (Pluto Press, 1990).

the level of milk production typically begins to decrease.[12] Data on use of rbST in dairy cows as of 2009 indicates that at that time rbST was used in the production of milk in more than 30 million cows in the U.S.[13]

Potential Benefits.

Perhaps the most obvious benefit of this technology is that it leads to more milk production. Since milk is a nutritious part of our diet starting in infancy, having a dependable supply of this product is of special importance to consumers. Being able to produce more milk from the existing stock of dairy cows could mean more milk without increasing the resources needed to make that milk. This means potentially more supply of milk without a need for more space, more food, or more time and money spent on animal care.

More milk production per cow without an increased demand for resources could lead to decreased costs in milk production overall, which could make an impact on lowering prices of milk at the market. If there is, in fact, as determined by the Food and Drug Administration (FDA), no material difference between milk that is produced using rbST and milk produced without it, then this 15-25 per cent increase in milk production per cow could go a long way to providing people with a steady supply of lower costing nutritional milk products.

Potential Concerns.

[12] Raymond, *supra* note 3.

[13] *Id*.

A lower cost supply of such an important part of our diet seems like a tremendous benefit, but if there were no potential downside then there would be no debate. The main concerns fall into a host of categories including the concern over biotechnology in food generally, concern over the effects on animal health, concern over the effects on human health, as well as concern for negative economic impacts on smaller local farms. Furthermore, there is also some debate over whether the benefits of increased production actually come without any complementary costs in the production process for farmers who do choose to use rbST in milk production.

One potential effect of using this artificial hormone to increase a cows production of milk is that it may lead to mastitis in the dairy cow.[14] Mastitis is a bacterial infection of the cow's udder. [15] While this increase in the occurrence of infection may be troubling enough, the trouble does not stop there. In order to treat these infections, or in some cases even to prevent them, farmers dose the cows with antibiotics. The United States Government Accountability office voiced concerns about the increased infection rate and what that might mean for the levels of antibiotic residue in milk products.[16] The FDA and the producers of rbST argue that this is not a problem, because there are currently screening measures in place that test the levels of antibiotics in milk and call for discarding the milk if the levels are above that which is considered acceptable.[17]

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[14] *See* Christina Cusimano, *rbST, It Does a Body Good?: rbST labeling and the Federal Denial of Consumer' Right to Know*, 48 Santa Clara L. Rev. 1095, 1098-1102 (2008) (discussing the potential negative effects of rbST that may lead to effects on human health); *see also* Dairy Debate, *supra* note 1 at 74-98 (discussing the potential negative effects of rbST including human and cow health as well as economic effects).

[15] *See* Cusimano at 1101.

[16] *Id*.

[17] *Id*. at 1102.

However, these tests do not screen for all the possible antibiotic options, but only the top four most commonly used.[18] Furthermore, increased rates of mastitis in dairy cows can also lead to increased pus content in the milk, which contributes to faster spoiling and decreased quality in the product.[19] Thus, this effect can potentially have negative impacts on the animal, the product, and the health of the consumer.

Another concern of the use of rbST in milk production stems from the fact that increased levels of Insulin-like Growth Factor-1 have been detected in cows that are treated with the hormone.[20] While there is no definitive evidence that this will have negative impacts on human health, there is some evidence that suggests that this may contribute to premature growth in infants as well as be correlated with an increased occurrence of both breast and gastrointestinal cancers.[21] Monsanto, the leading seller of rbST, did not conduct any long term studies to identify the degree or existence of these potential effects on any long term basis. [22]

Furthermore, and from a completely different prospective, there are concerns over the potential impact that the continued use of the hormone may have on farms who choose not to use the hormone.[23] This is especially of concern in instances where farmers who are not using rbST cannot label their milk as such, and thus lose the benefits that

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[18] *Id*.

[19] *Id.*

[20] *Id.* at 1103.

[21] *Id.* at 1104.

[22] *Id.* at 1105.

may stem from the appeal that this would have to consumers. If farmers who are using rbST are able to reduce prices of their milk as a result of increased production, this will give them a competitive advantage over the farmers whose production continues at the same level. Over time this may either push some farmers out of business, or in the alternative drive more and more farmers to use rbST over time, thus lessening the availability of untreated milk as time goes on. At this point, after ten years of use without any real indication of a serious detrimental impact in this arena, this fear may be unwarranted. Many consumers and retailers seem to be fighting back and demanding milk from untreated cows. The ongoing controversy over labeling indicates that processors who do not use milk from treated cows do still have a desire to differentiate themselves, which may indicate that there are some effects of an inability to use absence labels on the products, and that the fight may not be over.

