

## SIGNS OF CHANGE OR CLASH OF SYMBOLS? FDA REGULATION OF NUTRIENT PROFILE LABELING

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### ABSTRACT

A new generation of food labels uses symbols and ratings on the front of packages and on supermarket shelves to indicate a product's nutritional value. Proponents of these new labels assert that they help consumers make healthier dietary choices. Critics contend that the new labels are confusing and misleading. This article argues that, with some minor reforms, the FDA's existing regulatory framework governing nutrient content claims on food labels is well suited to balance these competing considerations. With regard to the most novel and complex labels – those that rate the overall nutritional value of food products based on detailed algorithms – the article proposes that the FDA provide minimum standards that would prevent fraudulent or misleading claims while allowing for genuine experimentation and competition within the private sector that is likely to advance knowledge in the areas of nutrition and food labeling as a public health strategy.

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## INTRODUCTION

Until recently, most nutrition information on food packaging was relegated to the back and sides of food packages.<sup>1</sup> But the food industry is beginning to change this by placing symbols and ratings prominently on the front of packages and on supermarket shelves to indicate the nutritional value of products. Simple claims like “fat-free” and “fortified with 9 essential vitamins and iron” have long appeared on the front of food packages.<sup>2</sup> But a new generation of front-of-package and shelf labels provides a lot more nutrition information. For example, the Nutrition Highlights panel shows the quantities of six nutrients at a glance.<sup>3</sup> The Smart Choices logo designates more nutritious foods.<sup>4</sup> The NuVal Nutritional Scoring System rates the overall nutritional value of food items from one to one hundred.<sup>5</sup> The industry has launched dozens of these front-of-package and supermarket-shelf nutrition labels in the past five years.<sup>6</sup> The proliferation of these labels has generated increasing controversy and attracted the attention of federal regulators.

Proponents of the new nutrition labels assert that these labels help consumers make healthier dietary choices.<sup>7</sup> The average consumer

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<sup>1</sup> Federal regulations require the placement of a Nutrition Facts label and ingredient list on the principal display panel of a food package or an adjacent side panel. Where the side panel is unsuitable, the Nutrition Facts label and ingredient list may be placed the rear panel. In practice, the Nutrition Facts label and ingredient list are rarely printed on the principal display panel (i.e. front) of food packages. *See* 21 C.F.R. § 101.2 (2009); U.S. FOOD & DRUG ADMIN., DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE (2008), ch. VII n.G1, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm> [hereinafter 2008 GUIDANCE ON FOOD LABELING].

<sup>2</sup> *See, e.g.*, Captain Crunch Crunchy Sweet Cereal, <http://www.theimaginaryworld.com/box330.jpg> (last visited Nov. 14, 2009); Brewer’s Ice Cream, [http://images.businessweek.com/ss/07/08/0814\\_softdrinks/image/dc-free-creamy-vanilla.jpg](http://images.businessweek.com/ss/07/08/0814_softdrinks/image/dc-free-creamy-vanilla.jpg) (last visited Nov. 14, 2009).

<sup>3</sup> *See* General Mills, Nutrition Highlights, [http://www.generalmills.com/corporate/health\\_wellness/nutrition\\_highlights.aspx](http://www.generalmills.com/corporate/health_wellness/nutrition_highlights.aspx) (last visited Nov. 14, 2009).

<sup>4</sup> Smart Choices Program, <http://www.smartchoicesprogram.com> (last visited Nov. 14, 2009).

<sup>5</sup> NuVal, FAQ, <http://www.nuval.com/How> (last visited Nov. 14, 2009).

<sup>6</sup> *See* Fooducate.com, 1862 – 2009: A Brief History of Food and Nutrition Labeling (Oct. 25, 2008), <http://www.fooducate.com/blog/2008/10/25/1862-2008-a-brief-history-of-food-and-nutrition-labeling> (last visited Nov. 14, 2009) (detailing the history of front-of-package and supermarket-shelf nutrition labels).

<sup>7</sup> *See* T. Lobstein & S. Davies, *Defining and Labelling ‘Healthy’ and ‘Unhealthy’ Food*, 12 PUB. HEALTH NUTRITION 331, 331, 338–39 (2009); Adam Drenowski, *What’s Next for Nutrition Labeling and Health Claims?: An Update on*

has neither the time nor the inclination to analyze the complex tradeoffs required to compare two or more processed foods, each with multiple ingredients and a mix of nutritional benefits and detriments.<sup>8</sup> Front-of-package and shelf labels, explain proponents, offer a quick way to determine which foods contribute more, overall, to a healthy diet.<sup>9</sup> Moreover, proponents assert, the influence that these new nutrition labels have on consumer purchasing decisions has a feedback effect on the nutritional quality of products as manufacturers reformulate their products to make them more nutritious in order to qualify for symbols of approval or higher ratings.<sup>10</sup>

Critics argue that the new labeling schemes are confusing and misleading. Increasingly, multiple nutrition labels accompany products, printed on the front of packages by manufacturers and placed on store shelves by retailers.<sup>11</sup> Whether merely redundant or conflicting, all of this competing nutrition information complicates the task of product comparison. “What started out as one or two front of package labels,” opines a prominent food blog, “has turned into a cacophony of labeling schemes . . . .”<sup>12</sup> Moreover, manufacturers’ and retailers’

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*Nutrient Profiling in the European Union and the United States*, 42 NUTRITION TODAY 206, 213 (2007); Andrew Martin, *Store Chain’s Test Concludes that Nutrition Sells*, N.Y. TIMES, Sept. 6, 2007, at C3; Andrew Martin, *Is It Healthy? Food Ratings Battle to Become the Standard*, N.Y. TIMES, Dec. 1, 2007, at A12.

<sup>8</sup> See Smart Choices Program, *supra* note 4; see also Michael F. Jacobson, *An Important New Way to Rate the Nutritional Quality of Foods*, 24 AM. J. HEALTH PROMOTION 144 (2009). During the course of a major shopping trip to the supermarket, the average consumer purchases about 30 items in just under an hour. Point of Purchase, Bestfindings Research, <http://www.point-of-purchase-bestfindings.com/research.htm> (last visited Sept. 15, 2009).

<sup>9</sup> *Food Labeling: Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria: Public Hearing Before the Food and Drug Admin.*, FDA-2007-N-0198, 18-19, 24-25 (Sept. 11, 2007) (statement of David Katz, M.D.), available at <http://www.regulations.gov/search/Regs/home.html#documentDetail?R=090000648042a9d5> [hereinafter *FDA Hearing Sept. 11*].

<sup>10</sup> Lobstein & Davies, *supra* note 7, at 338; Interview with Chip LeBlanc, Dir. of Operations, Guiding Stars Licensing Co. (Apr. 9, 2009).

<sup>11</sup> See, e.g., Bev Sklar, *Food Rating Labels—Confused Yet?* (July 17, 2009), <http://www.thatsfit.com/2009/07/17/food-rating-labels-confused-yet/>; CTR. FOR SCI. IN THE PUB. INTEREST, PETITION FOR ADVANCE NOTICE OF PROPOSED RULEMAKING ON THE USE OF SYMBOLS ON THE PRINCIPAL DISPLAY PANEL TO COMMUNICATE THE HEALTHFULNESS OF FOODS 7-13 (Nov. 30, 2006), [http://www.cspinet.org/new/pdf/healthy\\_symbol\\_petition.pdf](http://www.cspinet.org/new/pdf/healthy_symbol_petition.pdf) [hereinafter CSPI PETITION].

