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## Note

### How Can Better Food Labels Contribute to True Choice?

*J.C. Horvath\**

#### I. INTRODUCTION

To enter a grocery store today is to expose oneself to a glut of information. Everywhere one looks there are colorful messages competing for attention. At one time these messages primarily touted the taste or value of the food, but more and more of the messages today concern invisible properties of the food. A food may claim it helps fight disease, or accords with a particular diet, such as high fiber or low cholesterol, or with a particular lifestyle, such as organic or kosher.

This Note sets out to explore what these messages really mean and to answer a critical question: are these messages providing useful information that promotes informed choice, or are they serving only to confuse? Part II of this Note will dive into the past and present law determining what can, what must, and what cannot be said on food packaging. Part III will explore how satisfactory the developments in law have been in establishing meaningful choice for consumers. Throughout, this Note will explore three subtopics: the First Amendment issues relating to marketing claims, the effectiveness of the protections provided by mandatory allergy information, and the use of deceptive catch-all terms on ingredient labels that thwart a consumer's attempt to make informed health and ethical choices. This Note concludes that consumers still do not have meaningful choice in the selection of food products and proposes a method for standardizing the disclosure of helpful information.

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\* J.D. Candidate, University of Minnesota Law School. I would like to thank Professor Prentiss Cox for helping inspire this article and providing careful notes as well as Professor Ralph Hall for extensive and sometimes contentious discussions on both the history and current landscape of food law. I would also like to thank the excellent staff and editors of this journal for greatly enhancing the final version of this article.

## II. BACKGROUND

## A. REGULATORY STRUCTURE

Regulation of food and drugs has been conducted in the United States at the federal level since the 1906 Food and Drugs Act—the first comprehensive federal consumer protection law.<sup>1</sup> From the beginning, the primary focus was on misbranded and adulterated food and drugs in interstate commerce.<sup>2</sup> However, many dangerous products remained uncovered by the 1906 Act.<sup>3</sup> In 1938, the Food, Drug, and Commerce Act (FD&C Act) tightened the Food and Drug Administration's (FDA) control over food and drugs.<sup>4</sup>

The FDA undergoes “notice and comment rulemaking” in promulgating regulations in addition to producing less formal Good Guidance Practice regulations, which are nonbinding descriptions of “the agency’s current thinking on a regulatory issue.”<sup>5</sup> Because guidance regulations are not binding final actions by a federal agency, they are not judicially reviewable.<sup>6</sup> However, the FDA will send warning letters, also non-binding, to those it believes are not in compliance with its guidance on a case-by-case basis.<sup>7</sup> While the guidance and these letters will not be afforded deference in courts, most parties will comply in an effort to avoid costly litigation against the FDA, which has typically been seen as having broad discretion to set policy as it sees fit.<sup>8</sup> In recent years, however, the FDA’s wide discretion

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1. *How Did the Federal Food, Drug, and Cosmetic Act Come About?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214416> (last updated Aug. 19, 2010).

2. *Id.*

3. *Id.*

4. *Id.*

5. *What is the Difference Between the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA Regulations, and FDA Guidance?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194909> (last updated Aug. 19, 2010).

6. *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166, 171–72 (D.D.C. 2000) (holding that statements of non-binding guidance were non-reviewable).

7. See, e.g., Peggy Chen, *Education or Promotion?: Industry-Sponsored Continuing Medical Education (CME) as a Center for the Core/Commercial Speech Debate*, 58 FOOD & DRUG L.J. 473, 482 (2003).

8. See Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 168–70 (2000) (discussing why so many choose to voluntarily comply with FDA guidance).

has been restricted by legislation and has been more successfully challenged in court, primarily on constitutional First Amendment grounds.<sup>9</sup>

#### B. LABELING STANDARDS

Federal regulation of food has long been concerned with a consumer's ability to fully understand just what it is that he is consuming. Under the original 1906 Food and Drugs Act, "misbranded" was an expansive term. For example, in one 1924 case, a supply of "apple cider vinegar made from selected apples" was declared misbranded because the vinegar was made from evaporated apples.<sup>10</sup> The court stated that while the final product resulting from evaporated apples was comparable in taste and healthfulness to an apple cider vinegar made from fresh, unevaporated apples, and in fact was nearly chemically indistinguishable, the difference still had to be pointed out to consumers who would normally assume fresh apples had been used.<sup>11</sup>

A different act now covers the rules of food labeling, and there are many more specific regulations, but the need for careful analysis and scrutiny of the claims made on product labels is, if anything, greater than in the past. The modern FD&C Act requires a new drug to undergo an extensive review process before it is approved for marketing; this oversight gives consumers confidence that the drug is safe and effective.<sup>12</sup> In contrast, labeling is the primary means by which a shopper can evaluate whether or not he wishes to consume a particular food product.<sup>13</sup>

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9. See *infra* Part II.B.1–2.

10. *United States v. Ninety-Five Barrels of Vinegar*, 265 U.S. 438, 444–45 (1924) ("The name 'apple cider vinegar' included in the brand did not represent the article to be what it really was; and, in effect, did represent it to be what it was not,—vinegar made from fresh or unevaporated apples. The words 'made from selected apples' indicate that the apples used were chosen with special regard to their fitness for the purpose of making apple cider vinegar. . . . as used on the label, they aid the misrepresentation made by the words 'apple cider vinegar.'").

11. *Id.* at 440–45.

12. *Development and Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm> (last updated Oct. 27, 2009).

13. See U.S. FOOD & DRUG ADMIN., HAVE FOOD ALLERGIES? READ THE LABEL 1–2 (2011), available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM254727.pdf> ("[F]irst look for the 'Contains' statement and if your allergen is listed, put the product back on the shelf . . . . Manufac-

Food producers and packagers have not ignored this fact and have long plastered their packaging with bold claims about the quality of their products.<sup>14</sup> In recent years, producers have attempted to catch the attention of diet-conscious consumers through health claims.<sup>15</sup> Although almost all prepared foods are the result of a long chain of mechanical processes, producers would like their food to invoke wholesome images of farms and nature, so tags such as “all-natural” are widely employed.<sup>16</sup> The FDA has largely backed down from attempting to sort the evaporated apples from the fresh, and have put out press releases explaining that “natural” is too nebulous a word for them to attempt to set any enforceable standard around its use.<sup>17</sup>

While rules keeping potentially misleading labels off of food have largely relaxed, many more recent rules mandate the inclusion of useful information. If any of the “major food allergens” appear in a food product, consumers must be informed about its presence in one of two ways: either in some form that uses the common name of the allergen in the ingredients list or separately labeled in a “Contains” statement.<sup>18</sup> While this is a

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turers can change their products’ ingredients at any time, so . . . it’s a good idea to check the ingredient list *every time* you buy the product—even if you have eaten it before and didn’t have an allergic reaction.”) (emphasis in original).

