

## REGULATING FUNCTIONAL FOODS: PRE- AND POST-MARKET STRATEGY

*A new breed of products has begun to crowd our grocery shelves—orange juice with calcium, soup with St. John’s Wort, even carrot cake with fiber.<sup>1</sup> This emerging class of super-foods, called “functional foods” or “nutraceuticals” blur the line between food and dietary supplement, challenging the FDA to adapt its regulatory policy to the evolving food industry.*

### Introduction

The Food and Drug Administration’s (“FDA”) regulatory policy creates tidy classifications for products: foods are treated one way, drugs another.<sup>2</sup> But because scientists continue to strengthen the link between nutrition and health,<sup>3</sup> the barrier between food and drug is becoming more and more difficult for the FDA to maintain. Although dietary supplements are a subcategory of food,<sup>4</sup> dietary supplements, like drugs, are consumed for the health benefits they convey to the consumer. The emerging food species called “functional foods” or “nutraceuticals” possess attributes of both foods and dietary supplements. Consumers may choose functional foods not only for their aroma, taste, or nutritional value (characteristics associated with food),<sup>5</sup> but also for specific dietary benefits (characteristic of a dietary supplement).<sup>6</sup>

Scientists aren’t the only ones interested in the link between nutrition and health; industry executives and average consumers also have an eye toward the future of functional foods.<sup>7</sup> One “industry group estimated the size of the nutrition industry to be \$49.5 billion in 2000.”<sup>8</sup> Companies currently catering to the conventional food and conventional drug market are clamoring to feed consumers’ desires for “more health-related products.”<sup>9</sup>

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<sup>1</sup> Lauran Neergaard, *Eyes on ‘Functional Foods’: Products with Supplements May Be Regulated*, ABC News (1999), at [http://abcnews.go.com/sections/living/DailyNews/supplement\\_foods990325.html](http://abcnews.go.com/sections/living/DailyNews/supplement_foods990325.html).

<sup>2</sup> See generally Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 342, 351 (2002).

<sup>3</sup> See Clement Dimitri Pappas, *Maintaining a Level Playing Field: The Need for a Uniform Standard to Evaluate Health Claims for Food and Dietary Supplements*, 57 FOOD DRUG L.J. 25, 34 (2002).

<sup>4</sup> 21 U.S.C. § 321(ff).

<sup>5</sup> *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983).

<sup>6</sup> See 21 U.S.C. § 321(ff).

<sup>7</sup> Pappas, *supra* note 3, at 34.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

Just as the line between food and dietary supplement is becoming blurred on grocery shelves, the FDA's regulatory policy toward these new products seems equally muddled. The FDA faces two challenges: 1) pre-market regulation of product safety and 2) post-market regulation of product labeling. By tightening the reins on pre-market regulation for product safety and loosening its grip on post-market regulation of product labeling, the FDA can effectuate a coherent policy that maximizes consumer protection.

## **Pre-market Regulation: Ensuring Product Safety**

### *Overview of Food Safety Regulation*

Congress has regulated the safety of our food for almost 100 years now. "In 1906... Congress prohibited the introduction of adulterated or misbranded food and drugs into interstate commerce."<sup>10</sup> The food industry enjoyed a presumption of food safety while the government had to prove that a product "posed a reasonable possibility of injury" in order "to remove the product from the market."<sup>11</sup> The Federal Food, Drug, and Cosmetic Act ("FDCA"), enacted in 1938, perpetuated this "after-the-fact policing" system.<sup>12</sup>

Pre-market regulation of food ingredients began with the Food Additives Amendment of 1958, under which FDA approval of food ingredients was required *before* the products were available to consumers. Food manufacturers have two methods to introduce a new food ingredient through pre-market regulation: they may file a food additives petition for the new ingredient, or they may show that the ingredient is "generally recognized as safe" (GRAS).<sup>13</sup> The FDCA offers little guidance on how to determine whether a food ingredient is GRAS. It merely states that the ingredient must be "safe under the conditions of its intended use"<sup>14</sup> and that the determination must be "adequately shown through scientific procedures."<sup>15</sup> Food and dietary supplement manufacturers continue to voice complaints that both food additive petitions and GRAS determinations are too costly and time-consuming.<sup>16</sup>