<sup>12</sup> Fooducate blog, *The Problem with Supervalu’s Nutrition IQ Rating Program (Now at Cub Foods Too)* (July 15, 2009), <http://www.fooducate.com/blog/2009/07/15/the-problem-with-supervalus-nutritioniq-rating-program-now-at-cub-foods-too> (last visited Nov. 14, 2009) (critiquing Nutrition IQ rating system). Proponents of retail-sponsored storewide systems argue that storewide rating systems overcome

financial interest in selling products raises concerns about the integrity of industry-sponsored nutrition labels. Placement of the Smart Choices logo on Froot Loops and Cocoa Krispies cereals prompted allegations of a conflict of interest between reliable dietary advice and profits.<sup>13</sup>

Health advocates and some industry representatives have called on the federal government to promulgate standards for front-of-package and supermarket-shelf nutrition labeling that would provide greater uniformity and reliability.<sup>14</sup> Several European countries, including the United Kingdom, have already adopted such standards.<sup>15</sup> The Food and Drug Administration (FDA) is currently assessing the applicability of existing rules governing nutrition claims and considering regulatory changes in light of the growth of nutrition labeling.<sup>16</sup>

This new generation of nutrition symbols and ratings – which I shall refer to collectively as *nutrient profile labeling* – is a complex phenomenon that encompasses a variety of different types of label claims. In this article, I argue that the FDA’s existing regulatory framework governing nutrient content claims on food labels is well suited to address concerns about confusion and reliability raised by nutrient profile labeling. Several types of nutrient profile labels fall squarely within existing regulatory categories. For example, many labels present simple quantitative statements, such as “200mg of sodium,” or they make descriptive claims that a product is high in fiber, low in fat, or a good source of calcium. Such label statements are already covered by existing regulations that require quantitative

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confusion caused by multiple nutrient profile labels. They have compiled data, as yet unpublished, suggesting that when confronted by multiple labels, consumers rely on storewide rating systems. Email from Dr. David Katz to Timothy Lytton (Oct. 26, 2009) (on file with author).

<sup>13</sup> See William Neuman, *For Your Health, Froot Loops*, N.Y. TIMES, Sept. 5, 2009, at B1; William Neuman, *Connecticut to Scrutinize Food Labels*, N.Y. TIMES, Oct. 15, 2009, at B1; William Neuman, *Food Label Program to Suspend Operations*, N.Y. TIMES, Oct. 23, 2009, at B1; Letter from Rosa L. DeLauro, Congresswoman, to Margaret Hamburg, Comm’r, U.S. Food & Drug Admin. (Sept. 21, 2009), <http://delauero.house.gov/release.cfm?id=2653>.

<sup>14</sup> See CSPI NEWSROOM, CTR. FOR SCI. IN THE PUB INTEREST, FDA URGED TO CREATE NEW “HEALTHY FOOD” LABELING SYSTEM (Nov. 30, 2006), available at <http://www.cspinet.org/new/200611301.html>.

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

<sup>16</sup> CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: LETTER REGARDING POINT OF PURCHASE FOOD LABELING (Oct. 2009), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208.htm> [hereinafter GUIDANCE FOR INDUSTRY: LETTER REGARDING POINT OF PURCHASE FOOD LABELING].

statements to be accurate and descriptive claims to conform to FDA definitions.<sup>17</sup> Some types of nutrient profile labels, however, do not fit so neatly into existing regulatory categories. For example, a label may present a symbol of approval indicating that a food is, overall, of high nutritional value. I propose that existing regulations governing use of the term “healthy” on food labels be applied to such symbols. FDA regulations require that any food labeled “healthy” must contain requisite amounts of nutrients such as calcium, iron, and fiber while not exceeding limits for fat, cholesterol, and sodium.<sup>18</sup> Under my proposal, symbols of approval indicating that a food is of overall high nutritional value would have to meet this standard. Other types of nutrient profile labels are more complex, rating the overall nutritional value of food, for example on a scale of zero to three, or one to one hundred. With regard to these labels, I propose that the FDA develop a graduated scale of healthiness comprised of multiple thresholds for overall nutritional value that would provide a regulatory standard for ratings.<sup>19</sup>

Any proposal to regulate nutrient profile labeling must address free speech concerns. Litigation in the late 1990s and early 2000s produced federal court decisions applying First Amendment commercial speech protections to health claims on dietary supplement labels.<sup>20</sup> The courts rejected FDA attempts to ban health claims that did not meet a high standard of scientific verification. The courts ruled that the FDA must allow such claims so long as they were accompanied by disclaimers indicating the strength of the scientific evidence supporting the claim.<sup>21</sup> The First Amendment, explained the courts, embodies a “clear preference for disclosure over suppression of com-

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<sup>17</sup> See 21 C.F.R. § 101.13(i) (2009) (on simple quantitative statements); §§ 101.54, 101.56, 101.60, 101.61, 101.62 (on statements using descriptive terms); U.S. FOOD & DRUG ADMIN., DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY AND FDA: DEAR MANUFACTURER LETTER REGARDING FOOD LABELING (Jan. 2007), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053425.htm> [hereinafter DEAR MANUFACTURER LETTER] (containing nonbinding recommendations).

<sup>18</sup> 21 C.F.R. § 101.65(d)(2) (2009).

<sup>19</sup> My analysis in this article focuses exclusively on the FDA. The USDA regulates food labels on meat and poultry and shares jurisdiction with the FDA over food labels on processed foods containing meat and poultry. See INST. OF MED., NUTRITION LABELING: ISSUES AND DIRECTIONS FOR THE 1990S 51–54 (Donna V. Porter & Robert O. Earl eds., 1990). Any comprehensive regulation of nutrient profile labeling would require coordination between the two agencies.

<sup>20</sup> See, e.g., *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

<sup>21</sup> *Whitaker*, 248 F. Supp. 2d at 5-15.

mercial speech.”<sup>22</sup> While it is unclear how this emerging jurisprudence would apply to FDA restrictions on nutrient profile labeling, no reform proposal would be complete without addressing First Amendment implications.

Aside from First Amendment concerns, my proposal to regulate nutrient profile labeling under the existing regulatory framework for nutrient content claims faces several other potential objections. First, one might be skeptical of government standards as a way to measure or guarantee the accuracy of claims about overall nutritional value given industry influence in the regulatory process and lack of consensus among nutrition experts. Second, one might be concerned that the imposition of stricter government standards would impede experimentation and innovation that might lead to advances in nutrition science and food labeling. Third, one might object that nutrient profile ranking schemes are essentially a marketing tool for industrially processed foods – fortified with positive nutrients and modified to reduce negative nutrients – that are unhealthy for individuals and are produced in ways detrimental to the environment. Accordingly, one might argue, the best way to regulate nutrient profile labeling is not to standardize it but to prohibit it entirely.

In the discussion that follows, I elaborate my analysis of nutrient content claims, explain my proposal to regulate them, and respond to potential objections. Part I of the Article presents a taxonomy of different types of nutrient profile labeling, highlighting variations that have regulatory implications. Part II offers a brief history of FDA regulatory action concerning nutrient profile labeling to date. Part III maps out the existing FDA regulatory framework governing nutrient content claims, distinguishing between different categories of nutrient content claims. Part IV analyzes the emerging jurisprudence of First Amendment commercial speech protections applied to FDA regulation of health claims on dietary supplements and its implications for regulation of nutrient profile labeling. Part V locates the different types of nutrient profile labeling schemes within the appropriate categories of nutrient content claims and demonstrates how the existing FDA regulatory framework can address concerns about confusion and reliability. This Part includes my proposal to adapt FDA regulations to deal with novel features of nutrient profile labels that rate the overall nutritional value of foods. Part VI addresses potential objections to my proposal.