14. See, e.g., Joyce Slaton, *50 Years of Packages That Fool Stupid People*, CHOW.COM (July 7, 2011), <http://www.chow.com/food-news/85244/50-years-of-packages-that-fool-stupid-people/> (describing common packaging claims from the last 5 decades).

15. See *Understanding Front-of-Package Violations: Why Warning Letters Are Sent to Industry*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/LabelingNutrition/ucm202784> (last updated Mar. 3, 2010) (listing specific erroneous claims made by various companies); see, e.g., Jennifer Corbett Dooren, *Cheerios’ Health Claims Break Rules, FDA Says*, WALL ST. J., May 13, 2009, at B1 (“[T]he Cheerios box’s message saying the cereal can ‘lower your cholesterol 4% in six weeks’ has been used for more than two years. The box cites a clinical study involving Cheerios as part of a diet low in saturated fat and cholesterol.”).

16. See *Understanding Front-of-Package Violations: Why Warning Letters Are Sent to Industry*, *supra* note 15.

17. Press Release, Inst. Of Food Technologists, *Is There a Definition for Natural Foods?* (June 30, 2008), available at <http://www.amfe.ift.org/cms/?pid=1000744>.

18. See OFFICE OF NUTRITION, LABELING AND DIETARY SUPPLEMENTS, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE § 6 (2009), available at <http://www.fda.gov/food/guidancecompliance/regulatoryinformation/guidancedocuments/foodlabelingnutrition/foodlabelingguide/ucm064880> (defining “major food allergens” as “an ingredient that is one

commendable step, it is somewhat confusing that the FDA has not determined and selected the one most effective means of communicating allergy warnings in place of the current either/or requirement.

In addition, almost all commercially available foods are required to include an ingredient list somewhere on their packaging.<sup>19</sup> These lists must conform to a number of highly restrictive requirements: each ingredient in a food must be listed in descending order by weight,<sup>20</sup> water must be listed if it is not present in the food's normal state,<sup>21</sup> common names like "sugar" must be used over scientific names like "sucrose,"<sup>22</sup> alternative listings (such as "soybean oil and/or corn oil") are discouraged,<sup>23</sup> chemical preservatives must be accompanied by their use,<sup>24</sup> and complex foods must have their own ingredients listed parenthetically.<sup>25</sup> Despite the clarity that typically results from the above regulations, others leave much room for confusion. A fairly innocuous example is that of tomato paste, puree, pulp, and concentrate, all of which are precisely defined terms of art that an average consumer is unlikely to appreciate.<sup>26</sup> These requirements do not come directly from official regulations but rather originate in the kind of nonbinding recommendations described above. Another place of confusion that will be thoroughly discussed in this Note is the approved use of phrases such as "spices," "artificial flavor," "natural flavor," and "artificial coloring" that often hide pertinent details about the nature of a food.<sup>27</sup>

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of the following eight foods or food groups or an ingredient that contains protein derived from one of them: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans").

19. *Id.* (clarifying that "raw agricultural commodities (generally fresh fruits and vegetables) are exempt" from FALCPA labeling requirements). For a full list of exempted foods, see 21 C.F.R. § 101.100 (2011).

20. 21 C.F.R. § 101.4(a) (2011).

21. 21 C.F.R. § 101.4(a) & (c) (2011).

22. 21 C.F.R. § 101.4(a) (2011).

23. OFFICE OF NUTRITION, *supra* note 18 ("Listing alternative fat and oil ingredients ('and/or' labeling) in parentheses following the declaration of fat and oil blends is permitted only in the case of foods that contain relatively small quantities of added fat or oil ingredients . . . and only if the manufacturer is unable to predict which fat or oil ingredient will be used.").

24. 21 C.F.R. § 101.22(j) (2011).

25. 21 C.F.R. § 101.4(b)(2) (2011).

26. OFFICE OF NUTRITION, *supra* note 18.

27. 21 C.F.R. § 101.22(h)(1), (k)(1), & (k)(2) (2011).

### 1. Say Anything?

The rules regarding misleading claims on packaging have changed greatly since the 1924 “apple cider vinegar” case.<sup>28</sup> What is surprising is the direction of these changes. Until 1990, the rule was that “[i]f a food or dietary supplement label contained a health claim, the FDA deemed the product to be a drug, and it then became subject to the FDA’s rigorous drug approval and drug labeling requirements.”<sup>29</sup> However, following several years of tacit and then explicit FDA approval of foods proclaiming health benefits on their packaging, the 1990 Nutrition Labeling and Education Act (NLEA) amended the FD&C Act. The NLEA allowed a food producer to place a health claim on its packaging without prior approval, but “only if the [FDA] determines, based on the totality of publicly available scientific evidence . . . that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”<sup>30</sup>

While this standard seems to fully empower the FDA to restrict dubious health claims, nine years later the D.C. Circuit in *Pearson v. Shalala* limited the FDA’s discretion.<sup>31</sup> Citing previous case law, the court in *Pearson* noted that commercial speech on packaging is entitled to First Amendment protection provided that it is truthful and “related to lawful activities.”<sup>32</sup> In addition, such speech cannot be prohibited unless it is *inherently*, rather than just *potentially*, misleading.<sup>33</sup> Despite the FDA’s argument that dubious health claims are inherently misleading because consumers would have no way of verifying such claims prior to purchase, and might in fact assume government endorsement of such claims, the court stated that health claims on foods and dietary supplements could only ever be potentially misleading if backed by significant evidence.<sup>34</sup> In addition, the *Pearson* court held that while the FDA had an undeniable substantial interest in “promoting the health, safety, and welfare

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28. *United States v. Ninety-Five Barrels of Vinegar*, 265 U.S. 438 (1924).

29. *Whitaker v. Thompson*, 248 F.Supp.2d 1, 3 (D.D.C. 2002) (citing 21 U.S.C. §§ 321(g)(1)(B), 355 (1988)).

