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# Got (rbST-free) Milk? The Sixth Circuit Overturns Ohio's Milk Labeling Restrictions

## INTRODUCTION

Over the past several decades, the United States has increasingly grown genetically engineered crops.<sup>1</sup> As genetically modified food becomes more common, so too have controversies over “Frankenfood.”<sup>2</sup> One recent controversy, played out in *International Dairy Foods Ass’n v. Boggs*,<sup>3</sup> concerns not only the usual environmental and health issues, but also constitutional free speech issues, related to genetically modified milk. In *Boggs*, the International Dairy Foods Association and the Organic Trade Association (collectively “Processors”)<sup>4</sup> claimed that regulations imposed by the Ohio Department of Agriculture violated their First Amendment rights and the dormant Commerce Clause.<sup>5</sup> The regulations at issue prohibited dairy processors from stating that their milk products do not contain recombinant bovine somatotropin (rbST), a genetically engineered artificial hormone given to cows to increase milk production,<sup>6</sup> and required dairy processors to include a disclaimer when making claims that no rbST was used in the production of their milk.<sup>7</sup> The Sixth Circuit struck down the regulations<sup>8</sup> in a victory for both the environment<sup>9</sup> and the free

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1. See *Adoption of Genetically Engineered Crops in the U.S.*, U.S. DEP’T OF AGRIC., ECON. RESEARCH SERV., <http://www.ers.usda.gov/Data/BiotechCrops/> (last updated July 1, 2010). For example, genetically engineered soybeans comprise over 90 percent of soybeans grown in the United States. *Id.*

2. See Olga Manda, *Controversy Rages over ‘GM’ Food Aid*, AFR. RENEWAL, Feb. 2003, at 5, available at <http://www.un.org/ecosocdev/geninfo/afrec/vol16no4/164food2.htm>; *Genetically Modified Foods and Organisms*, HUMAN GENOME PROJECT INFO., [http://www.ornl.gov/sci/techresources/Human\\_Genome/elsi/gmfood.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/gmfood.shtml) (last modified Nov. 5, 2008). See generally Stella G. Uzogara, *The Impact of Genetic Modification of Human Foods in the 21st Century: A Review*, 18 BIOTECHNOLOGY ADVANCES 179 (2000).

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

4. Int’l Dairy Foods Ass’n v. *Boggs (Boggs I)*, Nos. 2:08-CV-628 & 2:08-CV-629, 2009 WL 937045, at \*20 (S.D. Ohio Apr. 2, 2009), *aff’d in part and rev’d in part*, 622 F.3d 628 (6th Cir. 2010).

5. *Id.* at \*4.

6. *Boggs II*, 622 F.3d at 632. Recombinant bovine somatotropin (rbST) is also known as recombinant bovine growth hormone (rbGH). *Id.* When combined with naturally occurring bovine somatotropin (bST), rbST can increase milk production by 10 percent. *Id.*

7. *Boggs I*, 2009 WL 937045, at \*2–3.

8. *Boggs II*, 622 F.3d at 632.

market, giving consumers the freedom to choose whether to drink milk that contains artificial hormones, and enabling the market to reward dairy processors meeting the growing demand for rbST-free milk.

## I. BACKGROUND

In 1993, the Food and Drug Administration (FDA) approved the use of rbST in cows.<sup>10</sup> The FDA concluded that rbST was safe for cows, and milk from rbST-treated cows was safe for human consumption.<sup>11</sup> Furthermore, the FDA found no significant difference between milk from rbST- and non-rbST-treated cows,<sup>12</sup> and noted there is currently no test available distinguishing between bST (bovine somatotropin, a naturally occurring hormone) and rbST in milk.<sup>13</sup> While the use of rbST in dairy production has been allowed in the United States since the FDA's approval, such use has been banned in many countries, including Australia,<sup>14</sup> New Zealand,<sup>15</sup> Japan,<sup>16</sup> Canada,<sup>17</sup> and the European Union.<sup>18</sup>

Recognizing some consumers may prefer milk from cows not treated with rbST, the FDA permitted dairy processors to label their products as such, so long as any such statements were "truthful and not misleading."<sup>19</sup> The FDA issued an interim guidance document<sup>20</sup> proposing guidelines for two types of claims: composition claims, referring to the final composition of the milk or milk product (such as "rbST free"); and production claims, referring to the

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9. See, e.g., Press Release, Ctr. for Food Safety, Federal Court Strikes Down Ohio Ban on rBGH-Free Labels on Dairy Products (Sept. 30, 2010), <http://www.centerforfoodsafety.org/2010/09/30/federal-court-strikes-down-ohio-ban-on-rbgh-free-labels-on-dairy-products/>; Charles Margulis, *Ohio Victory! Court Rules GMO Milk Is Inferior to Natural Milk*, GENERATION GREEN: BLOG OF THE CTR. FOR ENVTL. HEALTH (Oct. 4, 2010), <http://generationgreen.org/2010/10/ohio-victory-court-rules-gmo-milk-is-inferior-to-natural-milk/>.