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<sup>22</sup> *Id.* at 15.

## I. A TAXONOMY OF NUTRIENT PROFILE LABELING

Nutrient profile labeling schemes are distinguishable along a number of dimensions that are relevant to subsequent discussion of how to regulate them. The first dimension is the *source* of a labeling scheme. Some schemes are created by manufacturers who use them to label their own products. For example, General Mills in 2007 launched the front-of-package Nutrition Highlights panel on its cereal products, indicating the per serving amount of six nutrients which, depending upon the food, may include calories, total fat, saturated fat, sodium, sugars, fiber, calcium, Vitamin A, and Vitamin C.<sup>23</sup> Retail food sellers, such as supermarkets and restaurants, also sponsor schemes. Hannaford Brothers supermarket chain in 2006 instituted its Guiding Stars shelf label system which rates over 25,000 store items with either one, two, three, or no stars.<sup>24</sup> Schemes may also be developed by experts outside of industry. The NuVal Nutritional Scoring System, introduced on supermarket shelves in 2008, was developed by a team of twelve academic medical and nutrition experts.<sup>25</sup> Some schemes are created by coalitions of industry and non-industry contributors. The Smart Choices logo, which first appeared on products in 2009, was the product of such a mixed group organized by the non-profit Keystone Center.<sup>26</sup> The Smart Choices logo was designed to replace a number of competing labels employed by individual companies.<sup>27</sup> Finally, several schemes in Europe are government sponsored. The United Kingdom Food Standards Agency (FSA) created the Traffic Light front-of-package labeling system, indicating the level of calories, fat, saturated fat, sugars, and salt in food products using numerical quantities and one of three colors – green (low in that nutrient, eat freely), amber (neither high nor low in that nutrient, eat in moderation), and red (high in that nutrient, eat sparingly) – and in 2008

<sup>23</sup> Press Release, General Mills, General Mills Announces Children's Advertising Pledge: Company to Strengthen Nutrition Criteria; Enforce New Sugar Guideline (July 18, 2007), available at [http://www.mycereal.com/corporate/media\\_center/news\\_release\\_detail.aspx?itemID=27134&catID=20369](http://www.mycereal.com/corporate/media_center/news_release_detail.aspx?itemID=27134&catID=20369).

<sup>24</sup> Andrew Martin, *The Package May Say Healthy, But This Grocer Begg to Differ*, N.Y. TIMES, Nov. 6, 2006, at A1.

<sup>25</sup> Progressive Grocer, *Three Chains to Bow Topco's ONQI Food Scoring System Under New Name*, (July 11, 2008), available at [http://www.progressivegrocer.com/progressivegrocer/content\\_display/supermarket-industry-news/e3ia50cdecb373435f1b6b7eba0f975072d8](http://www.progressivegrocer.com/progressivegrocer/content_display/supermarket-industry-news/e3ia50cdecb373435f1b6b7eba0f975072d8).

<sup>26</sup> Fooducate blog, "Smart Choices" Food Labeling—A Step In the Right Direction (Oct. 28, 2008), <http://www.fooducate.com/blog/2008/10/28/smart-choices-food-labeling-a-step-in-the-right-direction>.

<sup>27</sup> Smart Choices, For Companies, <http://www.smartchoicesprogram.com/index.html> (last visited Nov. 14, 2009).

launched a campaign to convince food industry firms to adopt it.<sup>28</sup> So far, government-sponsored schemes have all been voluntary.

A second dimension along which nutrient profile labeling schemes are distinguishable is the *scope* of foods the scheme covers. Some schemes cover only recommended foods, while other schemes cover all foods. The Smart Choices program, for example, allows participating manufacturers to place a symbol of approval only on products that meet specified nutritional criteria for more nutritious foods.<sup>29</sup> By contrast, the NuVal and Guiding Stars systems cover all foods in the supermarket, many of which receive low scores and no stars.<sup>30</sup> One scheme, sponsored by the Finnish government, covers only non-recommended foods, affixing a “high salt” warning label on selected products.<sup>31</sup>

A third dimension is *character*. Labels may provide information that places the product in a positive light only, a negative light only, or both a positive and negative light. For example, the Guiding Stars system only presents positive information about a product, by utilizing one, two, or three stars to represent good, better, best. By contrast, the Finnish high salt label presents only negative information about the products on which it appears. Finally, the UK Traffic Light system presents both positive and negative information with its combination of green, amber, and red lights.

A fourth dimension is *gradation*. Schemes may employ a simple quantitative statement of the amount of a nutrient, a threshold, or a rating scale. For example, the Nutrition Highlights panel presents the amount in grams and percentage of Daily Value per serving for each of six nutrients. The Smart Choices logo identifies products that meet a nutritional threshold.<sup>32</sup> The Guiding Stars system rates foods from zero to three stars, and the NuVal system rates them on a scale from one to one hundred.<sup>33</sup>

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<sup>28</sup> Food Standards Agency, *Traffic-Light Labelling*, <http://www.eatwell.gov.uk/foodlabels/trafflights/> (last visited Nov. 14, 2009); Food Standards Agency, *Agency's New Traffic Light TV Ad Launched* (Mar. 5, 2007), <http://www.food.gov.uk/news/newsarchive/2007/mar/tvadsignpost>; Food Standards Agency, *New TV Ads make Healthier Choices Easy* (Jan. 14, 2008), <http://www.food.gov.uk/news/newsarchive/2008/jan/tvadsignpost>; Faculty of Public Health, *Traffic-light Food Labelling: A Position Statement* (Aug. 2008), available at [http://www.fphm.org.uk/resources/AtoZ/ps\\_food\\_labelling.pdf](http://www.fphm.org.uk/resources/AtoZ/ps_food_labelling.pdf).

<sup>29</sup> NuVal, *supra* note 5.

<sup>30</sup> Martin, *supra* note 24.

<sup>31</sup> World Action on Salt and Health, *Europe Salt Action Summary*, <http://www.worldactiononsalt.com/action/europe.doc> (last visited Feb. 9, 2010).

<sup>32</sup> Smart Choices Program, *supra* note 4.

<sup>33</sup> NuVal, *supra* note 5; Martin, *supra* note 24.

Fifth, schemes differ in terms of *metric*. Some schemes present foods as nutritious in an absolute sense, while others merely indicate that foods are relatively more or less nutritious when compared to other foods. The American Heart Association (AHA) certifies “heart-healthy” foods that are “part of a sensible eating plan.”<sup>34</sup> These foods are marked with the AHA’s Heart Check mark, which is meant to indicate that a food is of high nutritional value in an absolute sense. Similarly, the Guiding Stars system presents starred products as having “good,” “better,” and “best,” nutritional value in an absolute sense.<sup>35</sup> The three stars on broccoli and raw oats are meant to indicate that these are highly nutritious foods. By contrast, the PepsiCo Smart Spot label indicates a product’s nutritional value in a relative sense. For example, the label appears on Baked! Cheetos and Tropicana Twister Diet Soda to indicate that these products are more nutritious, as compared with other PepsiCo snack foods and soft drinks.<sup>36</sup>

Sixth, and related to metric, nutrient profile schemes differ in their *segmentation* by food group. Some systems evaluate all foods using the same criteria, while others employ different criteria for different categories of food. The NuVal system uses a single Overall Nutritional Quality Index (ONQI) algorithm for the entire food supply, rating all foods on the same one to one hundred scale.<sup>37</sup> The Smart Choices program, by contrast, employs different nutrient criteria for each of nineteen different product categories.<sup>38</sup> Schemes that segment thus evaluate foods relative to other foods in the same food group.