30. 21 U.S.C. § 343(r)(3)(B)(i) (2006).

31. *Pearson v. Shalala*, 164 F.3d 650, 651 (D.C. Cir. 1999).

32. *Id.* at 655.

33. *Id.*

34. *Id.*

of its citizens,” the means established by the NLEA did not reasonably fit the FDA’s legitimate ends.<sup>35</sup> The *Pearson* court ordered the FDA to develop disclaimers to attach to dubious health claims that would explain that the FDA did not endorse such claims or that the evidence supporting such claims was inconclusive, though leaving the exact wording up to the FDA.<sup>36</sup> The court also provided that “where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright.”<sup>37</sup>

Following the *Pearson* result, the FDA analyzed over 150 studies concerning one of the claimed health benefits at issue in the case.<sup>38</sup> It concluded that the evidence against the claim outweighed the evidence in support, and again denied approval, leading to another suit.<sup>39</sup> In that suit, *Whitaker v. Thompson*, the court held the FDA’s conclusion unreasonable because approximately one-third of the available studies suggested the health claim might be legitimate.<sup>40</sup> The court asserted that if some evidence supported a claim, “a complete ban of the [c]laim cannot be justified.”<sup>41</sup> The *Whitaker* court also held that the other requirements for injunction had been met in the case and ordered the FDA to attach disclaimers to the dubious health claims and approve them.<sup>42</sup> As *Whitaker* appears to be the last major word on the issue at the moment, potentially misleading and, in fact more-likely-than-not untrue health claims, cannot constitutionally be kept off of food labels if there is any evidence supporting them.

## 2. Allergen Warnings

Common allergens did not need to be listed specifically on food packaging until recently. The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) was passed based on Congress’ finding that about one in fifty adults and about one in twenty infants and young children “suffer from food allergies,” leading to about 30,000 emergency room visits and 150

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35. *Id.* at 656.

36. *Id.* at 659.

37. *Id.*

38. *Whitaker v. Thompson*, 248 F.Supp.2d 1, 11 (D.D.C. 2002).

39. *Id.*

40. *Id.* at 11–13.

41. *Id.* at 13.

42. *Id.* at 15–17.



deaths per year in the United States.<sup>43</sup> The FDA notes that “[t]here is no cure for food allergies. Strict avoidance of food allergens—and early recognition and management of allergic reactions to food—are important measures to prevent serious health consequences.”<sup>44</sup> The Act only covers eight major food allergies—milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans—based on the assertion that 90% of allergies are one of these eight products.<sup>45</sup> Research on major allergen occurrences is far from comprehensive, and a number of different surveys and studies have turned up widely varying results. One study from the *Journal of Allergy and Clinical Immunology* believes the rate of dangerous allergic reactions in adults may be as high as one in twenty-five.<sup>46</sup> The same study also shows that sesame may be as dangerous to children as some of the other “major allergens.”<sup>47</sup> The FDA has pledged to continue research into major allergens, but for now is sticking to mandating warnings for only eight of the more than 160 known food allergens.<sup>48</sup>

If any of the regulated major allergens is used in a product, its presence must be noted in one of two ways. The first way is to list the allergen’s name somewhere in the ingredients list. The allergen may be listed independently by its name (e.g., “milk”) or in parentheses following a specific ingredient’s common name (e.g., “whey (milk”).<sup>49</sup> It is also considered adequate if a specific ingredient’s common name contains the major allergen’s name, such as “wheat flour,” which already contains the word “wheat.”<sup>50</sup> The second option for listing major allergens is much more straightforward. A packager may list the

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43. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 202(1), 118 Stat. 905.

44. U.S. FOOD & DRUG ADMIN., FOOD ALLERGIES: WHAT YOU NEED TO KNOW 1 (2010), available at <http://www.fda.gov/food/resourcesforyou/Consumers/ucm079311.htm>.

45. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 202(2), 118 Stat. 905.

46. Scott H. Sicherer & Hugh A. Sampson, *Food Allergy*, 125 *J. ALLERGY & CLINICAL IMMUNOLOGY* S116, S116 (2010), available at <http://www.jacionline.org/article/S0091-6749%2809%2901270-6/fulltext>.

47. See *id.* at S117 tbl.1 (listing the prevalence of sesame allergies in children at 0.1%—the same rate as both fish and shellfish allergies).

48. FOOD ALLERGIES: WHAT YOU NEED TO KNOW, *supra* note 44, at 1.

49. OFFICE OF NUTRITION, *supra* note 18.

50. *Id.*

common names of ingredients by their common names alone, and then attach a “Contains” statement directly below the ingredients list.<sup>51</sup> The “Contains” statement simply lists each major allergen present in the food product.<sup>52</sup> Either way, *every* major allergen product must be listed, even when it is only a sub-ingredient in a larger ingredient; for example “Enriched flour (*wheat* flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid).”<sup>53</sup> The allergens, which themselves are collections of several foods—fish, Crustacean shellfish, and tree nuts—must be identified by their specific food source (e.g., “crab” rather than “Crustacean shellfish” or “walnuts” rather than “tree nuts”).<sup>54</sup> These requirements reflect an admirable attempt on the part of the FDA to provide the clearest information possible. The only major question remaining is: why allow a choice between the ingredient list requirements and a “Contains” statement rather than selecting one consistent method that affected consumers can rely upon? This is especially puzzling given that a “Contains” statement seems to be superior in terms of achieving the clarity sought by the FALCPA and the FDA.

### 3. Nondescriptive Descriptors

The three phrases “artificial flavor,” “natural flavor,” and “artificial coloring” can stand in for over 3900 food additives that come from a widely divergent range of sources.<sup>55</sup> The FDA does monitor these additives, and new additives must be approved before they can be used.<sup>56</sup> The FDA undergoes careful testing to set maximums on allowable amounts of new additives, but this does not eliminate all dangers.<sup>57</sup> Once the use of an additive is Generally Recognized As Safe (GRAS), it may be

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51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. See *Everything Added to Food in the U.S. (EAFUS)*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=eafusListing&displayAll=true> (last updated July 14, 2011) (listing all known food additives used in the United States); see also INT’L FOOD INFO. COUNCIL FOUND. & U.S. FOOD & DRUG ADMIN., FOOD INGREDIENTS AND COLORS 2–3 (2010), available at <http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/ucm094249.pdf> (explaining the use of “artificial flavors,” “natural flavors,” and “artificial coloring”).