The last negative effect that will be addressed here is less of a negative effect, and more of a counter to the arguments in favor of the use of rbST. While the addition of more of this growth hormone does unarguably increase the production of milk from cows that are treated, the actual benefits of this increased production are disputed. Cows that are treated with rbST require more feed, as they need more energy to turn into milk during the milk production phase.[24] There is also potential for increased costs to the farmer concerning mastitis issues. The farmer will have to treat the infection and pay for antibiotics, or they will have to preemptively treat their stock which also means paying for antibiotics. Furthermore, there is the potential for decreases in productivity if an

[24] *See generally* Foltz, J and Chang, H, The adoption and profitability of rbST on Connecticut dairy farms, American Journal of Agricultural Economics, 2002, 84: 1021-1032 (showing "there is no evidence that it [rbST] increases profits on a per cow basis."); *see also* Nottingham, *supra* note 2 at 29 (describing hidden costs which may arise from long term rbST use).

animal can't produce for a period of time due to infection, or more seriously, the loss of an animal due to an infection that goes untreated. The farmer may run into issues with the infections becoming resistant to the antibiotics[25] that they typically use to treat them due to overuse, which will cause the farmer to have to resort to different, potentially more expensive, forms of antibiotics.

There is also the issue of the costs associated with the purchase of the actual rbST product to inject into the cows in order to increase the production in the first place. Lastly, the farmer must take into account the consumer demands, and the effects this may have in lowering the market for the product. This effect may increase as consumers become more and more aware of the product and potential problems with rbST use. Clearly this is a complicated mix of factors to consider in determining any true monetary benefit that really stems from using rbST in production, and makes in nearly impossible to determine on which side of the scale the weight will fall.

The FDA's Approach to Food regulation and the Labeling Dilemma

First, it is essential to understand what role the Food and Drug Administration plays in the regulation of this product, and where they are granted the power to do such regulation. The FDA is the agency in charge of regulating food, drug, animal drug, medical device and cosmetic safety[26] to ensure that these products, which are distributed

[25] *See* Martin Donohoe et al., A public health response to Elanco's "Recombinant Bovine Somatotropic (rbST): A Safety Assessment,"(2009) http://www.nffc.net/Issues/Dairy/12.11.09%20Elanco%20Rebuttal%20on%20rBST.pdf.

[26] *See generally* Federal Food Drug and Cosmetics Act, 21 U.S.C. § 301-395 (2002).

through interstate commerce, are "free from deleterious substances."[27] The agency regulates these substances through its power granted in the Federal Food, Drug, and Cosmetics Act (FFDCA).[28] When regulating food standards, it is directed that the FDA formulate and enact regulations "[w]henever ... such action will promote honesty and fair dealing in the interest of consumers."[29] The FDA also has the power to regulate product labeling and potential instances of misbranding under the same act.[30]

It is important to next have an awareness of the methods through which the FDA approves food products created through biotechnology. It is the *product* that is regulated by the FDA, and not the *process*. This means that products that are created through the process of biotechnology are judged by the FDA through the same standards as food produced through conventional methods.[31] If the product is materially different[32], for instance if there is a change in the nutritional composition of the product, or there was a possible allergen used in the process, then labels may be required. However, in the

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[27] Anne Miller, The National Agriculture Law Center, Time for Government to Get Mooo-ving: Facing Up to the RBST Labeling Problem (1995), http://www.nationalaglawcenter.org/assets/bibarticles/miller_time.pdf.

[28] Federal Food Drug and Cosmetics Act, *supra* note 26.

[29] *Id.* at § 341 (stating the FDA may fix and establish a "reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container.")

[30] *Id.* at § 352 (indicating that a substance is "misbranded if its labeling is false or misleading").

[31] Food and Drug Administration, U.S. Department of Health and Human Services, "FDA's Policy for Foods Developed by Biotechnology," CFSAN Handout, (1995) http://vm.cfsan.fda.gov/~lrd/biopolcy.html, (indicating that the FDA"…believe[s] that most of the substances being introduced into food by genetic modification…are substantially similar to [conventional] substances.")

[32] "Background Document: Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon," (2010) http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm, (A material difference is a term used by the FDA to mean that two products "differ materially in nutritional value, organoleptic properties, or functional characteristics. Therefore, FDA does not consider the fact that a food was made using genetic engineering, in and of itself, to be a material difference.")

absence of one of these material differences, the FDA does not have the authority under the FFDCA to require labels solely because the process of genetic engineering was used in the creation of the product. [33]

For a probationary study period, the FDA initially ruled that milk from rbST treated cows kept in experimental herds was safe for human consumption, and limited amounts of milk from these cows was introduced to the food supply before its final approval. In 1993 the Food and Drug Administration approved rbST to be used in dairy cows as a means to increase marketable milk production.[34] The agency approved the use of rbST after they came to the conclusion that the product is "safe and effective for dairy cows, milk from rbST-treated cows is safe for human consumption, and that production and use of the product do not have a significant impact on the environment". The FDA determined that there was no "significant difference" between milk from cows that were treated with rbST and milk from cows that were not. [35]

Because of this determination the agency concluded that they did not have authority, under the Federal Food, Drug, and Cosmetic Act, to require that milk from rbST-treated cows carry any special labeling. The FDA did state, however, that processors who do not use any milk from supplemented cows may choose to make this

[33] *Stauber v. Shalala,* 895 F.Supp. 1178 (W.D.Wis.,1995) (Here the Wisconsin Federal Court determined that absent evidence of a material difference, the FDA could not require additional labels, specifically in the case of rbST milk products).