<sup>34</sup> *FDA Public Hearing on Nutritional Labeling*, Docket ID FDA-2007-N-0198, 121-122 (Sept. 10, 2007), available at <http://www.regulations.gov/search/Regs/home.html#documentDetail?R=090000648042a9d4> [hereinafter *FDA Hearing, Sept. 10*] (testimony of Rose Marie Robertson, Chief Science Officer, AMA); Am. Heart Ass’n, *Nutritional Criteria for Certified Foods* (2009), <http://www.americanheart.org/presenter.jhtml?identifier=4973> (last visited Nov. 14, 2009).

<sup>35</sup> Guiding Stars, *Nutrition Choices Made Simple*, <http://www.guidingstars.com/what-is-guiding-stars/how-it-works/sample-food-ratings> (last visited Nov. 14, 2009).

<sup>36</sup> See PepsiCo, *Smart Spot*, <http://www.smartspot.com/products/chipscripspretzels> (last visited Nov. 14, 2009); see also *FDA Hearing, Sept. 10, supra* note 34, at 75, 80 (statement of Nancy Green, PepsiCo). As a collaborator in the development of the Smart Choices program, PepsiCo was in the process of phasing out the Smart Spot and replacing it with the Smart Choices logo on eligible products. Following negative publicity surrounding the placement of the Smart Choices logo on highly sweetened breakfast cereals, however, PepsiCo has announced that it is withdrawing from the Smart Choices program. Neuman, *Food Label Program to Suspend Operations, supra* note 13.

<sup>37</sup> NuVal, The ONQI Algorithm, <http://www.nuval.com/science> (last visited Nov. 14, 2009).

<sup>38</sup> Smart Choices, *Nutrition Criteria & Calorie Indicator*, <http://www.smartchoicesprogram.com/nutrition.html> (last visited Nov. 14, 2009).

Seventh, schemes differ in terms of information *aggregation*. Schemes like General Mills' Nutrition Highlights present separate information for each of six nutrients. By contrast, schemes like NuVal present one summary rating for a food item.<sup>39</sup>

Eighth, and finally, schemes differ in terms of *transparency*. Some schemes are based on complex algorithms that are not publicly available. These schemes are proprietary and provided to food manufacturers and supermarkets under license for a fee. NuVal and Guiding Stars are examples of proprietary schemes based on unpublished algorithms.<sup>40</sup> By contrast, other schemes publish their algorithms or simply rely on information already available on the rear or sides of food packages. For example, the Smart Choices algorithm is published on the program's website,<sup>41</sup> and the Nutrition Highlights panel presents information already available in the Nutrition Facts Panel. Figure 1 presents a summary of the eight dimensions along which schemes vary.

**Figure 1. Taxonomy of Nutrient Profiling Labeling Schemes**

Scheme	Source	Scope	Character	Grada-tion	Metric	Segmen-tation	Aggre-gation	Transparency
Nutrition Highlights General Mills	manu-facturer	all foods*	positive & negative	quantity grams & % DV	absolute	applies only to cereals	no	published
Guiding Stars Hannaford Bros.	retailer	all foods	positive only	scale 0-3 stars	absolute	yes	yes	unpublished
NuVal	experts outside of industry	all foods	positive & negative	scale 1-100	absolute	no	yes	unpublished
Smart Choices Keystone Center	coalition of industry & outside experts	recom-mended foods only	positive only	threshold	relative	yes	yes	published
Traffic Light U.K. FSA	govern-ment	all foods	positive & negative	quantity & scale grams green, amber, red	absolute	no	no	published
High Salt Label Finland	govern-ment	not recom-mended foods only	negative only	threshold	absolute	no	no	published
Heart Check Am. Heart Ass'n	experts outside of industry	recom-mended foods only	positive only	threshold	absolute	no	yes	published
Smart Spot PepsiCo	manu-facturer	recom-mended foods only	positive only	threshold	relative	yes	yes	published

\* General Mills' Nutrition Highlights label covers only cereals, but it covers all of the cereals that the company makes.

<sup>39</sup> The FDA refers to these two approaches to aggregation as "nutrient-specific" and "summary" schemes. GUIDANCE FOR INDUSTRY: LETTER REGARDING POINT OF PURCHASE FOOD LABELING, *supra* note 16.

<sup>40</sup> See NuVal, About NuVal, <http://www.nuval.com/About> (last visited Feb. 5, 2010); Guiding Stars, What is Guiding Stars, <http://www.guidingstars.com/what-is-guiding-stars> (last visited Feb. 5, 2010).

## II. FDA REGULATORY ACTION ON NUTRIENT PROFILE LABELING TO DATE

The Center for Science in the Public Interest (CSPI) has been the most prominent advocate for greater regulation of nutrient profile labeling. CSPI has long supported nutrition labeling and has applauded the development of front-of-package nutrient profile labels. Front-of-package symbols, according to CSPI, offer consumers an easily understandable summary of the information contained in the Nutrition Facts panel and the ingredient list, which are relegated to the back or side of the package.<sup>42</sup> In November 2006, CSPI petitioned the FDA and warned that the variety of nutrient profile labels using inconsistent nutrient criteria threatened to render the labels more confusing than helpful to consumers.<sup>43</sup> In addition, CSPI suggested that industry self-interest raised concerns that nutrient profile labels might be misleading.<sup>44</sup> Accordingly, the CSPI requested that the FDA develop “a simple, uniform science-based system [that] would bring consistent and reliable information to the marketplace and help consumers choose more healthful diets.”<sup>45</sup> The petition recommended that the FDA make this government system mandatory and that private labeling schemes inconsistent with it be prohibited.<sup>46</sup>

At a subsequent FDA public hearing in September, 2007, reactions to CSPI’s proposal were mixed. Some health advocates and industry representatives supported aspects of the proposal. A representative from the American Heart Association seemed to support a government-sponsored nutrient labeling scheme, encouraging “the FDA to establish a . . . standardized comprehensive front of the package food icon system that has unified criteria . . . based on the best available science, featuring consumer education as the ultimate goal . . . highlighting foods and nutrients that are good for you and those that should be minimized or avoided.”<sup>47</sup> A spokesperson for industry giant Kraft Foods advocated uniform standards and advised the FDA panel that “[i]t is . . . critical that we come to an agreement on a common way of doing this.”<sup>48</sup>

<sup>41</sup> Smart Choices, *supra* note 38.

<sup>42</sup> CSPI NEWSROOM, *supra* note 14; CSPI PETITION, *supra* note 11, at 2.

<sup>43</sup> CSPI PETITION, *supra* note 11, at 7-13.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at i.

<sup>46</sup> *Id.* at 2.

<sup>47</sup> FDA Hearing, Sept. 10, *supra* note 34, at 125 (statement of Rose Marie Robertson, Chief Sci. Officer, Am. Heart Ass’n).

<sup>48</sup> *Id.* at 79 (statement of Richard Black, Kraft Foods).