10. *Boggs II*, 622 F.3d at 632.

11. *Id.* But see Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 78 (2d Cir. 1996) (Leval, J., dissenting) ("[C]ows injected with [rbST] are at an increased risk for: various reproductive disorders, 'clinical mastitis [udder infections] (visibly abnormal milk),' 'digestive disorders such as indigestion, bloat, and diarrhea,' 'enlarged hocks and lesions,' and 'swellings' that may be permanent." (quoting warning label of Posilac, Monsanto's brand of rbST)).

12. *Boggs II*, 622 F.3d at 632.

13. Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994).

14. FOOD STANDARDS AUSTRAL. N.Z., A RISK PROFILE OF DAIRY PRODUCTS IN AUSTRALIA 92 (2006), [http://www.foodstandards.gov.au/\\_srcfiles/P296%20Dairy%20PPPS%20FAR%20Attach%202%20FINAL%20-%20mr.pdf](http://www.foodstandards.gov.au/_srcfiles/P296%20Dairy%20PPPS%20FAR%20Attach%202%20FINAL%20-%20mr.pdf).

15. *Id.*

16. *Id.*

17. *Recombinant Bovine Somatotropin (rbST)*, HEALTH CANADA, <http://www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/rbst-stbr/index-eng.php> (last modified Oct. 1, 2004).

18. Council Decision 1999/879, 1999 O.J. (L 331) 71 (EC).

19. *Boggs II*, 622 F.3d 628, 633 (6th Cir. 2010); Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994).

20. Interim Guidance, 59 Fed. Reg. at 6279.

manner in which the product is produced (such as “from cows not treated with rbST”).<sup>21</sup> The FDA noted composition claims had the strong potential to mislead consumers because either they might be false,<sup>22</sup> or they could imply that milk from rbST-treated cows was less safe even though the FDA had determined that “there was no significant difference between milk from treated and untreated cows.”<sup>23</sup> Accordingly, the FDA favored production claims over composition claims.<sup>24</sup> Even then, it worried that, without proper context, such claims could also mislead consumers.<sup>25</sup> Consequently, the FDA encouraged producers to include a disclaimer, for example, that “[n]o significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows.”<sup>26</sup>

Consumer demand for milk from non-rbST-treated cows has grown since the issuance of the FDA guidance.<sup>27</sup> In response to this increased demand, many International Dairy Foods Association members procure milk only from producers that do not use rbST.<sup>28</sup> In response to advertising by several Processor members stating that they did not use milk from cows treated with rbST,<sup>29</sup> the governor of Ohio (the State) issued an executive order directing the Ohio Department of Agriculture (ODA) to propose regulations “defin[ing] what constitutes false and misleading labels on milk and milk products.”<sup>30</sup> The ODA rule (the Rule) prohibited composition claims entirely and required production claims to be accompanied by a contiguous additional disclaimer that the “FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows.”<sup>31</sup>

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21. *Boggs II*, 622 F.3d at 633.

22. For example, while milk can be “rbST-free,” it cannot be “bST-free” because bST is a naturally occurring hormone in milk. *Id.*

23. *Id.*; Interim Guidance, 59 Fed. Reg. at 6280.

24. Interim Guidance, 59 Fed. Reg. at 6280.

25. *Id.*

26. *Id.* Furthermore, because there is currently no test distinguishing between bST and rbST, the FDA recommended states require producers to maintain records and make them available for inspection to substantiate their claims. *Id.*

27. *Boggs II*, 622 F.3d at 633.

28. *Id.* This association is a trade organization representing approximately 85 percent of dairy producers and manufacturers of dairy products, including milk, cheese, and frozen desserts. *Id.* at 632. In addition, OTA members who label their products “organic” cannot, by law, use milk from cows treated with rbST. *Id.*; see *infra* note 32.

29. *Boggs II*, 622 F.3d at 633.