56. INT’L FOOD INFO. COUNCIL FOUND., *supra* note 55, at 5.

57. *Id.*

added to any and all foods without further testing for unexpected chemical interactions with the other ingredients in a food.<sup>58</sup> The FDA maintains authority to conduct further testing or removal of the GRAS label if complications do arise.<sup>59</sup>

One of the more troubling aspects of the use of general labels to cover all GRAS additives is that a consumer has no clue as to the nature of the substance. Beef tallow, gelatin, and lard can all be covered by these labels,<sup>60</sup> as well as stranger substances such as ambergris,<sup>61</sup> a waxy substance generated in the digestive system of and regurgitated by sperm whales;<sup>62</sup> L-cystine,<sup>63</sup> a dough conditioner often derived from duck feathers or human hair;<sup>64</sup> and tonquin, the musk that gives the Musk deer its name.<sup>65</sup> In addition, sometimes additives derived from one source are used in a food product of a different kind, such as when beef extracts are used in chicken products.<sup>66</sup> A number of vegetarian, religious, and consumer groups have attempted to inquire into the origin of food additives with limited success. *Vegetarian Journal* managed to acquire an admission from McDonald's that some of the "natural flavors" now used as cooking oil for their French fries derive from "animal products."<sup>67</sup>

In addition, the distinction between "natural" and "artificial" flavors is much more technical than meaningful. The dif-

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58. *Guidance for Industry: Frequently Asked Questions About GRAS*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm061846.htm#Q1> (last updated May 4, 2011); see also INT'L FOOD INFO. COUNCIL FOUND., *supra* note 55, at 5 ("GRAS (generally recognized as safe) ingredients—are those that are generally recognized by experts as safe, based on their extensive history of use in food before 1958 or based on published scientific evidence.").

59. INT'L FOOD INFO. COUNCIL FOUND., *supra* note 55, at 5.

60. See 21 C.F.R. § 182.70 (2011).

61. See 21 C.F.R. § 182.50 (2011).

62. *Ambergris*, DICTIONARY.COM, <http://dictionary.reference.com/browse/ambergris> (last visited Sept. 28, 2011).

63. See 21 C.F.R. § 172.320(b)(1) (2011).

64. Jeanne Yacoubou, *Questions About Food Ingredients*, VEGETARIAN RESOURCE GROUP, <http://www.vrg.org/nutshell/faqingredients.htm#cystine> (last visited Sept. 29, 2011).

65. See 21 C.F.R. § 182.50.

66. See, e.g., ERIC SCHLOSSER, *FAST FOOD NATION: THE DARK SIDE OF THE ALL-AMERICAN MEAL* 128 (2001) ("Wendy's Grilled Chicken Sandwich, for example, contains beef extracts.").

67. *Id.*

ference has nothing to do with the end product additive, but rather refers to the way the additive is produced. The FDA defines “natural flavors” in the following way:

The term *natural flavor* or *natural flavoring* means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional.<sup>68</sup>

“Artificial flavors” are defined negatively as any additive that doesn’t qualify as “natural.”<sup>69</sup> Notice that the list of origins of a “natural flavor” is expansive, covering seemingly every possible source, but the list of processes that allow a product to still qualify as a “natural flavor” is limited to roasting, heating, and enzymolysis—“the decomposition of a chemical compound catalyzed by the presence of an enzyme.”<sup>70</sup> In the words of Terry Acree, a professor of food science technology at Cornell, “[a] natural flavor is a flavor that’s been derived with an out-of-date technology.”<sup>71</sup>

Interestingly, flavors produced by a “natural” process often do not produce more healthful results. The FDA admits that “some ingredients found in nature can be manufactured artificially and produced more economically, with greater purity and more consistent quality, than their natural counterparts.”<sup>72</sup> For example, when benzaldehyde, a chemical used as an almond flavor, is derived “naturally” from the pits of peaches and apricots, it contains trace amounts of cyanide.<sup>73</sup> If the same benzaldehyde is made “artificially” by mixing oil of clove and amyl acetate, it does not contain any cyanide.<sup>74</sup> While the FDA is quite confident that those trace amounts of cyanide are not substantial enough to harm anyone, it seems strange to use a

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68. 21 C.F.R. § 101.22(a)(3) (2011).

69. See 21 C.F.R. § 101.22(a)(1) (2011) (“The term *artificial flavor* or *artificial flavoring* means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof.”).

70. *Enzymolysis*, DICTIONARY.COM, <http://dictionary.reference.com/browse/enzymolysis> (last visited Sept. 16, 2011).

71. SCHLOSSER, *supra* note 66, at 126.

72. INT’L FOOD INFO. COUNCIL FOUND., *supra* note 55, at 7.

73. SCHLOSSER, *supra* note 66, at 127.

74. *Id.*

more appetizing classification for a more suspect substance. Additionally, in many cases, the “natural” and “artificial” counterparts of the same flavor will be chemically identical and the differences between them indiscernible after the fact.<sup>75</sup> These two classes of additives are often produced side-by-side in the same facilities by the same chemists.<sup>76</sup> Despite these facts, many consumers have been misled by these catch-all phrases and prefer to buy products made with “natural” flavors.<sup>77</sup>

### III. ARGUMENT

#### A. DO *PEARSON* AND *WHITAKER* IMPOSE TOO HIGH A CONSTITUTIONAL BAR?

The attitude of the FDA toward front-of-pack health claims—leading to passage of the NLEA—involved a practical realization of the FDA that resources spent tightly monitoring innocuous and truthful health claims on foods could be better spent elsewhere. However, it was clear to the FDA and Congress that even if health claims did not need to be regulated in the same way as drug health claims, some oversight was useful. The NLEA required such claims to be supported by “significant scientific agreement” among qualified experts,<sup>78</sup> but modern courts have relaxed standards due to First Amendment concerns, arguably to the point of ineffectiveness. The *Pearson* court created a protected status for any claim where the evidence in support of the claim outweighed any evidence against, declaring such claims truthful enough to fall under freedom of speech protection.<sup>79</sup> The *Whitaker* court then expanded this class of claims, allowing any statement that can find minimal scientific support to be outside the power of the FDA to ban.<sup>80</sup> Both courts acknowledge that misleading statements can harm public safety and welfare and agree that preventing such harm is a legitimate government interest, but find the First Amendment considerations weightier than the more pragmatic con-

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75. *Id.* at 126–27.