Others testifying at the hearing raised several objections to new government regulation of nutrient profile labeling. A representative from the Grocery Manufacturers Association (GMA) objected that new government restrictions on nutrient profile labeling would be redundant. She asserted that the Federal Food, Drug, and Cosmetic Act (FDCA) already prohibits false or misleading claims on food labels and that FDA regulations impose extensive disclosure requirements on claims regarding the nutrient content of food items.<sup>49</sup> The GMA representative argued that “FDA policies and guidance around nutrition communication on labels and labeling are very clear and are being followed by the industry” and that the FDA already “ha[s] the enforcement authority in case they’re not.”<sup>50</sup>

Some who supported the idea of greater uniformity in nutrient profile labeling nevertheless objected that mandatory government standards would be counterproductive. NuVal developer David Katz, acknowledged the need to address consumer confusion from inconsistent label messages but suggested that advances in nutrient profile labeling would benefit from simultaneous experimentation with different kinds of schemes.<sup>51</sup> A representative from the Whole Grains Council argued that unfettered experimentation by non-governmental organizations and private industry is the most effective way to generate information and experience that, in the long run, could eventually be used as a basis for government standardization.<sup>52</sup> A Unilever representative argued against mandatory government standards, asserting that non-binding guidelines would better “promote flexibility in rapidly modifying the criteria as science and food technology emerges” and would “facilitate providing uniform symbols to consumers as quickly as possible.”<sup>53</sup>

A representative from Coca-Cola objected that any government regulation in the area was premature, arguing that not enough is known about the effectiveness of product labels as a means of moti-

<sup>49</sup> Federal Food, Drug, and Cosmetic Act § 403(a), 21 U.S.C. § 343(a) (West 2006); RALPH SHAPIRO, *A Comprehensive Review of the Nutrition Labeling and Education Act Regulations*, in NUTRITION LABELING HANDBOOK 166 (Ralph Shapiro ed., 1995).

<sup>50</sup> *FDA Hearing Sept. 11*, *supra* note 9, at 58, 61 (statement of Regina Hildwine, Grocery Mfrs. Ass’n).

<sup>51</sup> *Id.* at 34 (statement of David Katz, M.D.).

<sup>52</sup> *Id.* at 35 (testimony of Cinthya Harriman, Whole Grains).

<sup>53</sup> *FDA Hearing, Sept. 10*, *supra* note 34, at 99 (statement of Douglas Balentine, Unilever); *see also FDA Hearing Sept. 11*, *supra* note 9, at 61 (statement of Regina Hildwine, Grocery Mfrs. Ass’n) (asserting that government regulation would constrain food industry innovation in the development of nutrient profile labeling).

vating consumers to make healthier dietary choices. “There is simply no definitive indication at this point,” she asserted, “that creating yet another on pack[age] representation of nutrition information would be motivating or would make a difference.”<sup>54</sup> Thus, she concluded that “comprehensive population-based research is needed before embarking on any governmental approach to nutrition symbols.”<sup>55</sup>

Following the hearing, the FDA issued a document summarizing the comments and emphasizing the need for more information and further legal analysis as a precursor to any regulatory action. “Because of the diverse nature of the nutritional claims and criteria in the numerous nutrition symbol systems, the ability of consumers to use these symbols to make nutritional comparisons between products or to determine how a food fits into a diet is uncertain,” stated the summary document.<sup>56</sup> Since “the public hearing produced little usable research or other information on the majority of consumer issues listed in the public hearing notice,” the agency planned to conduct “additional quantitative research into consumer use and understanding of nutrition symbols.”<sup>57</sup> The agency further resolved to “[e]valuat[e] nutrition symbol systems individually in relation to applicable federal regulations and statutes.”<sup>58</sup>

In December 2008 the FDA issued a guidance document on the use of front-of-package symbols.<sup>59</sup> The guidance document cautioned manufacturers that “front-of-package symbols can at times constitute nutrient content claims.”<sup>60</sup> Nutrient content claims are statements that characterize the level of a nutrient in a food item, and they are subject

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<sup>54</sup> *FDA Hearing Sept. 11, supra* note 9, at 77 (statement of Helen Falco, Coca-Cola Co.); *Id.* at 59 (statement of Michael Jackson, Director, Ctr. for Sci. in the Pub. Interest) (stating, “I have gut feelings, not research . . .” in response to an FDA panelist’s request for evidence of the influence of nutrition symbols on consumer behavior).

<sup>55</sup> *Id.* at 76 (statement of Helen Falco, Coca-Cola Co.).

<sup>56</sup> Memorandum from the Office of Nutrition, Labeling, and Dietary Supplements, FDA, to Division of Dockets Management containing FDA Summary Comments on Symbols Public Hearing and Current Plans for Addressing Issues 2 (Apr. 21, 2009), available at <http://www.regulations.gov/search/Regs/contentStreamer?objectId=09000064809623e8&disposition=attachment&contentType=pdf> [hereinafter FDA Memorandum on Public Hearing].

<sup>57</sup> *Id.* at 3, 5.

<sup>58</sup> *Id.* at 5.

<sup>59</sup> OFFICE OF NUTRITION, LABELING, & DIETARY SUPPLEMENTS, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: DEAR MANUFACTURER LETTER REGARDING FRONT-OF-PACKAGE SYMBOLS (2008), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm120274.htm> [hereinafter GUIDANCE ON FRONT-OF-PACKAGE SYMBOLS].

<sup>60</sup> *Id.*

to restrictions set forth in existing FDA regulations.<sup>61</sup> I will discuss the regulations governing nutrient content claims in greater detail below.

In June 2009, the FDA issued an action notice “proposing to conduct an experimental study to assess quantitative consumer reactions to front-of-package nutrition symbols.”<sup>62</sup> The purpose of the study, the notice explained, is to learn more about how consumers understand and use front-of-package nutrient profile symbols. In particular, the study will examine how symbols affect consumer judgments about the nutritional attributes of products, the credibility of symbols in conveying information about products, the extent to which symbols help consumers identify more nutritious products when comparing similar items, and the impact of symbols on consumers’ use of nutrition information located elsewhere on the package.<sup>63</sup> The Institute of Medicine (IOM), under the sponsorship of the FDA and the Centers for Disease Control (CDC), also announced plans to evaluate the scientific bases of nutrient profile labeling schemes and “consider the potential benefits of a single, standardized front-of-package food guidance system regulated by FDA.”<sup>64</sup>

Events in the late summer and early fall of 2009 surrounding the launch of the Smart Choices logo heightened concerns about nutrient profile labeling. When the logo appeared on highly sweetened children’s breakfast cereals such as Froot Loops, Cocoa Krispies, Frosted Flakes, Lucky Charms and Cocoa Puffs as well as on full-fat mayonnaise and ice cream, the FDA sent a warning letter to Smart Choices Program General Manager Sarah Krol suggesting that the

FDA . . . would be concerned if any FOP [front-of-package] labeling systems used criteria that were not stringent enough to protect consumers against misleading claims; were inconsistent with the Dietary Guidelines for Americans; or had the effect of encouraging consumers to choose highly processed foods and refined grains instead of fruits, vegetables, and whole grains.<sup>65</sup>

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<sup>61</sup> 21 C.F.R. § 101.13; SHAPIRO, *supra* note 49, at 166.

<sup>62</sup> Experimental Study of Nutrition Symbols on Food Packages, 74 Fed. Reg. 26,244 (Dep’t of Health & Human Servs. June 1, 2009).