[34] Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, *58 Fed. Reg. 59946* (Nov. 12, 1993) (approving "Posilac (registered) is a recombinant deoxyribonucleic acid (DNA)-derived (i.e., biotechnology-derived) new animal drug….The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect [its] approval…in lactating dairy cows to increase the production of marketable milk.")

[35] Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 52 Fed. Reg. 6279 (Interim Guidance, February 10, 1994).

fact known to customers by labeling their products as such, as long as any statements on the label are determined to be truthful and not misleading.[36]

Soon after the approval, and the statement about labeling options, the FDA began receiving requests for guidance on labeling milk products coming from cows that were not receiving this newly developed form of hormone. The FDA responded to these requests in February of 1994 in its publication of the "*Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have not Been Treated With Recombinant Bovine Somatotropin."*[37]

In this guidance, the FDA identified concerns with any labeling regarding rbST could in fact be considered false and misleading.[38] Under the Federal Food, Drug, and Cosmetic Act products with false or misleading statements on their labels will be considered misbranded, and thus will be found to be unlawful. [39] Labels that imply a difference in the *composition* of the milk[40], such as those stating "rbST free" are discouraged under the guidance because there is no way to differentiate between naturally occurring bST and recombinant bST.[41] Furthermore, labels that indicate "hormone free"

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[36] *Id.*

[37] *Id.*

[38] *Id*.

[39] Federal Food Drug and Cosmetics Act, *supra* note 26 at § 343

[40] Voluntary Labeling, *supra* note 35(the FDA makes the distinction between the production process of the milk (some milk is produced through the use of rbST and some is make without the genetically modified hormone) and the composition of the milk product).

[41] *Id*

will also be considered false under the labeling guidance because in fact all milk contains some level of bST.[42]

Labels that imply a *production* difference, such as those stating "this milk comes from cows not treated with rbST" are favored over composition claims, but the FDA indicates that even these statements can be misleading if they are out of context.[43] Concerned over the possibility that these statements may indicate to consumers that milk from cows not treated with rbST is of better quality or safer than milk from cows that are treated the FDA encourages an accompanying disclaimer statement to put the label into the proper context.[44]

It is also advised in this interim guidance that, since there is in fact no way to analytically differentiate between the two types of milks, in order to be able to substantiate any labeling claims manufacturers who choose to use such claims must maintain records of their milk sources to verify the claims they make.[45] In essence, the producer of a product that contains a "made from cows not treated with rbST" label must keep record and be able to track all sources of milk back to suppliers who, in fact, do not use rbST.

Thus it is the standpoint of the FDA that rbST is safe for human consumption. Furthermore if processors choose to make use of labels indicating an absence of the use

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[42] *Id.*

[43] *Id.*

[44] *Id.* (Such a disclaimer may read "no significant difference was found between milk derived from rbST-treated-cows and non-rbST-treated-cows.")

[45] *Id*.

of rbST in milk production they are advised to do so with caution, as to not create labels that are false or misleading to the consumer. Finally, if such labels are used, processors are advised that they should be able to track the sources of their product such that they will have the ability to validate any claims they choose to make.

The Consumers Points of View

Since food is a necessary component of our day to day lives, consumers tend to take an active role in scrutinizing all aspects of food, from the way it's produced to the costs of the food.[46] As technology advances and novel processes are added to the food production chain, consumers are increasingly concerned with this aspect of food safety. [47] Throughout the introduction of all kinds of genetically engineered (GE)[48] food products into our food supply, consumers have expressed concerns with these products, and have felt that they have a right to know what is in their food. Labeling products that contain GE ingredients as such would give the consumer the right to choose whether or not they want to consume GE foods, as well as allow them to stay away from any products that may cause them problems.

[46] Hwang, Yun-Jae, Brian Roe, and Mario F. Teisl. *An Empirical Analysis of the United States Consumers' Concerns About Eight Food Production and Processing Technologies*. AgBioForum 8(1)(2008): 40-49 at 40.

[47] *Id*.

[48] This term may often be confused with, or used interchangeable with, genetically modified. The FDA's standpoint is that all food crops have been modified by plant breeders, and thus all crop foods are "genetically modified". Genetic engineering however is the process through which technology is used to modify or change the DNA of an organism in order to change a displayed characteristic of that or another organism.