76. *See id.* at 127 (“Natural and artificial flavors are now manufactured at the same chemical plants, places few people would associate with Mother Nature.”).

77. *Id.* at 126.

78. 42 U.S.C. §343(r)(3)(B)(i) (2006).

79. *Pearson v. Shalala*, 164 F.3d 650, 657–58 (D.C. Cir. 1999).

80. *Whitaker v. Thompson*, 248 F.Supp.2d 1, 13 (D.D.C. 2002).

cerns. From one perspective, the result is a fierce defense of crucial constitutional principles. From another, the result is a loss of informed consumer choice that overvalues commercial speech.

### 1. The Shift from *Central Hudson* and *Bates* to *Pearson*

When the *Pearson* court invalidated the FDA's interpretation of the NLEA, it employed the *Central Hudson* test for government regulation that may infringe on First Amendment commercial speech rights.<sup>81</sup> A *Central Hudson* analysis addresses four questions to be considered in weighing constitutionality: (1) the commercial speech, to be protected, "at least must concern lawful activity and not be misleading"; (2) the government interest, to overcome this protection, must be "substantial"; (3) the regulation, to be valid, must "directly advance[] the government interest"; and (4) the regulation, to be valid, must also be "not more extensive than is necessary to serve that interest."<sup>82</sup> The court quickly admitted the legitimate government interests of protecting public health and preventing consumer fraud<sup>83</sup> but found that only preventing fraud was directly advanced by requiring rigorous pre-approval of health claims.<sup>84</sup> The court looked to precedent from *Bates v. State Bar of Arizona*, which stated that "the preferred remedy is more disclosure, rather than less."<sup>85</sup> On this principle, the *Pearson* court declared the FDA's presumed ability to prohibit scientifically doubtful claims to be too broad, as the agency had not shown that permitting health claims with an approved disclaimer would not achieve its goals.<sup>86</sup>

The analysis in *Bates*, however, may not be so easily applied to the issue of health claims. The commercial speech found not to be "inherently" misleading in *Bates* and several other cases cited by the *Pearson* court was advertising by law-

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81. *Pearson*, 164 F.3d at 655.

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

83. *Pearson*, 164 F.3d at 655–56.

84. *Id.* at 656. In coming to this conclusion, the court makes assumptions about the FDA's connection between regulating health claims and protecting health, focusing on just one of several possible rationales. One possible connection that was not discussed might be that consumers who are misled into believing that they are receiving desired health benefits through their diet will do less to protect themselves from disease through lifestyle choices.

85. *Bates v. State Bar of Ariz.*, 433 U.S. 350, 375 (1977).

86. *Pearson*, 164 F.3d at 657–59.

yers of the costs of their legal services.<sup>87</sup> The truth of such statements is not at issue as such statements can be guaranteed by the lawyers making them.<sup>88</sup> Attorney advertising was considered to be potentially misleading because consumers could fail to consider other relevant considerations in making an informed choice when selecting representation.<sup>89</sup> This concern is quite different from the concern that a statement is simply not true, and the *Bates* court explicitly stated that the preference for disclosure over suppression pertained to “correct but incomplete information.”<sup>90</sup> Health claims that have not yet achieved substantial scientific agreement cannot truly be said to be correct but incomplete because they may in time be shown to be completely false.

The *Pearson* court also borrowed the *Bates* distinction between “inherently” and “potentially” misleading speech and applied it to health claim analysis. Under *Bates*, statements that could be guaranteed would always fall short of inherently misleading.<sup>91</sup> The *Pearson* court contracted the set of inherently misleading statements further, describing them as those that “have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled.”<sup>92</sup> Few health claims could ever have such a startling effect on consumers, and therefore those claims are only potentially misleading and are entitled to at least some First Amendment protection.

It is interesting to note that *Central Hudson*, in laying out the rubric for protected commercial speech, does not distinguish between inherently and potentially misleading statements. Its language is simple: “[f]or commercial speech to come within that provision [of First Amendment protection], it at least must concern lawful activity and not be misleading.”<sup>93</sup> While it is a fact of developing jurisprudence that earlier

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87. *Bates*, 433 U.S. at 372–73.

88. *Id.*

89. *Id.* at 375–76.

90. *Id.* at 375 (emphasis added).

91. *Id.* at 372–73.

92. *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999).

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

statements of law will become more nuanced by later decisions, *Pearson* seems to be a substantial carve-out from the *Central Hudson* rule that speech must *at least* not be misleading to receive protection at all.

## 2. *Whitaker* Finds Even More Weight in the Constitutional Concerns

The court in *Pearson* strongly favored disclaimers over prohibition but still acknowledged “that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright.”<sup>94</sup> *Pearson*’s successor, *Whitaker*, restrained the FDA even further, setting a very limited set of circumstances that would allow the FDA to issue a ban.<sup>95</sup> In doing so, the court in *Whitaker* keyed-in on two examples from *Pearson* of when the FDA would be justified in an outright ban: when “no evidence supports [the health] claim” or “where the claim rests on only one or two old studies.”<sup>96</sup> However, in context, these examples are used to demonstrate how crucial it is for the FDA to retain the power to ban unsupported claims and do not suggest that such situations are the only ones in which the FDA could prohibit a claim.<sup>97</sup> The *Pearson* test used the phrases “outweighed” and “the weight of the evidence,”<sup>98</sup> both of which typically indicate a preponderance of the evidence standard. The *Whitaker* court, however, did not see it this way, and found a health claim to be constitutionally protected even though about two-thirds of the credible evidence did not support it.<sup>99</sup> The *Whitaker* court felt a strong need to extend free speech protection to claims relying on novel scientific theories that might prove valuable in the future, and therefore did not wish to tag a claim not yet widely supported as misleading. The court went as far as to argue that declaring “the claim is misleading because the evidence against it outweighs the evidence in support of it[] is unreasonable.”<sup>100</sup> The takeaway from *Whitaker* is that

[A]ny complete ban of a claim would be [constitutionally] approved only under narrow circumstances, i.e., when there was almost no

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94. *Pearson*, 164 F.3d at 659.

95. *Whitaker v. Thompson*, 248 F.Supp.2d 1, 9–11.