The concerns of the dietary supplement industry were mitigated in 1994 when Congress enacted the Dietary Supplement Health and Education Act (DSHEA). Under DSHEA, dietary

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<sup>10</sup> Lars Noah & Richard A. Merrill, *Starting From Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U.L. REV. 329, 331 (1998).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> Ilene Ringel Heller, *Functional Foods: Regulatory and Marketing Developments*, 56 FOOD DRUG L.J. 197, 198 (2001).

<sup>14</sup> 21 U.S.C. § 321(s).

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

supplements need not satisfy the safety requirements the FDA imposes on food additives.<sup>17</sup> Manufacturers must merely notify the FDA and provide some evidence that the ingredient can “reasonably be expected to be safe”<sup>18</sup> 75 days before marketing the new product.<sup>19</sup> “Ingredients marketed prior to October 15, 1994, are exempt from even this minimal requirement.”<sup>20</sup> While the lack of a pre-market approval requirement for dietary supplements may be problematic, the way in which this exception may provide easier access to market for functional foods is unacceptable. Classification issues become crucial. When a product looks, smells, and tastes like food, but contains a dietary supplement ingredient, is that product a food, or is it a dietary supplement? If it is a food, the manufacturer must undergo the laborious task of pre-market approval for food ingredients. If it is a dietary supplement, the manufacturer gets to take the easy street to market under DSHEA. To protect consumers, the FDA needs to regulate dietary supplement ingredients in functional foods as they do conventional food additives.

### *Classification of Functional Food as Food*

Common sense dictates that functional foods should be regulated in the same manner as traditional foods.<sup>21</sup> Dietary supplements are defined as a subcategory of food.<sup>22</sup> The whole is the sum of the parts: a whole product should be regulated as a food when comprised of parts that may all be categorized as food. Functional foods look, smell, and taste like food, and FDA should regulate them as such.<sup>23</sup> Even if the FDA continues to regulate ingredients of conventional dietary supplements under relaxed safety standards, ingredients of functional foods should not enjoy the same leniency. The FDCA specifies that a “dietary supplement means a product that is not represented for use as a conventional food...”<sup>24</sup> Thus, the regulation scheme for dietary supplements was not meant to apply to products that are used as conventional foods. As with conventional foods, functional foods are likely to be used by people of all ages and perhaps, over an extended period of time.<sup>25</sup> The lax safety measures for conventional dietary supplements are inappropriate for functional foods that are likely to be consumed by children, by the elderly, or for many years.

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<sup>17</sup> 21 U.S.C. §§ 301, 321(ff).

<sup>18</sup> 21 U.S.C. § 350b(b).

<sup>19</sup> *Id.* at § 350b(a)(2).

<sup>20</sup> *Id.* at § 350b(c).

<sup>21</sup> *See Pappas, supra* note 3, at 36. (“The FDCA defines dietary supplements as food; therefore, common sense compels the conclusion that they should be regulated using the same standard.”)

<sup>22</sup> 21 U.S.C. § 321.

<sup>23</sup> *See Heller, supra* note 13, at 218.

<sup>24</sup> 21 U.S.C. § 321(ff)(2)(B).

<sup>25</sup> Noah & Merrill, *supra* note 10, at 386.

In addition, consumer use of functional foods differs from use of dietary supplements because of the risk of inadvertent consumption. Presumably, consumers of dietary supplements purchase and consume dietary supplements specifically to obtain expected physiological effects. In contrast, consumers choose food for a variety of reasons. For example, one may choose a breakfast beverage, say coffee or orange juice, based on taste, aroma, nutritional value, or for physiological effects. As opposed to purposefully seeking out the health benefits of a dietary supplement, consumers of functional foods may inadvertently take on the risks and benefits associated with these ingredients. Thus, because consumer use of functional foods more closely resembles consumer use of conventional foods, functional food ingredients should be regulated under the strict safety requirements for food additives rather than the relaxed standards for dietary supplements.