30. *Id.* (quoting Ohio Governor Exec. Order 2008-03S (Feb. 7, 2008), available at [http://www.agri.ohio.gov/public\\_docs/news/2008/news\\_admn\\_020708\\_RBSTOrder.pdf](http://www.agri.ohio.gov/public_docs/news/2008/news_admn_020708_RBSTOrder.pdf)).

31. These contiguous disclaimers were required to be “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.” OHIO ADMIN. CODE 901:11-8-01 (2008).

The Processors<sup>32</sup> initiated lawsuits against the State, alleging that the Rule was unconstitutional because it violated their First Amendment rights.<sup>33</sup> After the district court granted summary judgment in favor of the State,<sup>34</sup> the Processors appealed to the Sixth Circuit.<sup>35</sup>

## II. SIXTH CIRCUIT DECISION

In a unanimous decision, the Sixth Circuit held that the Rule infringed on the Processors' First Amendment rights, reversing the district court's grant of summary judgment.<sup>36</sup>

### A. *First Amendment Challenge to the Ban on Composition Claims*

Noting that commercial speech is afforded fewer First Amendment protections than noncommercial speech, the court evaluated the ban on composition claims under the four-part test set out in *Central Hudson*.<sup>37</sup> First, the court concluded that the Processors' composition claims were not inherently misleading because, contrary to the FDA's assertions, there is a compositional difference between milk from treated versus untreated cows.<sup>38</sup> The court noted that milk from rbST-treated cows contained elevated levels of insulin-like growth factor 1, a hormone that in high levels has been linked to

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32. The OTA represents companies spanning the organic food industry, including dairy production. *Boggs II*, 622 F.3d at 632. Several members of the OTA are certified organic dairy producers and thus must comply with the Organic Foods Production Act, which forbids the use of artificial hormones, antibiotics, and pesticides in dairy products. *Id.*

33. *Id.* at 634. In addition to the First Amendment claim, the Processors also alleged that the Rule was unconstitutional because it violated the dormant Commerce Clause, was unconstitutionally vague, and was preempted by the Organic Foods Production Act, 7 U.S.C. §§ 6501–6523. *Id.* The district court consolidated the Processors' two cases into a single lawsuit. *Id.*

34. *Id.* The court granted summary judgment in favor of the State on all counts except for the Processors' First Amendment claim against the restrictions on production claims, where it granted partial summary judgment. *Id.*

35. *Id.* at 635. The Processors contested only the district court's ruling on their First Amendment and dormant Commerce Clause claims. *Id.*

36. *Id.* at 639–40, 643. The court held that the Rule did not violate the dormant Commerce Clause because it did not affect interstate commerce extraterritorially, did not favor in-state interests at the expense of out-of-state interests, and did not lack a rational basis to believe that the Rule's benefit outweighed any burden it imposed, affirming the district court's grant of summary judgment in favor of the State on the Processors' dormant Commerce Clause claim. *Id.* at 648, 650.

37. *Id.* at 635–36.

[A] court first determines whether the speech concerns unlawful activity or is misleading. If a court finds in the affirmative on either prong, the speech is not entitled to First Amendment protection, and the analysis ends. But if the court finds that the speech is entitled to First Amendment protection, it then makes three additional inquiries: (1) whether the asserted governmental interest is substantial, (2) whether the regulation directly advances that interest, and (3) whether the regulation is more extensive than necessary to serve the asserted interest.

*Id.* at 636 (citations omitted) (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980)).

38. *Id.* at 636–37.

several types of cancers.<sup>39</sup> Furthermore, rbST induces unnatural milk production during a cow's "negative energy phase," during which milk produced is of a lower quality due to its increased fat content, lower levels of proteins,<sup>40</sup> and higher levels of somatic cell counts (pus<sup>41</sup>), which makes the milk turn sour more quickly.<sup>42</sup>

Next, the State did have a substantial interest in preventing the use of false or misleading labeling.<sup>43</sup> However, the Rule did not directly advance the State's interest, and was more extensive than necessary to serve that interest.<sup>44</sup> A disclaimer would sufficiently mitigate possible consumer confusion from a composition claim because together the composition claim and disclaimer would indicate a difference between milk from treated versus untreated cows without being deceptive.<sup>45</sup> As the ban on composition claims failed the *Central Hudson* test, the Sixth Circuit held it unconstitutional on First Amendment grounds.<sup>46</sup>

### B. First Amendment Challenge to the Disclosure Requirement for Production Claims

In evaluating the Rule's restriction on production claims, the court used the more lenient *Zauderer* standard, rather than the stricter *Central Hudson* standard, because *Zauderer* applies to disclosure requirements that regulate potentially misleading commercial speech, whereas *Central Hudson* applies to outright prohibitions on speech.<sup>47</sup> The court found that the Rule's disclosure requirement for production claims was reasonably related to the State's interest

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39. *Id.* at 636.