<sup>63</sup> *Id.*

<sup>64</sup> Marion Nestle, *Update on Not-so-Smart Food Choices*, FOOD POLITICS (Sept. 23, 2009), <http://www.foodpolitics.com/2009/09/update-on-not-so-smart-choice-labels/> (last visited Nov. 14, 2009) (quoting excerpts from IOM).

<sup>65</sup> Press Release, Conn. Attorney General’s Office, Attorney General Investi-

Congresswoman Rosa DeLauro – Chair of the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies – called on the FDA “to investigate whether products that bear, or in the future may bear, the Smart Choice labels are misbranded.”<sup>66</sup> Connecticut Attorney General Richard Blumenthal launched his own investigation of the Smart Choices program, expressing concern that the program’s nutrient profiling criteria were “overly simplistic, inaccurate and ultimately misleading.”<sup>67</sup> Blumenthal requested information regarding the scientific basis for the scheme from the Smart Choices program as well as companies, consultants, and professional organizations involved in developing it. “As a matter of common sense,” Blumenthal stated at a press conference, “these sugar-laden or fat-saturated products seem very questionable as so-called ‘Smart Choices’ nutritionally. . . . Were the choices of products shaped by an advertising strategy rather than scientific evidence?”<sup>68</sup> Shortly thereafter, FDA Commissioner Margaret Hamburg held a news conference on the issue and the agency issued a guidance document to industry outlining the agency’s regulatory plans.<sup>69</sup>

- First . . . examining existing FOP labels for violations of our labeling rules – that is, for labels that are false or that mislead consumers. . . .

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gates “Smart Choices” Food Labels that Endorse Mayonnaise and Sugary Cereals (Oct. 15, 2009), *available at* <http://www.ct.gov/AG/cwp/view.asp?A=3673&Q=448878>; Letter from Michael R. Taylor, Senior Advisor for Food & Safety, U.S. Food & Drug Admin., to Sarah Krol, Gen. Manager, Smart Choice Program (Aug. 19, 2009), *available at* <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm180146.htm>.

<sup>66</sup> Press Release, House Appropriations Subcomm. on Agric., Rural Dev., Food & Drug Admin., & Related Agencies, DeLauro Calls for Federal Investigation into “Smart Choices” Labeling (Sept. 21, 2009), *available at* [http://delauro.house.gov/text\\_release.cfm?id=2653](http://delauro.house.gov/text_release.cfm?id=2653).

<sup>67</sup> William Neuman, *Connecticut to Scrutinize Food Labels*, N.Y. TIMES, Oct. 14, 2009.

<sup>68</sup> *Id.*

<sup>69</sup> See the press conference discussing and linking to talking points provided at the FDA to clean up front-of-package mess at Food Politics Blog, FDA to Clean up Front-of-Package Mess, <http://www.foodpolitics.com/2009/10/fda-to-clean-up-the-front-of-package-mess/> (Oct. 20, 2009 post); GUIDANCE FOR INDUSTRY: LETTER REGARDING POINT OF PURCHASE FOOD LABELING, *supra* note 16; see list in text from press conference talking points for Peggy Hamburg, Comm’r of Food & Drugs, *available at* <http://www.foodpolitics.com/2009/10/fda-to-clean-up-the-front-of-package-mess/>.

- Second . . . drafting a new regulation that will provide a single set of science- and nutrition-based criteria that should be used when FOP labels should be used. . . .
- Third . . . launching a consumer research program to determine how consumers view these symbols and whether certain symbols or types of symbols are better ways to impart useful nutrition information to our citizens. . . .
- Fourth . . . reaching out to manufacturers, retailers, and others to determine if a single FOP symbol can give our citizens a quick, but accurate, way to select healthy foods in the grocery store. . . .

By late October, all eight major food companies participating in the Smart Choices program announced their withdrawal from the program, and the program itself announced that it would “voluntarily postpone active operations and not encourage wider use of the logo at this time by either new or currently enrolled companies.”<sup>70</sup> Blumenthal promised to broaden his investigation, “supported by the FDA,” by subjecting other food labels to the same scrutiny.<sup>71</sup> In the wake of these events, the regulation of nutrient profile labeling has moved to the top of the FDA’s regulatory agenda.

### III. FDA RULES GOVERNING NUTRITION CLAIMS ON FOOD LABELS

FDA regulations distinguish between four general types of nutrition claims on food labels: health claims, structure/function claims, dietary guidance, and nutrient content claims. Health claims are claims that characterize the relationship between a food or food component and a disease or a health-related condition.<sup>72</sup> An example of a health claim would be: “Diets low in sodium may reduce the risk of

<sup>70</sup> Press Release, Smart Choices Program Postpones Active Operations (Oct. 23, 2009), *available at* [http://www.smartchoicesprogram.com/pr\\_091023\\_operations.html](http://www.smartchoicesprogram.com/pr_091023_operations.html); Neuman, *Food Label Program to Suspend Operations*, *supra* note 13; Press Release, Conn. Attorney General’s Office, Attorney General Announces All Food Manufacturers Agree To Drop Smart Choices Logo (Oct. 29, 2009), *available at* <http://www.ct.gov/ag/cwp/view.asp?Q=449880&A=3673> [hereinafter Attorney General Announces All Food Manufacturers Agree To Drop Smart Choices Logo].

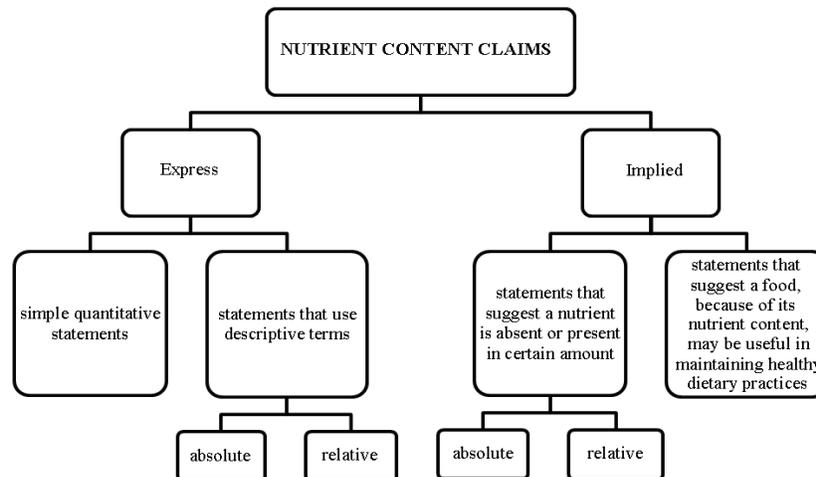
<sup>71</sup> Attorney General Announces All Food Manufactures Agree to Drop Smart Choices Logo, *supra* note 70.

<sup>72</sup> Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C. § 343(r)(1)(A) (West 2006); 21 C.F.R. § 101.14(a)(1) (2009); DEAR MANUFACTURER LETTER, *supra* note 17.

high blood pressure, a disease associated with many factors.”<sup>73</sup> Only health claims approved by the FDA may be placed on food packages.<sup>74</sup> Structure/function claims describe the general effect of nutrients on the normal structure or function of the human body, for example, “calcium builds strong bones.”<sup>75</sup> Structure/function claims do not require FDA approval so long as they are truthful and not misleading.<sup>76</sup> Dietary guidance statements refer more generally to dietary advice – “dietary patterns, practices, and recommendations that promote health” – and they typically refer broadly to a category of foods rather than specific nutrients or substances, for example, “eat five servings daily of fruits and vegetables.”<sup>77</sup> These claims do not require FDA approval and may be used so long as they are truthful and not misleading.<sup>78</sup>

Nutrient content claims are claims that describe the level of a nutrient in a food.<sup>79</sup> Nutrient content claims – the category of claims most relevant to regulation of nutrient profile labeling – are worthy of their own taxonomy. Figure 2 presents a chart that may be helpful in following the subsequent analysis.