### *Pre-Market Regulatory Strategy for Functional Foods*

That the FDA will adopt the position that functional foods should be regulated like conventional foods seems likely based on recent events. For example, the FDA required the manufacturer of a margarine product called Benecol to file a petition for FDA pre-market approval.<sup>26</sup> The manufacturer claimed Benecol was a dietary supplement based on its “plant stanol ester” ingredient, but the FDA rejected this assertion<sup>27</sup> because the statutory definition of dietary supplement “means a product that is not represented for use as a conventional food...”<sup>28</sup> Thus, the FDA correctly recognized that “dietary supplements cannot masquerade as foods—Benecol looks and tastes like regular margarine and will be sold in supermarkets next to the butter.”<sup>29</sup>

Despite the FDA’s proper treatment of the functional food Benecol, the agency has failed to take authoritative action for functional foods as a group. Instead of implementing an overarching policy that functional food ingredients should be treated as food additives, the FDA has only “issued only a handful of Warning Letters to manufacturers of functional food products containing herbal ingredients that it does not believe to be GRAS for use in food.”<sup>30</sup> The FDA has the right idea—to treat functional food ingredients as food additives. However, the FDA has not followed through with this appropriate regulatory objective.

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<sup>26</sup> Heller, *supra* note 13, at 210.

<sup>27</sup> *Id.*

<sup>28</sup> 21 U.S.C. § 321(ff)(2)(B).

<sup>29</sup> Neergaard, *supra* note 1.

<sup>30</sup> Heller, *supra* note 13, at 212. The herbal ingredients targeted by these Warning Letters “include some of the most popular on the market, such as kava kava, ginkgo, echinacea, and St. John’s wort.”

As described *supra*, new food ingredients must earn pre-market approval by filing a food additives petition or by showing that the ingredient is GRAS. Dietary supplements and ingredients in dietary supplements are specifically excluded from the pre-market approval requirements for food additives.<sup>31</sup> The public concern over the safety of dietary supplement products might motivate a legislative change to eliminate the dietary supplements exemption altogether. Whether products that are plainly dietary supplements should comply with strict pre-market safety approval regulations is a separate, but related discussion. Regulating all dietary supplement products and dietary supplement ingredients by food additive standards is certainly one way to accomplish the desired result for functional food products, but such a broad sweeping change is not necessary to effectively regulate the more limited field of functional foods. Perhaps the FDA could define functional food as a new subcategory of food and describe a tailored regulatory scheme accordingly. More simply, the FDA could creatively modify present rules to fit functional foods within the existing framework. For example, whole foods are not regulated as food additives.<sup>32</sup> (Think of nuts as whole foods versus nuts as an ingredient in another food product.<sup>33</sup>) The treatment of whole foods provides an example of a food that is treated differently as an ingredient than when it stands alone. Similarly, a rule that distinguishes between dietary supplements as standalone products versus dietary supplements as ingredients in a food product would accomplish the desired regulatory result for functional foods without drastically affecting regulation of other products.

### *Food Industry Response*

The desired effect of this regulatory strategy for functional foods is to channel functional food ingredients through the routes of pre-market approval for food additives: a food additive petition or a showing that the ingredient is GRAS. While this policy more stringently ensures product safety, it operates in direct conflict with the objective of the food industry to get products to market as soon as possible. The bar for food additive safety is set high. Both the food additive petition and a GRAS determination require costly scientific studies as well as valuable years waiting for FDA approval.<sup>34</sup> Under the proposed regulatory scheme, manufacturers of functional food products bear a heavy burden of proof, and they are likely to loudly object to carrying the load. The burdens of time and cost are addressed in turn below.

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<sup>31</sup> 21 U.S.C. § 321(s)(6).