However, are labels really needed if the authority that we have entrusted with the safety of our food supply has determined that there are in fact no significant differences between many GE foods and their conventional counter parts? Requiring labels on GE foods would surely cause an increase in food prices, and this increase would affect both consumers who do have a desire to know, as well as those who do not. Furthermore, those who do desire to eat only non GE foods already have an option – certified organic products, by definition, may not contain and ingredients that use GE production methods.[49]

One study that demonstrates consumer attitudes specifically towards rbST milk indicated that "the provision of labeling information increased the quantity demanded of rbGH-free milk…"[50] The study analyzed purchase data of labeled milk, compared to purchase data from unlabeled milk. The purchase differences confirmed findings of previous studies that were based on surveys of consumer attitudes. This study actually demonstrates the practical effects of these attitudes on consumer behavior at the market. Furthermore, there was "no evidence that consumer preference for rbGH-free milk products have diminished since the introduction in 1994… rbGH-free fluid milk demand appear[s]…to have increased in the period 1998-1999 as compared to 1995-1997."[51] This suggests that food processors, who hypothesize that the consumer concerns over GMO

[49] P. Byrne, *Labeling of Genetically Engineered Foods* (Colorado State University Extension, 2010). Available at http://www.ext.colostate.edu/pubs/foodnut/09371.html

[50] Kristen Kiesal et al., *Consumer Acceptance and Labelling of GMOs in Food Product: a Study of Fluid Milk Demand*, 20-21 in R.E. Evenson and V. Santaniello (eds.), Consumer Acceptance of Genetically Modified Foods (CAB International, 2004) .

[51] *Id.*

products will diminish over time in response to a lack of evidence about adverse health effects, may be wrong." [52]

In a different survey of consumer attitudes to different types of food technologies, artificial growth hormones ranked second highest on the list of concern when compared with seven other processing techniques or technologies.[53] This study did seem to indicate that consumers were most concerned with those technologies that were newer, and that they were less familiar with, when compared to technologies or processes that were older and that the customer was used to. However, the study did recognize that unfamiliarity isn't the only driving force, and that consumers are also concerned with health and environmental impacts, as well as the possibility for residuals of the technology to be left on the product. [54]

It is also important to consider whether any preference in consumer habits or opinions are based on their careful valuation of the attributes of the product, or whether they are based on an impulsive response to the label.[55] Consumers who are informed about the product may respond to the information on a label in a different way than a consumer who sees the label without any background knowledge. The consumer who has

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[52] *Id.*

[53] Hwang, Yun-Jae et al., *supra* note 47(Technologies surveyed included pesticides, artificial growth hormones, antibiotics, GM ingredients, irradiation, preservatives, artificial flavors/colors, and pasteurization. This list is in order of consumers concern rankings from highest concern to lowest concern).

[54] *Id*.

[55]*See* Kolodinsky, Jane. *Affect or Information? Labeling policy and consumer valuation of rBST free and organic characteristics of milk*. Food Policy 33 (2008) 616-623(Finding that if consumers' choices are driven by unbiased information, then labels will allow them to execute their purchases based on this information. However, if consumers are basing their decision on impulsive reactions to the labels at the time of purchase then the labels may do more harm than good).

no prior knowledge will benefit more from products that have more detailed labels, such as those that contain disclaimers[56], to prevent an impulsive assumption that if its labeled "rbST free" it must be better than something that contains rbST. In an uninformed consumer, this disclaimer can alleviate and misleading attributes of a standalone label.[57]

All of this creates a hard job for those involved with labeling regulations. A balance must be struck between satisfying the consumers desire to know about things that are in their food that concern them, and making sure that their desire to know is satisfied in a format that will present all the facts without misleading the consumers' opinions of the products.

The States Respond and the Federal Court Weighs in: **The case of the Ohio Department of Agriculture's Anti-Absence Labeling rule**

The case of the validity of a forced labeling requirement found itself in the Second Circuit in 1996, with a challenge to a Vermont statute that required milk to be labeled if rbST was used in the production process.[58] However, until recently, no challenges to absence labeling restrictions had been decided by a federal court. The case

[56]*See* Voluntary Labeling, *supra* note 35(for example the FDA recommended "no significant difference has been shown between milk derived from rbst-treated and non-rbst-treated cows.")

[57] *See* Kolodinsky, *supra* note 56, (showing that the more unbiased information a consumer has the less likely they are to make a decision based on attitude, and more likely they are to make a decision based on actual preference).

[58] *See International Dairy Foods Association v. Amestoy*, 92 F.3d 67 (2nd Cir. 1996) (Where the court held that a Vermont statute requiring all milk produced from cows that were given rbST to be labeled as such was unconstitutional in violation of the plaintiffs First Amendment rights. The statute required that all milk that came from cows that were supplemented with rbST be labeled with a blue sticker to indicate the use of the synthetic hormone in production. The court relied on the FDA's published interim guidelines and found that although there was a strong interest in consumers for labeled milk, there was no substantial state interest that followed considering that the FDA had found no significant difference between the two types of milk).

of rbST absence labeling made its way to Federal Court in the Sixth Circuit in June of 2010.[59] Several dairy processors had taken to using labels advertising their nonuse of rbST in their milk production process. The Ohio Department of Agriculture (ODA) responded to this behavior by enacting a regulation that would thwart the use of such labels in an allegedly misleading fashion.[60] The rule was adopted in May of 2008, and reads in relevant part:

> (A) …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 …unless:
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> > (1) The labeling entity has verified that the claim is accurate, and proper documents… 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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> (C) Making claims regarding the composition of milk … such as "No Hormones", "Hormone Free", "rbST Free", "rbGH Free", "No Artificial Hormones" and "bST Free", is false and misleading…
> (D) Statements may be considered…misleading if they indicate the absence of a compound not permitted by the…FDA to be present in any dairy product...Except as otherwise provided in this rule, accurate production claims will not be deemed false or misleading.[61]

[59] *See Generally International Dairy Foods Association; Organic Trade Association v. Boggs*, 622 F.3d 628 (2010).