96. *Id.* at 10 (emphasis omitted) (citing *Pearson*, 164 F.3d at 659 & n.10).

97. *Pearson*, 164 F.3d at 659 & n.10.

98. *Id.* at 659.

99. *Whitaker*, 248 F. Supp. 2d at 11–12.

100. *Id.* at 13.



qualitative evidence in support of the claim and where the government provided empirical evidence . . . proving that the public would still be deceived even if the claim was qualified by a disclaimer.<sup>101</sup>

### 3. Summary and Conclusions

In just two related cases, the scope of First Amendment protection of corporate speech expanded from *Central Hudson's* statements that are not misleading—"misleading" generally being a fairly inclusive term—to *Whitaker's* claims that are supported by some reliable evidence. The potential problem with these cases is that the positives of keeping suspect health claims off of packaging were devalued. Health claims are good for consumers when they add meaningful, dependable information that consumers can rely on to make informed dietary choices. Well-founded claims serve an important role in a free market in that they allow food producers who offer foods that comply with discriminating diets to attract new customers and benefit from their efforts. Health claims that are not supported by substantial scientific agreement may ultimately prove false, and if so they serve only to mislead consumers. Indeed, many consumers identify the uncertainty of trusting health claims and have become cynical—ignoring all health claims because they are not in a position to discern the genuine from the tenuous claims at the point of sale. While freedom of speech is not to be dismissed lightly, it has always been thought of as a limited protection to be weighed against other valid concerns of government. In extending the reach of First Amendment protections, we necessarily reduce government power to combat the harm that can result from misleading speech. The damage to informed choice and free market competition might be too great to justify *Pearson* and *Whitaker's* expansion of constitutional protection over dubious corporate claims.

#### B. ALLERGY LABELS: ALMOST THERE

The FALCPA did much to increase access to allergy information for affected consumers. A great deal of research by the FDA helped shape the terms of the Act, but a few concerns raised by the FDA were not addressed. In addition, concerns have emerged about reactions to ingredients accidentally entering foods they are not designed to be a part of, and therefore

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101. *Id.* at 11.

left off the warnings mandated by the Act. Some efforts to address this new problem have been undertaken, but no uniform solution has yet been established. However, the most recent FDA research may provide the answer to formulating a label that can clearly explain the concern to consumers.

#### 1. Where the FALCPA Did and Did Not Align with FDA Research

In drafting the FALCPA, Congress clearly tried to align the Act with previous FDA determinations and policy statements. The FDA had become increasingly aware—even before Congress passed the FALCPA in 2004—that the current ingredient list requirements did not go far enough to protect consumers with allergy concerns. Of particular note was the lack of guidance provided by the category-based names used to describe flavors, colors, and spices. In the FDA’s own words: “Food labels with collectively named additives may confuse individuals who wish to avoid allergenic substances, particularly when the allergenic substance is not clearly labeled.”<sup>102</sup> The FALCPA’s list of findings expresses similar concerns.<sup>103</sup> The FDA also recommended that the weaknesses in the current labeling requirements scheme be resolved by the exact method the FALCPA later made law.<sup>104</sup>

There are, however, a few interesting discrepancies between the FDA’s guidance statements and the FALCPA. The most noticeable change is in the identified “eight major allergenic foods.” Whereas the FALCPA lists the “major allergens” as: “milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans,”<sup>105</sup> a 2001 guidance statement groups soy and peanuts together under the heading of legumes, and lists

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102. Kenneth J. Falci et al., *Ask the Regulators—Food Allergen Awareness: An FDA Priority*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm105998> (last updated May 20, 2009).

103. *Compare* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 202, 118 Stat. 905 (describing the prevalence and danger of food allergies), *with* Falci et al., *supra* note 102 (expressing similar concerns).

104. *Compare* Falci et al., *supra* note 102 (recommending that manufacturers call attention to the presence of any allergen by the food source name) *with* Food Allergen Labeling and Consumer Protection Act § 203(a) (requiring the same type of labeling scheme); *see also* OFFICE OF NUTRITION, *supra* note 18.

105. Food Allergen Labeling and Consumer Protection Act § 202(2).

mollusks (e.g. squid, octopus, and snails) as the eighth group.<sup>106</sup> In addition, the 2001 guidance statement expressed concern over additional allergens such as sulfites,<sup>107</sup> used as preservatives in some foods but already banned for use on raw vegetables or fruits,<sup>108</sup> and coloring agents carmine (also known as cochineal extract) and FD&C Yellow No. 5.<sup>109</sup> No effective action has been taken by Congress or the FDA to modify labeling in relation to any of these concerns to date, nor have any changes in regulations been proposed to address sesame or non-wheat gluteins, both common allergens regulated in Canada.<sup>110</sup>

## 2. Cross-contamination Concerns and the Search for a Perfect Warning

The most recent action in regard to allergens is designed to address concerns over allergens mistakenly entering foods through an occurrence known as cross-contamination or cross-contact.<sup>111</sup> “Cross-contact occurs when a residue or other trace amount of a food allergen is present on a food contact surface or production machinery, or is air-borne, and unintentionally becomes incorporated into a product not intended to contain the allergen.”<sup>112</sup> While the FDA issues Current Good Manufacturing Processes to minimize food contamination,<sup>113</sup> it recognizes that total elimination of cross-contamination is unfeasible.<sup>114</sup> In 2008, the FDA issued a request for comments from the food industry and consumers regarding the effectiveness of advisory warnings that many food companies have been employing, with an eye toward recommending such statements in the future.<sup>115</sup>

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106. Falci et al., *supra* note 102.

107. *Id.*

108. Paul Grotheer et al., *Sulfites: Separating Fact from Fiction*, U. FLA. IFAS EXTENSION NO. FCS8787, Apr. 2005, at 1–3, available at <http://edis.ifas.ufl.edu/pdffiles/FY/FY73100.pdf>.

109. Falci et al., *supra* note 102.

110. *QUESTIONS AND ANSWERS ABOUT THE NEW REGULATIONS TO ENHANCE THE LABELLING OF FOOD ALLERGENS, GLUTEN AND ADDED SULPHITES*, Health Canada, [http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/project\\_1220\\_qa\\_qr-eng.php](http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/project_1220_qa_qr-eng.php) (last modified July 22, 2008).

111. FDA’s Request for Comments on Use of Allergen Advisory Labeling, 73 Fed. Reg. 46,302 (Aug. 8, 2008) [hereinafter Allergen Comments].