<sup>32</sup> PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW* 326-27 (2d. ed. 1991).

<sup>33</sup> Lecture by William Zoffer, Duke University School of Law (Sept. 18, 2002).

<sup>34</sup> See Noah & Merrill, *supra* note 10, at 352, 381.

The manufacturers of functional foods legitimately complain that requiring them to follow food additive procedure would significantly delay product marketing. Although the FDCA sets a short 90 day review period for food additive petitions, “this deadline is almost never met.”<sup>35</sup> According to a study of food additive petition approvals conducted by Center for Food Safety and Applied Nutrition (CFSAN) in the early 1990s, “the Agency found a bimodal distribution, with review times ranging from one to three years and three to six years. Of the forty-two substances affirmed as GRAS between 1979 and 1992, none took less than one year to review and more than half (twenty-six) took more than four years.”<sup>36</sup> Considering that “no one seriously disputes that review of new food additives has become extremely slow,”<sup>37</sup> the industry’s aversion to the process is understandable. However, there is still the meaningful distinction between functional foods and drugs. During the delay of regulatory process, no one’s life hangs in the balance for lack of herbal soup or fiber cake. Certainly, we stand to gain health benefits from improved nutrition science. However, in light of the lack of urgency and the importance of consumer safety, the food industry must simply be more patient.

Additionally, the industry can take advantage of the GRAS affirmation procedure as opposed to filing a food additive petition. If a manufacturer can demonstrate that the ingredient is GRAS, the manufacturer can request that the FDA formally affirm the GRAS determination.<sup>38</sup> Both GRAS affirmation and a food additive petition require the manufacturer to satisfy a high scientific bar for product safety and endure a lengthy wait for FDA approval. However, filing a GRAS affirmation presents a golden opportunity “because a sponsor is permitted to, and typically does, market the substance while its petition is awaiting a formal decision.”<sup>39</sup> GRAS affirmation offers another significant advantage. Food manufacturers can seek GRAS determination from “non-governmental scientific organizations.”<sup>40</sup> Some express concern about marketing a product prior to formal FDA approval, “but the fact is that the Agency has never challenged a self-determination of GRAS based on the published extramural review of a reputable scientific body, such as FASEB [Federation of American Societies for Experimental Biology] or FEMA’s [Flavor and Extract Manufacturer’s Association] expert committee.”<sup>41</sup> Furthermore, FDA is often criticized for making overly conservative conclusions. Perhaps such criticism can be mitigated by offering manufacturers the opportunity to obtain a GRAS determination from a third party.

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<sup>35</sup> *Id.* at 373.

<sup>36</sup> *Id.* at 424.

<sup>37</sup> *Id.* at 426.

<sup>38</sup> 21 C.F.R. 170.30 (2002).

<sup>39</sup> Noah & Merrill, *supra* note 10, at 379.

<sup>40</sup> *Id.* at 439.

By allowing manufacturers to market products during review, GRAS affirmations alleviate the delay in product marketing, but the issue of monetary expense remains. Proving a product ingredient as safe under the food additives standard involves unavoidable monetary costs.<sup>42</sup> Rather than placing the burden on FDA's limited resources, the suggested regulatory scheme places the monetary burden on manufacturers that desire to market functional foods and in turn, on the consumers that demand these products. By subjecting functional food ingredients to stricter pre-market regulation, manufacturers will surely face increased production costs. However, deregulating post-market restrictions on product claims will allow functional food manufacturers to appeal to a wider consumer base thereby allowing easier cost recovery.