**Figure 2. Nutrient Content Claims**



<sup>73</sup> DEAR MANUFACTURER LETTER, *supra* note 17.

<sup>74</sup> 21 U.S.C. §§ 343(r)(3)-(4); 21 C.F.R. § 101.70 (2009).

<sup>75</sup> DEAR MANUFACTURER LETTER, *supra* note 17.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*; Food Labeling, General Requirements for Health Claims for Food, 58 Fed. Reg. 2,478, 2,484 (Jan. 6, 1993).

<sup>78</sup> DEAR MANUFACTURER LETTER, *supra* note 17.

Nutrient content claims may be express or implied.<sup>80</sup> Express nutrient content claims describe the level of a nutrient in a food by referring directly to the level of nutrients such as sodium or calcium.<sup>81</sup> Express nutrient content claims that take the form of *simple quantitative statements*, such as “200 mg of sodium,” may be used for any level of a nutrient so long as they are accurate.<sup>82</sup> Express nutrient content claims that employ *descriptive terms*, such as “low in sodium” or “high in fiber,” may be made only for nutrients for which FDA has established a Reference Daily Intake (RDI) or Daily Reference Value (DRV), may be used only if the food meets specified threshold requirements for the nutrient, and may employ only descriptive terms approved by the FDA.<sup>83</sup> Importantly, express nutrient content claims that use descriptive terms not specifically approved by the FDA are prohibited, although manufacturers may petition the FDA for approval of such terms.<sup>84</sup>

Descriptive terms may be absolute or relative. Examples of absolute terms are “high,” “low,” and “free,” while examples of relative terms include “more,” “reduced,” and “light.”<sup>85</sup> Absolute nutrient content claims must conform to standards based on a percentage of the RDI or DRV present in reference amounts customarily consumed (RACC) as defined by FDA and U.S. Department of Agriculture (USDA) regulations.<sup>86</sup> For example, a tub of yoghurt labeled “high in calcium” must contain at least twenty percent of the RDI of calcium

<sup>79</sup> 21 U.S.C. § 343(r)(1)(A); 21 C.F.R. § 101.13 (2009); SHAPIRO, *supra* note 49, at 166-99.

<sup>80</sup> 21 C.F.R. § 101.13(b).

<sup>81</sup> § 101.13(b)(1); SHAPIRO, *supra* note 49, at 167.

<sup>82</sup> 21 C.F.R. § 101.13(b); DEAR MANUFACTURER LETTER, *supra* note 17.

<sup>83</sup> 21 C.F.R. §§ 101.54-101.62; 2008 GUIDANCE ON FOOD LABELING, *supra* note 1, at ch. VIII. n. 19; 2008 GUIDANCE ON FOOD LABELING, *supra* note 1, at ch. X; SHAPIRO, *supra* note 49, at 172-77. The term Reference Daily Intake (RDI) was adopted by the FDA in regulations arising out of the Nutrition Labeling and Education Act (NLEA) of 1990. RDI applies to recommendations for vitamins, minerals, and protein and replaces the earlier term “U.S. Recommended Daily Allowances” (U.S. RDA) established in 1973. The term Daily Reference Value (DRV) was adopted by the FDA at the same time as RDI and applies to recommendations for nutrients and food components required on food labels following the NLEA but for which no previous standard existed. RDI covers fat, saturated fatty acids, cholesterol, total carbohydrate, fiber, sodium, potassium, and protein. (The recommendation for protein is included in both RDI and DRV lists.) For the sake of simplicity, RDIs and DRVs are listed on food packages as Daily Value (DV). SHAPIRO, *supra* note 49, at 151-52.

<sup>84</sup> 21 C.F.R. §§ 101.54(a), 101.69; SHAPIRO, *supra* note 50, at 193.

<sup>85</sup> 21 C.F.R. §§ 101.54-101.62; 2008 GUIDANCE ON FOOD LABELING, *supra* note 1, at chs. VIII n. 19, X; SHAPIRO, *supra* note 49, at 166-77.

<sup>86</sup> 21 C.F.R. §§ 101.12-101.13; SHAPIRO, *supra* note 49, at 171.

per 225 grams of yoghurt (the RACC for yoghurt).<sup>87</sup> Absolute nutrient content claims may sometimes employ descriptive terms that are defined in sets that specify three levels or tiers of nutrient content, for example “low sodium,” “very low sodium,” and “sodium free.”<sup>88</sup> Relative nutrient content claims must name the reference food to which the product is being compared, and they must state the percentage or fraction of the amount of the nutrient in the reference food by which the nutrient has been modified.<sup>89</sup> For example, a label for reduced-sodium potato chips must include the statement “contains 30 percent less sodium than regular potato chips.” Nutrient content claims on foods that contain levels of fat, saturated fat, cholesterol, and sodium above specified threshold amounts must be accompanied by a referral statement to the Nutrition Facts panel, such as: “See nutrition information for fat content.”<sup>90</sup>

Implied nutrient content claims are of two types. The first is *statements that describe a food or food ingredient in a manner suggesting that a nutrient is absent or present in a certain amount* (e.g. ‘high in oat bran’).<sup>91</sup> Such label statements must conform to the standards for express nutrient content claims or must include a disclaimer, such as “not a good source of fiber,” or “not a low sodium food.”<sup>92</sup>

The second type of implied nutrient content claim is *statements that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices* (e.g. ‘healthy, contains 3 grams (g) of fat’).<sup>93</sup> FDA considers use of the term “healthy,” when “placed in a nutritional context,” to constitute an implied nutrient content claim and has defined the term accordingly.<sup>94</sup> Foods labeled “healthy,” or any derivative of the term such as “healthier” or “healthful,” must not exceed specific thresholds of fat, saturated fat, sodium, and cholesterol and must contain requisite amounts of other nutrients such as vitamin A, vitamin C, calcium, iron, protein, and fiber, depending upon

<sup>87</sup> See SHAPIRO, *supra* note 49, at 591. It is worth noting here that the term “contains” is regulated as a descriptive term equivalent to “a good source of” and is defined in terms of percentage of RDI or DRV per RACC. 21 C.F.R. § 101.54(c)(1).

<sup>88</sup> SHAPIRO, *supra* note 49, at 182. Note that the FDA definition of “sodium free” does not mean that a food contains no sodium. The threshold level of sodium for a “sodium free” food is less than 5 mg per RACC and per serving.

<sup>89</sup> 21 C.F.R. § 101.13(1)(ii)(B); SHAPIRO, *supra* note 49, at 169-70.

<sup>90</sup> 21 C.F.R. § 101.13(h)(1); 63 Fed. Reg. 26,978-02, 26,979 (May 15, 1998).

<sup>91</sup> 21 C.F.R. § 101.13(b)(2)(i).

<sup>92</sup> § 101.13(i)(2); see SHAPIRO, *supra* note 49, at 169.

<sup>93</sup> 21 C.F.R. § 101.13(b)(2)(ii).