[60] Ohio Admin. Code § 901:11-8 (2008).

[61] *Id.*

Soon after the rule was adopted by the ODA, claims were brought separately by the International Dairy Foods Association (IDFA) and the Organic Trade Association, against Robert Boggs as the Director of Agriculture in Ohio. These claims were later combined into the case discussed here. The processors alleged that the labeling rule violated their First Amendment rights to free speech, as well as the dormant Commerce Clause.[62] The court addressed these claims in three parts: the challenge to the prophylactic ban on composition claims, the challenge to the disclosure requirement for production claims, and the challenge to the dormant Commerce Clause.[63] I will address each of these in turn.

Disclosure Requirement.

The ODA rule starts by limiting the circumstances in which a dairy label containing a production claim may be used.[64] The rule advises that production claims, for example a label stating "this milk is from cows not supplemented with rbST," may be considered misleading unless "the labeling entity has verified that the claim is accurate, and proper documents…are made readily available to ODA."[65] Furthermore, the label must also contain a disclosure statement substantially equivalent to the following: "The

[62] *See International Dairy, supra* note 59, at 634. (Petitioners also claimed unconstitutional vagueness, preemption by the OFPA, and equal protection violations, however it is only the District Courts rulings on their First Amendment rights violation and dormant Commerce Clause violations that were appealed to the Circuit Court.)

[63] *Id.*

[64] Ohio Admin. Code, *supra* note 60.

[65] *Id.*

FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows."[66]

The Sixth Circuit started its analysis by identifying the applicable analytical framework under which to examine the disclosure requirement. The court comes to the conclusion that in this case, where there is a reasonable relationship to a State interest[67], the *Zauderer*[68] test should apply.[69] In order to pass muster under the *Zauderer* test, the ODA rule's disclosure requirement must be "reasonably related to the State's interest in preventing deception of consumers" and must not be "unjustified or unduly burdensome" on the processors.[70]

While the court did recognize a legitimate government interest, they went on to find that there was no reasonable relation "between this concern and the 'contiguous' requirement of such a disclosure." [71] Requiring the disclosure to be in the same label panel in effect proscribes the processors from setting the disclosure aside with an asterisk. In finding that there was no rational basis for this contiguity requirement the court based

[66] *Id*.

[67] *International Dairy, supra* note 59, at 641(Finding that the state has a legitimate state interest in "preventing consumers from being deceived by production claims.")

[68] *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471U.S. 626 (1985).

[69] *International Dairy, supra* note 59, at 640-641 (Petitioners contended that the court should apply the stricter *Central Hudson* test to the disclosure requirement. But the court relied on *Milavetz, Gallop, &Milavetz, P.A. v. United States*, 130 S. Ct. 1324 (2010) where the Supreme Court established that *Zauderer* is the applicable test to apply to disclosure requirements regulating "*misleading* commercial speech." While the *Milavetz* case dealt with a situation of inherently misleading statements, and the case before the court dealt with what they determined to be only potentially misleading statements they still found that the *Zauderer* test applied.)

[70]*See Zauderer, supra* note 68.

[71] *International Dairy, supra* note 59, at 643(The rule requires the disclosure to be "in the same label panel, inexactly the same font, style, case, and color and at least half the font size" of the production claim. The court saw a connection between the font requirements and the State's interest).

its decision on the fact that Director Boggs had no supporting evidence that the use of an asterisk would cause any confusion to consumers. Without a demonstrable link between the proscription and the government's interest in preventing consumer confusion, the limitation cannot be seen to realize its purpose.[72]

Petitioners further argued that the disclosure requirement was unduly burdensome, as it hindered their ability to compete in interstate commerce.[73] However the court finds this claim unwarranted in light of their other findings.[74] The petitioner's main concerns were with the restriction on the use of asterisks which the court already found to be unconstitutional.[75] The rest of the disclosure section of the rule, the court says, is similar to that of other states. Furthermore, the petitioners presented no evidence that any of the remaining requirements (i.e. font size) would impair their ability to convey their message to consumers.[76]

The court thus held that the banning of the use of asterisks in the formatting of the disclosure requirement did not pass the *Zauderer* test. However the rest of the ODA's disclosure requirement was reasonably related to the State's interest, and was not unduly burdensome to the processors, and thus it was upheld.[77]

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[72] *International Dairy, supra* note 59.