### **Post-Market Regulation: Putting an End to “Statutory Semantics”<sup>43</sup>**

#### *Overview of Food Labeling Regulation*

FDA has an important interest in allowing consumers access to valuable nutritional information while protecting consumers from fraudulent or misleading health claims.<sup>44</sup> To achieve a balance between these objectives, FDA regulates product labeling, carefully monitoring the types of claims that a manufacturer can display on product labels. Note that product *labeling*, regulated by the FDA, is distinct from product *advertising*, regulated by the Federal Trade Commission (FTC), and the two have different standards of required scientific substantiation.<sup>45</sup>

The most cogent type of claim that a manufacturer can display on a product label is a drug claim, prohibited for use on foods and dietary supplements.<sup>46</sup> Drug claims communicate to the consumer that the product “will cure, mitigate, treat or prevent disease.”<sup>47</sup> Thus, a food label cannot claim to cure, mitigate, treat or prevent disease. For example, “Drinking milk prevents osteoporosis” would be an unacceptable use of a drug claim for a food product.

Instead, foods and dietary supplements may utilize a second category of claims called health claims. The Nutrition Labeling and Education Act (“NLEA”) of 1990, “create[d] an explicit exception to the general prohibition of drug-like claims by authorizing FDA to pre-

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<sup>41</sup> *Id* at 442.

<sup>42</sup> *Id* at 375.

<sup>43</sup> The term “statutory semantics” is borrowed from Heller, *supra* note 13, at 206.

<sup>44</sup> Central Hudson Gas & Elec. Corp. v. Public Sev. Comm’n, 447 U.S. 557, 566 (1980).

<sup>45</sup> Stephen H. McNamara, *So You Want to Market a Food and to Make Health-Related Claims-- How Far Can You Go? What Rules of Law Will Govern the Claims You Want to Make?*, 53 FOOD DRUG L.J. 421, 422 (1998).

<sup>46</sup> Steven B. Steinborn & Kyra A. Todd, *The End of Paternalism: A New Approach to Food Labeling*, 54 FOOD DRUG L.J. 401, 403-04 (1999).

<sup>47</sup> Steinborn & Todd, *supra* note 46, at 403-04. See 21 U.S.C. § 321(g)(1)(B).

approve ‘health claims.’”<sup>48</sup> A health claim “characterizes the relationship of any nutrient... to a disease or health-related condition.”<sup>49</sup> To use a health claim, a manufacturer must get FDA authorization by demonstrating that the claim is supported by “significant scientific agreement.”<sup>50</sup> FDA reviews health claims restrictively; the manufacturer must meet “a very high bar of scientific proof” in order for the FDA to authorize the claim. The Food and Drug Modernization Act of 1997 (“FDAMA”) permits some health claims without the pre-approval of the FDA if they are substantiated by an “authoritative statement” published by “a scientific body of the Government with official responsibility for public health protection or research directly relating to human nutrition...”<sup>51</sup> For example, the following is the model health claim for calcium authorized by the FDA: “Regular exercise and a healthy diet with enough calcium helps teens and young white and Asian women maintain good bone health and may reduce their risk of osteoporosis.”<sup>52</sup> Further, the “Jelly Bean Rule” represents an interesting caveat to the general allowance of health claims under NLEA and FDAMA. Under the “Jelly Bean Rule,” health claims are prohibited on products containing “disqualifying nutrient levels.”<sup>53</sup> That is, products cannot carry health claims if they contain “excessive levels of fat, saturated fat, cholesterol, or sodium”<sup>54</sup> or contain virtually no nutritive value at all.<sup>55</sup> This regulation protects consumers by preventing manufacturers from marketing junk food as health food.

Lastly, foods and dietary supplements may also carry structure/function claims arising “from the nutritional [or nutritive] value”<sup>56</sup> of the product. A structure/function claim communicates how a certain product affects the structure or function of the body. The DSHEA of 1994 reinforced that structure/function claims for dietary supplement are permissible.<sup>57</sup> For example, “Calcium builds strong bones” is an acceptable structure/function claim.<sup>58</sup>

### *FDA’s Restrictive Policy Violates First Amendment Protection of Commercial Speech*

Despite the consumer demand for nutrition information, the FDA restrictively regulates the type of information manufacturers can use on product labels. In describing the FDA’s

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<sup>48</sup> Steinborn & Todd, *supra* note 46, at 403.

<sup>49</sup> 21 U.S.C. § 343(r)(1)(B).