40. *Id.* at 636–37.

41. See April Fulton, *Court OKs Hormone-Free Label on Dairy Products in Ohio*, NAT'L PUB. RADIO (Oct. 1, 2010, 4:31 PM), <http://www.npr.org/blogs/health/2010/10/01/130270131/court-give-hormone-free-label-on-dairy-products-an-ok-in-ohio>.

42. *Boggs II*, 622 F.3d at 637. The court also noted the inability to discover rbST in milk is not necessarily because rbST is absent. Rather, it is because scientists have yet to create a test to detect it. *Id.*

43. *Id.* at 638.

44. *Id.* at 639.

45. *Id.*

46. *Id.* at 639–40.

47. *Id.* at 640–41. "Under *Zauderer*, the [r]ule's disclosure requirement for production claims must be 'reasonably related to the State's interest in preventing deception of consumers' and cannot be 'unjustified or unduly burdensome.'" *Id.* at 642 (quoting *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 651 (1985)). Commercial speech is essentially subject to intermediate scrutiny as outlined in *Central Hudson*. ERWIN CHERMERINSKY, *CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES* 1090 (3d ed. 2006). Compelled noncommercial speech is subject to strict scrutiny. STEVEN G. BRODY & BRUCE E.H. JOHNSON, *ADVERTISING & COMMERCIAL SPEECH: A FIRST AMENDMENT GUIDE* § 12:1 (6th ed. 2010). However, there is no "clear guidance" when considering compelled commercial speech. *Id.* But see *Boggs II*, 622 F.3d at 641 ("The speech rights of advertisers, in contrast, are of less value; specifically, their 'constitutionally protected interest in *not* providing the required factual information is minimal." (internal quotation marks omitted) (quoting *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339 (2010) (citing *Zauderer*, 471 U.S. at 651))); see also *Milavetz*, 130 S. Ct. at 1343 (Thomas, J., concurring) (suggesting that compelled speech should be evaluated under strict scrutiny, regardless of whether it is commercial or noncommercial).

in preventing consumer deception.<sup>48</sup> However, there was no rational basis for requiring *contiguous* production claim disclaimers, since there was only a “paucity of evidence,” based on anecdotes and assertions, militating against the use of asterisks or other methods of linking noncontiguous disclaimers.<sup>49</sup> As a result, the court held the Rule violated the *Zauderer* test and was unconstitutional on First Amendment grounds.<sup>50</sup>

### III. ANALYSIS

In proposing the ban on composition claims, the State was concerned that such labels could be false and misleading.<sup>51</sup> As noted by the district court, “[e]ven if truthful, speech can still be misleading if its *implication* is misleading.”<sup>52</sup> Additionally, popular culture has recognized that truthful statements about the composition of food for marketing purposes can nonetheless be misleading.<sup>53</sup> But while states have a valid interest in protecting consumers from misleading statements,<sup>54</sup> Ohio’s regulations went too far. As the Sixth Circuit pointed out, because there is a difference between milk that contains rbST and milk that does not contain rbST, composition claims like “rbST-free” are not inherently misleading.<sup>55</sup> In such circumstances, “the preferred remedy is more disclosure, rather than less.”<sup>56</sup>

Furthermore, it was not surprising, considering the widespread usage of disclaimers throughout the country,<sup>57</sup> that the court upheld the requirement that disclaimers accompany production claims.<sup>58</sup> However, the court’s reasoning in striking down the ban on composition claims appears to rest substantially, if not entirely, on its finding of a compositional difference between milk from treated versus untreated cows.<sup>59</sup> This directly contradicts the FDA’s assertion that there is “no significant difference between milk from treated and untreated cows.”<sup>60</sup> If the court found that there was no compositional difference, then it would be forced to find that composition claims were misleading. As such, the “speech

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48. *Boggs II*, 622 F.3d at 642.

49. *Id.* at 643.

50. *See id.*

51. *See id.* at 634.

52. *Boggs I*, 2009 WL 937045, at \*6.

53. *See, e.g.*, Randall Munroe, *Free*, XKCD (Sept. 25, 2009), <http://xkcd.com/641/>.