[73] *Id.* at 643.

[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] *See generally Id.*

*Prophylactic Ban***.**

The ODA rule also contained a provision which imposed an across the board ban on advertising claims that dealt with milk composition in relation to hormone content.[78] Labels that contained statements such as "rbST Free" would be considered de facto false and misleading, and would therefore not be permitted by the ODA.[79] Processors contended that this prophylactic ban was a violation of their First Amendment right to free speech.[80]

The court first identified this type of speech as commercial speech, with which both parties to the case agreed.[81] Under the First Amendment commercial speech is afforded less deference than noncommercial speech. Commercial speech that is truthful and related to lawful activities is afforded protection under the First Amendment.[82] However if the speech is "false, deceptive, or misleading" then the government is entitled to intrude on its dispersal.[83]

In order to determine the validity of the prophylactic ban, the court goes into a set of successive tests which were set forth in *Central Hudson*.[84] First, the court must

[78] Ohio Admin. Code, *supra* note 61, at § C.

[79] *Id.*

[80] *International Dairy*, *supra* note 59, at 635.

[81] *Id.*

[82] *Id.* at 636, citing *In re R.M.J,* 455 U.S. 191 (1982).

[83] *Id.*, quoting *Zauderer*, *supra* note 68.

[84] *Id.* at 635.

determine if the speech concerns "unlawful activity or is misleading."[85] If the court comes to an affirmative conclusion on either of those elements, then the speech is unprotected under the First Amendment, and thus the analysis comes to an end. If, however, the court comes to a negative conclusion on both of those elements, then it must inquire further into "(1) whether the asserted government interest is substantial, (2) whether the regulations directly advances that interest, and (3) whether the regulation is more extensive than necessary to serve the asserted interest." [86]

In this analysis the district court had determined, on the first step of the analysis, that the composition claims were inherently misleading because "they imply a compositional difference between those products that are produced with rbST and those that are not" which is contrary to the findings of the FDA that there is in fact no measurable difference between the two.[87] However, on appeal, the circuit court disagrees. They find that there is in fact a compositional difference between milk from cows treated with rbST and those that are not.[88]

The circuit court points to studies which were presented by amici parties which indicate that using rbST in the production of milk can cause a number of compositional differences.[89] First, the use of the bioengineered hormone has been demonstrated to increase levels of Insulin-like Growth Factor-1, which is known to be linked to

[85] *Id.* at 636, citing *Central Hudson Gas and Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980).

[86] *International Dairy*, *supra* note 59.

[87] *Id.* at 635.

[88] *Id.* at 636.

[89] *Id.* at 637.

development of several types of cancers when it is in elevated levels.[90] The amici also point to several studies which indicate that the use of rbST in milk production may lead to lower quality milk with an increased fat content and decreased level of protein.[91] Lastly, milk from rbST treated cows may turn sour more quickly because it contains higher somatic cell counts that milk from untreated cows.[92] Based upon this evidence, the circuit court finds that there is indeed a compositional difference between the two types of milk.[93]

As another point in this preliminary test the court indicates that the fact that rbST cannot be detected in milk is not dispositive that it is not in the milk, but is rather a result of the lack of available technology to allow rbST detection.[94] The court points to the FDA's concession in its 1994 guidance which states that "there is currently no way to differentiate between naturally occurring bST and rbST in milk."[95] The court finds this statement to mean that the FDA has left undetermined the possibility that there may, one day, be a method that would differentiate between the two, and would thus allow us to determine if there was in fact rbST present in milk from treated cows.[96] However this seems to raise the concern that if the rbST is not currently detectable how are we to know

[90] *Id.*

[91] *International Dairy, supra* note 59 at 637 (referring to study presented by amici indicates that this is due to more milk production during a cows negative energy phase, which is an unnatural time to be producing milk).

[92] *Id.* (referring to study that shows high somatic cell count is also an indicator of poor milk quality).

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] *Id.*

that those who claim their milk is rbST free really is in fact free of rbST? The court does not see the possible for deception as an issue, and rather states that the above evidence collectively indicates that there are in fact two distinct types of milk – that which comes from cows who have never had rbST in their system and that which comes from cows that have.[97] In the first case, the court concludes that this milk will never have rbST in its contents, whereas in the second case it may. It seems though, that the problem remains on how we can differentiate between them at this point. But the court says that even if rbST is never to be found present in the milk, there are still other demonstrable differences that indicate compositional superiority of milk from untreated cows.

As such, the court finds that the "rbST free" types of claims "at best inform the consumer of a meaningful distinction between [rbST milk] and other types of milk and at worst potentially misleads them into believing that a compositionally distinct milk adversely affects their health."[98] With this spectrum in mind the court finds that it cannot hold these statements as being inherently misleading, and thus must move forward in its analysis and apply the remaining *Central Hudson* factors to determine the existence of a First Amendment Violation.[99] All three of the remaining factors would need to be upheld in order for the ODA rule to be upheld.[100]

The first of the three remaining factors, "whether the State's asserted interest is substantial," is addressed by looking to the purpose of the ODA rule, and the State's

[97] *International Dairy*, *supra* note 59.