<sup>50</sup> 21 C.F.R. § 101.70 (1998).

<sup>51</sup> 21 U.S.C. § 343(r)(2)(G).

<sup>52</sup> Heller, *supra* note 13, at Appendix.

<sup>53</sup> McNamara, *supra* note 45, at 424. See 21 C.F.R. § 100.14(a)(5).

<sup>54</sup> Perhaps these items could be considered GRAB, or “Generally Recognized As Bad”?

<sup>55</sup> Heller, *supra* note 13, at 201.

<sup>56</sup> McNamara, *supra* note 45, at 432.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

paternalistic stance, Stephen McNamara writes: “Like the character ‘Mr. Anderson’ in the television show ‘Father Knows Best,’ the Food and Drug Administration (FDA) has long dedicated itself to determining what is best for Americans when it comes to the information that appears on food labels.”<sup>59</sup> Critics have also suggested that the FDA’s conservative policy runs contrary to First Amendment commercial speech protection. The Court of Appeals for the District of Columbia agreed. Recently, in *Pearson v. Shalala*, the court held that FDA’s regulation of health claims violated the First Amendment.<sup>60</sup>

In *Pearson*, a dietary supplement manufacturer offered four health claims for FDA approval. The claims suggested that the product “may reduce the risk of” certain health-related conditions.<sup>61</sup> Despite evidence supporting the claims, FDA rejected all four claims as inconclusive because they were not supported by “significant scientific agreement.”<sup>62</sup> The manufacturer brought suit alleging that FDA failed to adequately define “significant scientific agreement.”<sup>63</sup> Furthermore, the FDA violated First Amendment protection of speech by rejecting the health claims altogether rather than using less restrictive means, such as requiring a disclaimer.<sup>64</sup> The Court held that the health claims were not inherently misleading. Accordingly, the FDA could not prohibit the health claims when using a less restrictive means, requiring a disclaimer, would satisfy the FDA’s objectives.<sup>65</sup>

The holding in *Pearson* requires manufacturers to use a disclaimer, but otherwise it has substantially lowered the bar of scientific substantiation for health claims. However, the *Pearson* holding has failed to instigate regulatory changes. The FDA drags its feet, reluctant to abandon its long-standing trend of restrictive regulation of product labeling. In fact, the FDA has “announced that it would not apply *Pearson* to conventional foods,” citing an NLEA distinction for support.<sup>66</sup> Nevertheless, if conventional food manufacturers actively pursue health claims on First Amendment grounds, courts are likely to reject federal limitations on conventional food labeling as well.<sup>67</sup>

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<sup>59</sup> *Id.* at 401.

<sup>60</sup> *Pearson v. Shalala*, 164 F.3d 650, 658 (D.C. Cir. 1999) (reh’g denied en banc).

<sup>61</sup> *Id.* at 652.

<sup>62</sup> *Id.* at 653.

<sup>63</sup> *See* 21 U.S.C. § 343(r)(3)(B)(i).

<sup>64</sup> *Id.* at 654.

<sup>65</sup> *Id.* at 658.

<sup>66</sup> Pappas, *supra* note 3, at 31.

<sup>67</sup> Pappas, *supra* note 3, at 30.

### *Post-Market Regulatory Strategy*

In light of *Pearson*, the FDA's attempt to maintain a restrictive labeling policy for conventional food is an untenable position unlikely to withstand judicial review. Of course, the FDA should continue to prohibit claims that are fraudulent or inherently misleading. The First Amendment offers no protection for such claims.<sup>68</sup> However, the FDA should lower the bar for scientific substantiation of claims when a disclaimer will achieve FDA's consumer protection goals. This regulatory strategy is especially appropriate for functional foods where the health claim is often related to an ingredient that, if sold separately, would be regulated according to the *Pearson* standard.