54. *Boggs II*, 622 F.3d at 638.

55. *Id.* at 637.

56. *Id.* at 636 (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350 (1977)).

57. *See, e.g.*, ALASKA STAT. § 17.20.013 (2010); VT. STAT. ANN. tit. 6, § 2762 (2010); WIS. ADMIN. CODE ATCP § 83.02 (2010).

58. *Boggs II*, 622 F.3d at 643.

59. *See id.* at 636.

60. *Id.* at 637; Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994).

[would not be] entitled to First Amendment protection,” thus ending the *Central Hudson* analysis at the first step.<sup>61</sup>

Finally, *Boggs* has major implications for genetically engineered food labeling, since the FDA lacks the authority to mandate labeling of products that are produced differently but do not differ materially in composition.<sup>62</sup> For example, in 2010, the FDA began holding public meetings on the possible approval of AquAdvantage salmon, a salmon genetically engineered for use as food.<sup>63</sup> The AquAdvantage salmon grows twice as fast as other salmon and consumes 25 percent less feed.<sup>64</sup> The FDA has determined that “there are no material differences in food from [AquAdvantage] salmon and other Atlantic salmon.”<sup>65</sup> However, test results show that AquAdvantage salmon contain nearly 40 percent higher levels of insulin-like growth factor 1 compared to regular salmon.<sup>66</sup> Using the reasoning from *Boggs*, a court could rule that there is a compositional difference between AquAdvantage salmon and conventional salmon, contravening the FDA’s finding. Future marketers might then be able to claim that their salmon is “GMO-free.” This may also give the FDA the authority needed to mandate labeling of genetically engineered salmon.

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61. *Boggs II*, 622 F.3d at 636. This result would mirror *International Dairy Foods Ass’n v. Amestoy*, a Second Circuit case striking down Vermont’s requirement (rather than prohibition) of a statement differentiating between milk from rbST-treated cows and untreated cows. 92 F.3d 67 (2d Cir. 1996). The decision in *Amestoy* rested strongly on the Second Circuit’s conclusion, following the FDA’s findings, that there was no significant difference between milk from treated and untreated cows. *See id.* at 73–74. More specifically, the court accepted the FDA’s finding that rbST “has no appreciable effect on the composition of milk produced by treated cows,” and concluded that Vermont “plain[ly] . . . could not justify the statute on the basis of ‘real’ harms.” *Id.* at 73. The fact that the Sixth Circuit found otherwise, however, suggests that *Amestoy* should have come out differently. The Second Circuit noted that “[a]bsent . . . some indication that this information [disclosing whether the milk came from rbST-treated cows] bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern, the manufacturers cannot be compelled to disclose it.” *Id.* at 74.

62. U.S. FOOD & DRUG ADMIN., BACKGROUND DOCUMENT: PUBLIC HEARING ON THE LABELING OF FOOD MADE FROM THE AQUADVANTAGE SALMON 4 (2010), available at <http://www.fda.gov/downloads/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/UCM223913.pdf>; see *Stauber v. Shalala*, 895 F. Supp. 1178 (W.D. Wis. 1995).

63. U.S. FOOD & DRUG ADMIN., PUBLIC MEETINGS ON GENETICALLY ENGINEERED ATLANTIC SALMON (2010), 2010 WL 3453346.

64. Andrew Zajac, *FDA Advisors to Vote on Genetically Engineered Salmon*, L.A. TIMES (Sept. 18, 2010), <http://articles.latimes.com/2010/sep/18/nation/la-na-salmon-fda-20100919>.

65. CNTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., BRIEFING PACKET FOR AQUADVANTAGE SALMON VETERINARY MEDICINE ADVISORY COMMITTEE 109 (2010), available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf>.

66. *Id.* at 68; see Meredith Melnick, “Frankenfish” May Soon Be Spawning: Is Genetically Modified Salmon Safe?, TIME (Sept. 19, 2010), <http://healthland.time.com/2010/09/19/frankenfish-may-soon-be-spawning-is-genetically-modified-salmon-safe/>.

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## CONCLUSION

The court's decision on production claim requirements is not particularly groundbreaking, but with the potential that consumers could soon be eating genetically engineered animals in addition to genetically engineered plants, its determination that there is a difference between milk from rbST-treated cows versus non-rbST-treated cows may have major ramifications for labeling genetically engineered food in the future. In the meantime, the court has preserved for consumers the right to know what the milk they drink contains or does not contain, and the freedom to support those dairy producers accordingly.

*Tony Au*