[98] *Id.*

[99] *Id.*

[100] *Id.*

burden to demonstrate that it is asserting a real danger and that its method of alleviation will in fact alleviate the danger.[101] The identified interest, again, is to prevent the use of "false or misleading" labeling. But the court finds any evidence of deception to be "weak at best."[102] As its main piece of evidence the ODA offers comments made to its proposed rule, which the court finds to be unhelpful in showing any signs of any real deception stemming from the labels.[103] The court stops its analysis on this point short by saying it need not address the issue in detail because the court concludes that the ODA rule does not meet the final two prongs, as it is "not directly advance[ing] the State's interest and is more extensive than necessary to serve that interest." [104]

The last two factors are addressed by the court simultaneously. If there are less burdensome alternatives, and no reasonable fit between the more burdensome alternative and the State's goal, then the State's action cannot be upheld.[105] Petitioners suggest that any possibility of deception could be alleviated by including a disclosure statement that would inform customers, similar to that required for the production claims discussed above.[106] The court agrees. Since there are in existence methods "by which the potential difference between the two types of milk can be presented without also being deceptive"

[101] *International Dairy*, *supra* note 59 at 638.

[102] *Id.*

[103] *Id.* at 638-639.

[104] *Id.*

[105] *Id.*

[106] *Id.*

the absolute prohibition of composition claims must be overturned under the *Central Hudson* analysis framework.[107]

*Dormant Commerce Clause***.**

Under the Constitution, the right to regulate commerce among the several states is a power granted to congress. While the text of the Constitution actually grants this affirmative power, the Commerce Clause has been long recognized as also a limiting power on the states. This limiting power serves in preventing states from enacting legislation which would burden such commerce. In order to determine if a state has imposed a regulation in violation of this negative power, the court goes through a series of three analyses: (1) whether the rule governs extraterritorially; (2) whether the rule is protectionist and (3) a balancing test of the rule's burdens and benefits. If a rule if found to be either extraterritorial or protectionist, then it will be found to be per se invalid under this analysis. If it is neither of those, then the court will move on to the deferential balancing test set forth in *Pike*.[108]

In assessing any extraterritorial governing of the ODA rule the court looked to prior decisions concerning price fixing statutes which the Supreme Court struck down as having improper extraterritorial direct effects. The court differentiated the ODA rule from the price fixing statutes because there is no direct effect on out of state conduct, nor is

[107] *International Dairy*, *supra* note 59.

[108] *Id.*

there a direct effect on the Ohio processors' out-of-state labeling conduct.[109] Furthermore, the ODA rule was not found to "impede or control the flow of milk products across the country."[110] Therefore, the rule does not implicate any regulation of "conduct occurring wholly outside the state" and the processors' argument that the rule violates the dormant Commerce Clause due to extraterritorial regulation is rejected.

Since the court found no extraterritorial governance, they moved on to the second part of the analysis to determine whether or not the ODA rule violates the dormant Commerce Clause as being protectionist.[111] A protectionist rule is one that treats in state and out of state economic interests differently by favoring those that are in state.[112] The processors alleged that the ODA rule had a discriminatory purpose, but the discrimination they allege seems to be against individuals who want to advertise the sale of rbST free milk regardless of whether they are in state, or out of state. This lack of differentiation between individuals in and out of state undermines their argument.[113] The processors also present an argument that the ODA rule is discriminatory in effect, but once again the

[109] *International Dairy*, *supra* note 59, at (finding that "the rule does not purport to regulate conduct occurring wholly outside the state as compliance with the rule does not raise the possibility that the processors would be in violation of the regulations of another state.")

[110] *Id.* at 647

[111] *Id.*

[112] *See Id*. at 648 (where the court further describes ways in which a regulation may favor in state commerce over interstate commerce as falling into three categories: (a) facial discrimination, (b) purposeful discrimination, or (c) practical effect discrimination. The processors in this case allege the latter two of these).

[113] *See Id.* (where the court says that the processors argument is undermined by their own evidence that the legislation may have been driven by lobbying efforts by Monsanto to prevent *Ohio* dairy processors from switching to using milk from cows not treated with rbST).

court finds that any discriminatory effect is equal between in and out of state processors, but rather differentiates only between products.[114]

Based on these findings, that the ODA rule is neither extraterritorial in nature nor protectionist, the court must move on to the balancing test, originating in *Pike*, which requires that the rule be upheld "unless the burden imposed on commerce is clearly excessive in relation to the putative benefits."[115] The processors main argument here is that the burden on them is the fact that the more stringent ODA requirements are impeding their ability to participate in the interstate market. The Court quickly dismisses this claim indicating that it has already overturned the more stringent aspects of the rule, and that the remaining portions do not impose a significant burden on interstate commerce. Ohio has a rational basis for its legislation, which in this case is found to outweigh any burden it imposes. Thus the rule passes constitutional muster in regards to the dormant Commerce Clause under the *Pike* analysis.[116]

***Disclosure Statement.*

So what exactly does all of this, perhaps very confusing language actually mean for the ODA? In the end the Sixth Circuit found that there was a compositional difference between milk from cows treated with rbST and milk from those that were not. It held that the prophylactic ban on composition claims was impermissible, meaning that the ODA comprehensive ban on labeling with statements such as "rbST free" must be lifted. It also held that the contiguity requirement of the ODA rule, which banned the use of asterisks

[114] *International Dairy, supra* note 59 at 648.