Expanding the *Pearson* standard to conventional food products, and especially functional food products, is consistent with FDA's policy objectives to simultaneously inform and protect consumers. Drug claims are still prohibited for food and dietary supplement products. Consumers will not be misled that product X will cure disease Y. Consumers can appreciate that health claims and structure/function claims carry some uncertainty. Requiring the high bar of "significant scientific agreement"<sup>69</sup> discounts the responsibility demonstrated by and expected of the consumer. Justice Silberman explains:

As best we understand the government, its first argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they 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. We think this contention is almost frivolous.<sup>70</sup>

Considering the other avenues of consumer access—structure/function claims and advertising—maintaining a stranglehold on health claims does not effectively protect consumers from information. Consumers consider health claims when making food choices,<sup>71</sup> but will consumers consider the nuances of "statutory semantics?"<sup>72</sup> Will a consumer distinguish between "calcium may help prevent osteoporosis" versus "calcium builds strong bones?" The two food claims may carry varying standards of substantiation, but the distinction will probably be lost on the consumer. Instead of being stingy with health claims, FDA should rely on more lenient and equally effective means to protect consumer health, such as *Pearson* disclaimers. Also, the Jelly

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<sup>68</sup> Steinborn & Todd, *supra* note 46, at 411-12.

<sup>69</sup> See 21 U.S.C. § 343(r)(3)(B)(i).

<sup>70</sup> *Pearson*, *supra* note 63, at 655.

<sup>71</sup> Pappas, *supra* note 3, at 34.

<sup>72</sup> Heller, *supra* note 13, at 206.

Bean Rule ensures consumer safety by prohibiting health claims on products with “disqualifying nutrient levels.”<sup>73</sup> When this relaxed post-market regulatory strategy is coupled with the proposed pre-market strategy described above, consumer protection is maximized. These safeguards should calm fears that consumers will be “‘duped’ into buying products that would jeopardize their health”<sup>74</sup> because consumers are unlikely to be “duped,” and also because products required to pass pre-market safety regulations will not jeopardize consumer health.

In addition to lowering the bar for substantiation of health claims, the FDA should also relax requirements for structure/function claims. The “nutritive value” requirement hinders effective food labeling regulation. A structure/function claim for a food product must arise “from the nutritional [or nutritive] value.” First, the term “nutritive value” is hopelessly ambiguous. Even the FDA seems unable to determine whether a food constituent contributes “nutritive value.”<sup>75</sup> Secondly, the property of nutritive value does not appear in the statutory definition of food. Although the ordinary way people use food is “primarily for taste, aroma, or nutritive value,”<sup>76</sup> confining food to these properties is “unduly restrictive.”<sup>77</sup> Thus, requiring structure/function claims for food products to relate to “nutritive value” is worthless and simply incorrect. In short, relaxing post-market regulation of product labeling promotes consumer access to nutrition information without compromising consumer safety.

## **Conclusion**

The suggested strategy for regulating functional foods is comprised of two complementary parts: the FDA should constrict pre-market regulation of product safety while relaxing post-market regulation of product labeling. This comprehensive approach distributes responsibility so as to maximize consumer protection. Food and dietary supplement manufacturers must expend more time and money ensuring that products are safe. While the GRAS affirmation option mitigates their time concerns, the more lenient post-market strategy enables manufacturers to more easily pass on costs to consumers. Meanwhile, consumers who desire functional food products take on additional responsibilities. These particular consumers must accept the increased monetary cost that accompanies greater assurance of product safety. They must also continue to recognize that product labels may claim uncertain results. Lastly,

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<sup>73</sup> McNamara, *supra* note 45, at 424. See 21 C.F.R. § 100.14(a)(5) (1998).

<sup>74</sup> Pappas, *supra* note 3, at 25.

<sup>75</sup> Steinborn & Todd, *supra* note 46, at 416.

<sup>76</sup> McNamara, *supra* note 45, at 432-33, citing *Nutrilab*, *supra* note 5, at 338.

<sup>77</sup> *Id.*

FDA must refocus its attention on consumer safety by paying more attention to what is *in* the package than what is *on* it.

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