112. *Id.* at 46, 303 n.2.

113. 21 C.F.R. § 110.5 (2011).

114. See Allergen Comments, *supra* note 111 at 46,304.

115. *Id.*

The FDA stressed its desire for advisory labeling that is “truthful and not misleading and [that is] clear, uniform, and accurate.”<sup>116</sup>

Several different advisory statements are used regularly in the United States, with mixed results. The FDA found in a survey of mixed-food-allergic and non-food-allergic adults that statements of the form “may contain” suggest the presence of an allergen more than do “manufactured on the same equipment as” statements or longer descriptive statements about possible contact.<sup>117</sup> A Canadian survey of only food allergy sufferers found that the most deterring statements were those of a “not suitable for people with an allergy to” form, followed by “may contain” and “manufactured on the same equipment as” statements.<sup>118</sup> Statements that only suggested foods “may contain traces of” or were “packaged/manufactured in a facility that also” were least deterring.<sup>119</sup> Of course, deterrent effect is only one factor. There is a great demand for clarity and great disagreement over what is clear. Some comments received in response to the FDA’s 2008 request were skeptical of advisory labeling, claiming it is only used to protect the industry from being sued or that it frightens allergy sufferers into unnecessarily restricting their diets.<sup>120</sup> These comments indicate confusion over just what is meant by these advisory statements. However, others argue adamantly that advisory statements are highly desired and useful. Kids with Food Allergies conducted a survey of 455 participants, overwhelmingly parents of children with food allergies, in which 99.8% responded that they wished advisory statements to be mandatory for the eight major food allergens.<sup>121</sup> Additionally, 89.6% responded that a consistent

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116. *Id.*

117. *Id.*

118. SAMUEL BENREJEB GODEFROY, HEALTH CANADA, USE OF ALLERGEN PRECAUTIONARY LABELLING IN PREPACKAGED FOODS IN CANADA, 21, *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0429-0212> (follow “View Attachment” hyperlink).

119. *Id.*

120. *See, e.g.*, Anonymous, Comment to Notice, Food Labeling; Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception; Public Hearing; Request for Comments, 73 Fed. Reg. 147 (Jan. 14, 2009, 12:00 AM), <http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0429-0188>.

121. Kids with Food Allergies, Food Labeling; Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception; Public Hearing; Request for Comments, 73 Fed. Reg. 147 (Jan. 14, 2009, 12:00 AM), <http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0429-0195>

location for such statements would be helpful.<sup>122</sup>

### 3. Conclusions and the Golden Formulation

These survey results, when taken as a whole, suggest a related pair of conclusions. One is that these advisory labels are heeded to a substantial enough degree that the FDA's emphasis on uniformity is warranted. Because there is substantial demand for this information, and it is easier to ignore a warning you find overbroad than heed a warning that is not present, the use of advisory labels would be in consumers' best interests. In addition, consumers react most effectively to clear statements that they understand, so the most effective form would likely be "Due to the possibility of cross-contamination, may contain" This phrasing clarifies to consumers both why the allergen is not known with certainty to be present and why it is not listed in the ingredients. There is ample evidence to suggest that "cross-contamination" is already a commonly understood term: the FDA did not use it in formulating its questions,<sup>123</sup> but 55 of the 230 comments received contained "cross-contamination" somewhere in the response.<sup>124</sup>

Close scrutiny of the FDA's goals suggests additional methods to shore up the FALCPA's shortcomings. Uniformity, clarity, and prudence recommend (1) inclusion of at least sesame and glutes in the category of "major food allergens" and (2) that major allergens always be listed in a "Contains" statement below the ingredients list. It is far more useful to consumers to be able to know that checking one standard location on a label will always provide the information they need. And just as consumers have become accustomed to referring to Nutrition Facts panels and ingredient lists, they will become accustomed to checking and understanding allergy "Contains" and cross-contamination "May contain" statements.

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(follow "View Attachment" hyperlink).

122. *Id.*

123. Allergen Comments, *supra* note 111, at 46,302. However, "Cross-contact" appeared in two of the twelve questions posed in the FDA request. *Id.*

124. REGULATIONS.GOV, <http://www.regulations.gov> (search "Enter Keyword or ID" for "FDA-2008-N-0429"; then search within results for "Cross-contamination") (last visited Sept. 13, 2011) (demonstrating that the first search returns 215 results, the second 55 results).

### C. BETTER INFORMATION THROUGH FRONT-OF-PACK LABELING

The inclusion of ingredient lists on the packaging of foods provides some insight into the nature of a product, but they do not go far enough to allow consumers to make informed health- and ethics-based purchasing choices. This remains the case because the scientific names and catch-all terms found on food labels cannot be easily and timely translated into meaningful information.<sup>125</sup> Such practical information has been offered by food companies through front-of-pack labeling, but a lack of standardization among companies and the lack of FDA power to effectively regulate such statements have rendered them untrustworthy. However, useful models have been suggested, and from these it may be possible to develop a reliable and understandable tag to attach to foods. If all food products were required to use the same, universal front-of-pack label, consumers might finally have the information they need to make informed decisions at the point of purchase.

#### 1. Ingredient Lists Do Not Reveal Key Traits About Foods

It is difficult for consumers to make meaningful choices about what they wish to consume because ingredient lists are intimidating and confusing. Even though many ingredients are listed by their common names,<sup>126</sup> many others are listed by technical, odd-sounding names. Several vegetarian groups have created databases describing various chemical ingredients and their origins,<sup>127</sup> but these may be of little practical help at the moment of sale. Even if a vegan has carefully studied the several hundred ingredients listed in the *Vegetarian Journal's Guide to Food Ingredients*,<sup>128</sup> it seems unlikely that in selecting between similar products he will remember that a food containing lactic acid may be vegan, but one containing lactase is vegetarian at best.<sup>129</sup> Even if he has a printed copy of such information, looking up each ingredient while standing in a busy grocery store aisle is terribly impractical.

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125. See *supra* Part II.B.3.

126. As required by 21 C.F.R. § 101.4(a) (2011).

127. E.g., Jeanne Yacoubou, *Vegetarian Journal's Guide to Food Ingredients*, VEGETARIAN RESOURCE GROUP, <http://www.vrg.org/ingredients/index.php> (last visited Sept. 13, 2011).