[115] *See Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).

[116] *International Dairy, supra* note 59, at 648.

to set aside disclosure statements, was invalid. So, practically speaking, processors may label their milk as "rbST free", or label their milk as "coming from cows not supplemented with rbST." The ODA may still permissibly require a disclosure statement with all of the font size and color requirements previously included in the rule, as long as they allow the disclosure statement to be asterisked.

Was the Sixth Circuits Decision False or Misleading?

The Courts decision raises some issues of confusion, especially in the areas of separation of powers and federalism.[117] While the power to regulate food moving through the channels of interstate commerce has been clearly assigned to the FDA by congress, the Sixth Circuit has, in this case, not deferred to the agencies finding but rather has found in opposition. The court, when balancing the concerns of First Amendment protection with deference to an agencies findings, weighted more heavily on the side of First Amendment protections.

The court explicitly found that, after reviewing evidence presented by the amici, there was in fact a material difference between milk from treated cows and milk from those that are not treated with rbST. In light of the agencies presumed expertise in the area of food regulation, and its experience in the science and technology involved in the process of making such decisions with regard to food safety and labeling, this decision may seem suspicious.

Furthermore, what implications does this alternate finding have for the current FDA standpoint, and its position that it does not have the authority under the FFDCA to

[117] Cordaro Rodriguez, *Ban on Milk Labeling Violates First Amendment – International Dairy Foods Ass'n v. Boggs*, 39 J.L. Med. & Ethics 96 (2011).

impose mandatory labeling requirements on milk from treated cows? If the federal courts decision could be seen as being effectively overruling the FDA's finding, then the FDA in essence may now be required to change their standpoint and enact legislation that does require labeling.[118] Since the FDA has seen this as an area of mainly state regulation, this is where the issues of federalism may come in to play. At the very least, this discrepancy in the findings of the FDA, compared to those of the federal court, will cause consumers and processors alike to look to the FDA for some kind of explanation.

Conclusion: The Future of rbST

Labeling.

After the Sixth Circuit decision there are a couple potential changes that may come into play regarding the labeling of milk. Other states may, after hearing of this decision, decide to enact or amend current legislation to allow for absence labeling that is consistent with the court's findings. This is especially true for states that currently have legislation in effect banning a processors ability to place absence labels on their dairy products. If states with such legislation do not decide to amend legislation that is in violation of the court's decision, and they are in another federal district, there is the potential that in the near future we will see the perspective of courts from other districts – which may in turn lead to the potential for a circuit split and the case winding up in the Supreme Court. Furthermore, the FDA may respond, either on its own, or as a response to pressure from consumers or producers for guidance on this issue.

Use in Production.

[118] *Id.*

There are multiple factors that will play into the future use of rbST in the production of milk. First, if there are changes in labeling requirements over time this will certainly impact decisions made at the production level. If there were changes at the federal level, either deeming the product materially different from its untreated counterpart and thus requiring labeling that indicated this difference, or just a general loosening of absence labeling restrictions, then the consumer awareness that may follow could possibly have quite and impact on the sales of rbST milk.

Furthermore, if over time farmers who use rbST start to notice that the costs to them are exceeding the benefits that stem from the use of the hormone, then there may be a bottom up check on the use of this bioengineered hormone. While the supplement has been in use for well over ten years, and it may be assumed that most of the farmers using it have weighed the direct costs and benefits by now, the impact of labeling decisions similar to that in the Sixth Circuit may influence consumers and thus impact sales of rbST milk. These laws, however, unless the FDA does take action, will continue to be on a state to state basis and thus will affect farmers in the same manner.

Depending on how the decision of the Sixth Circuit is construed – either as an overruling of the FDA's determination of there being no material difference between milk from treated cows and milk from cows that are not treated, or simply as an indication to the states that relying solely on the FDA's determination will not give cause to show a substantial state interest in limiting the First Amendment right as it applies to milk labels – the effects of the decision on rbST use, as well as on milk labels will vary. Consumers' demands will also continue to play a role in the use of the hormones, as well as the demand for labeling indicating the contents of the products they consume. It is

likely that this may be just the beginning for the rbST labeling story, and that there will be more challenges and court decisions as well as words from the FDA in the future that will shape the path down which this story will go.