128. *Id.*

129. See *id.* (providing basic data on many common ingredients, including source, use and whether the ingredient is vegan, vegetarian, or non-vegetarian).

What's more, these same food ingredients often go essentially unlisted by qualifying as a "natural flavor" or "artificial flavor" as used in the product.<sup>130</sup> No matter how extensive a consumer's knowledge, there is no chance of discerning useful information from these tags. The food industry is reluctant to relinquish all information about its recipes for fear of having the products it has invested in easily reproduced by competitors.<sup>131</sup> Focusing on this concern, however, suggests a conflict where there need not be one. The information that would actually be useful to consumers tends to be categorical information: does this product comport with vegetarianism, a religious diet, or a diet free of artificial hormones or genetically engineered products? Has this product actually been demonstrated to lower cholesterol or the risk of heart disease? Providing answers to these ethical and health-related questions can help consumers make choices about the foods they wish to consume without disclosing trade secrets.

## 2. Attempts to Respond to the Demand

In response to consumer demand for substantive categorical information, many American food companies are starting to incorporate symbols, charts, and other graphics in "principle display panels" of their packaging, generally with an eye toward advertising a desirable aspect of their product.<sup>132</sup> The FDA has taken notice of these "front-of-pack" labels and has several times declared Requests for Comments and Information, most recently on April 29, 2010, in order to gain information on the effect these symbols have.<sup>133</sup> The FDA believes that "[t]hrough these mechanisms of improved consumer understanding and use of nutrition information and product reformulation, it is possible that a well-designed and science-based front-of-pack nutrition labeling program could bring about significant positive changes in Americans' diet and play a role in lowering the incidence and prevalence of diet-related disease."<sup>134</sup>

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130. 21 C.F.R. § 101.22(a)(1), (3) (2011).

131. SCHLOSSER, *supra* note 66, at 121, 125.

132. FDA's Request for Comments on Front-of-Pack and Shelf Tag Nutrition Symbols, 75 Fed. Reg. 22,602, 22,603 (Apr. 29, 2010) [hereinafter Front-of-Pack Comments].

133. *Id.* at 22,602–04.

134. *Id.* at 22,603–04.

There is reason to believe that detailed labeling is affecting real change in consumer habits. The 2008 U.S. Health and Diet Survey, which polled over 2500 adults across the country, found that a majority “often” read a product’s label before deciding to purchase it for the first time.<sup>135</sup> However, the survey also found high levels of skepticism towards tags such as “low fat,” “high fiber,” and “cholesterol free.”<sup>136</sup> In order to make these labels a useful tool for consumers, the FDA believes that front-of-pack labels should be standardized, widely adopted, easily understood, and based on scientific evidence found in the Dietary Guidelines for Americans put out by the Department of Health and Human Services.<sup>137</sup>

### 3. Ethical Guidance and a Workable Model

Should a uniform tag embodying the FDA’s principles be adopted, consumers might finally be provided with unbiased, reliable health information. However, the FDA has not, to this point, expressed intent to provide similar labeling for ethical concerns. Consumer demand has led to many localized efforts to have foods tagged as kosher, halal, or vegetarian.<sup>138</sup> But again, a lack of standardization has led to confusion and dependability issues.<sup>139</sup> It is difficult to know whether a product lacking a certification symbol actually fails to meet a particular standard or if its producers simply failed to seek certification.

One particularly well-conceived campaign designed to resolve such ambiguities is the NOVA Key, developed by British organizations Looking-Glass and VeggieGlobal.<sup>140</sup> The NOVA Key provides four different ethical designations on foods and other products including whether they are vegetarian and vegan safe. The simple idea that makes it notable is that it de-

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135. Press Release, U.S. Food & Drug Admin., FDA Survey Finds More Americans Read Information on Food Labels (Mar.2, 2010), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm202768.htm>.

136. *Id.*

137. Front-of-Pack Comments, 75 Fed. Reg. at 22,604.

138. *See, e.g.*, Shayna M. Sigman, *Kosher Without Law: The Role of Nonlegal Sanctions in Overcoming Fraud Within the Kosher Food Industry*, 31 FLA. ST. U. L. REV. 509, 524–25, 591–93 (2003) (discussing Kosher and Halal labeling).

139. *E.g., id.* at 578–80 (discussing problems posed by the lack of standardization in Kosher labeling).

140. *Campaigns Gateway*, LOOKING-GLASS, <http://www.looking-glass.co.uk/campaigns> (last visited Sept. 13, 2011).



notes either compliance or noncompliance with each factor.<sup>141</sup> In this manner, a potential buyer is never left uncertain of the factors tested. The same set of factors evaluated and uniformly expressed on every product allows for quick comparison in a manner that is easy to use.

It is reasonable to expect that the decision of which factors to include in any widespread FDA-endorsed label will deviate somewhat from those the NOVA Key has focused on, but the NOVA Key model seems exceptionally well-suited to meeting the FDA's goals. Standards could be set for meeting various levels of compliance with each factor, based on accepted scientific evidence and expert consultation. As long as no more than eight or ten factors are chosen and no more than three or four designations are possible for each factor, such a label would quickly become familiar to consumers. In addition, the uniformity and regulation of such labels by an independent body such as the FDA would encourage a level of trust in the assurances made by these labels that are unlikely to be achieved by nonstandard unregulated claims made by the food producers and packagers.

#### IV. CONCLUSION

The goal of labeling restrictions and requirements on food has always been clarity. Misleading statements are dangerous, both because of their effect on consumers and because they taint competition in a free market. The FDA is uniquely situated to require and regulate these messages and has provided a valuable service to this country for many years. The supporters of an expansive First Amendment have always cited an increase in available information as their driving principle. If the costs of expanding the FDA's abilities to ban claims are too great, mandating universal allergen warnings and front-of-pack labels should be mutually agreeable solutions, as they would increase available information without any loss of freedom of speech. In addition, such labels could provide information based on neutrality and scientific study, rather than leave consumers to wonder about bias and scientific unreliability. Finally, universal labels are the easiest for consumers to understand and regularly incorporate into their decision-

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141. See *The NOVA Key*, LOOKING-GLASS, <http://www.looking-glass.co.uk/ethical-labeling/index.htm> (last visited Sept. 13, 2011).

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making processes. This Note strongly recommends the development and implementation of FDA-mandated universal allergen warnings and front-of-pack labels.