<sup>94</sup> Final Rule, 59 Fed. Reg. 24,232 (May 10, 1994) (codified at 21 C.F.R. § 101 (2009)).

the food.<sup>95</sup> The term “healthy” is placed in a nutritional context, the agency explains in the Federal Register, when it is “presented in a context that explicitly or implicitly suggests that the food has a particular nutrient profile.”<sup>96</sup> When not placed in a nutritional context, the term may be used so long as it is truthful and not misleading.<sup>97</sup> The agency has declined to further define standards for “truthful” and “not misleading” in the use of the term “healthy” where the term does not constitute a nutrient content claim, preserving its discretion to make individual determinations on a case-by-case basis.<sup>98</sup> The agency has also declined to provide definitions for related terms such as “nutritious,” “wholesome,” and “good for you.” Since these terms have not been defined by the FDA, they may not be used in a nutritional context, which would render them unapproved nutrient content claims.<sup>99</sup>

The FDA’s nutrient content claim standards aim to “ensure that descriptive terms, such as *high* or *low* are used consistently for all types of food products and are meaningful to consumers.”<sup>100</sup> FDA standards governing the term “healthy” go beyond this purpose. “The agency views the term ‘healthy’ as a unique nutrient content claim. This term not only characterizes the level of the nutrients in a food but also implies a judgment about the food itself, based on its nutrient profile.”<sup>101</sup> “FDA’s goal in defining ‘healthy,’” explains the agency, “is to define the term in such a way that it will highlight foods that, because of their nutrient content, will be most helpful to consumers in constructing a diet that is consistent with dietary recommendations.”<sup>102</sup>

#### IV. FIRST AMENDMENT LIMITS ON FDA LABELING REGULATIONS

The First Amendment protection of commercial speech places limits on FDA regulation of labeling. In a series of cases brought by dietary supplement manufacturers challenging the FDA’s refusal to approve certain health claims, lower federal courts in the District of Columbia held that the First Amendment protection of commercial

<sup>95</sup> 21 C.F.R. § 101.65(d)(2); Final Rule, 59 Fed. Reg. at 24,232.

<sup>96</sup> Final Rule, 59 Fed. Reg. at 24,235.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* The FDA considers a label statement misleading if it would be likely to mislead a reasonable consumer under the circumstances. 67 Fed. Reg. 78,002-01, 78,003 (Dec. 20, 2002); 103 F.T.C. 177.

<sup>99</sup> 59 Fed. Reg. at 24,236.

<sup>100</sup> See DEAR MANUFACTURER LETTER, *supra* note 17.

<sup>101</sup> Final Rule, 59 Fed. Reg. at 24,232.

<sup>102</sup> *Id.* at 24,233.

speech requires the FDA to approve such claims with accompanying qualifying statements rather than prohibit them altogether if the qualified claims are truthful and not misleading.<sup>103</sup> The First Amendment, explained the courts, expresses a “clear preference for disclosure over suppression of commercial speech.”<sup>104</sup> The application of First Amendment commercial speech doctrine to FDA labeling restrictions is a relatively new development, and many important questions have yet to be addressed by courts. In this Part, I explain in greater detail the courts’ application of First Amendment commercial speech doctrine to health claims on dietary supplements, and I speculate about how this might apply to FDA regulation of nutrient profile labeling of conventional foods.

The Nutrition Labeling and Education Act (NLEA) of 1990 amended the FDCA to authorize health claims for conventional foods where the Secretary of Health and Human Services “determines, based on the totality of publicly available scientific evidence . . . that there is significant scientific agreement . . . that the claim is supported by such evidence.”<sup>105</sup> With regard to dietary supplements, the Act provided for approval of health claims “subject to a procedure and standard . . . established by regulation of the Secretary.”<sup>106</sup> In 1993, the FDA promulgated regulations to implement these statutory provisions in which the agency adopted the significant scientific agreement (SSA) standard for approval of health claims on both conventional foods and dietary supplements.<sup>107</sup> In 1995, dietary supplement manufacturers challenged the agency’s SSA standard and the agency’s refusal to approve four particular health claims as a violation of the First Amendment’s protection of commercial speech.<sup>108</sup>

<sup>103</sup> See, e.g., *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002). For a general overview of this litigation, see Elizabeth M. Walsh et al., *The Importance of the Court Decision in Pearson v. Shalala to the Marketing of Conventional Food and Dietary Supplements in the United States*, in REGULATION OF FUNCTIONAL FOODS AND NUTRACEUTICALS: A GLOBAL PERSPECTIVE 109-35 (Clare M. Hasler ed., 2005).

<sup>104</sup> *Whitaker*, 248 F. Supp. 2d at 15.

<sup>105</sup> Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C. § 343(r)(3)(B)(i) (West 2006). The Food and Drug Administration Modernization Act (FDAMA) of 1997 subsequently provided an alternative to authorization by the Secretary based on significant scientific agreement (SSA) where the health claim accurately conveys an authoritative statement of “a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention).” 21 U.S.C. § 343(r)(3)(C)(i).

<sup>106</sup> 21 U.S.C. § 343(r)(5)(D).

<sup>107</sup> 21 C.F.R. § 101.14.

<sup>108</sup> *Pearson v. Shalala*, 14 F. Supp. 2d 10, 12 (D.C. Cir. 1998), *rev’d*, 164 F.3d

In a 1999 decision issued in *Pearson v. Shalala*, the United States Court of Appeals for the District of Columbia held that the First Amendment's protection of commercial speech prevented the FDA from banning health claims that lack significant scientific agreement if the claims could be qualified in such a way as to render them truthful and not misleading.<sup>109</sup> Inherently false or misleading claims, explained the Court, are not protected by the First Amendment, and the government may prohibit them.<sup>110</sup> By contrast, claims that are merely "potentially misleading," – claims that could be presented in a non-misleading way – constitute commercial speech protected under the First Amendment.<sup>111</sup> The court relied on the Supreme Court's 1980 opinion in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York* which held that a government restriction on commercial speech is unconstitutional unless the government can establish that the restriction "directly advances" a "substantial" government interest and that there is a "reasonable fit" between the restriction and the interest it is designed to serve.<sup>112</sup> The court concluded that if the health claims at issue could be presented in a non-misleading way using disclaimers or other qualifications, an FDA ban on them would be unconstitutional.<sup>113</sup> An outright ban on such claims, explained the court, would be an excessively broad means of advancing the government's interest in preventing consumer fraud and would therefore violate the "reasonable fit" requirement.<sup>114</sup>

The FDA's subsequent refusal to allow the health claims at issue in *Pearson* led to further litigation. In the 2002 *Whitaker v. Thompson* decision, the United States District Court for the District of Columbia interpreted "reasonable fit" to mean that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the government must do so."<sup>115</sup> The *Whitaker* court interpreted the *Pearson* court's holding to mean that a complete ban would be reasonable only: (1) where the FDA determined that no evidence supports a health claim; or (2) where the claim rests on qualitatively weak evidence, such as "only one or two old studies."<sup>116</sup> In

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650 (D.C. 1999).

<sup>109</sup> *Pearson*, 164 F.3d at 650.

<sup>110</sup> *Id.* at 655 (citing *In re R.M.J.*, 455 U.S. 191, 203 (1982)).

<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at 656; *Cent. Hudson v. Pub. Serv. Comm'n. of New York*, 447 U.S. 557, 566 (1980).

<sup>113</sup> *Pearson*, 164 F.3d at 657.

<sup>114</sup> *Id.*

<sup>115</sup> *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 9 (D.D.C. 2002) (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002)).

<sup>116</sup> *Id.* at 10.

either case, the government would have to “demonstrate with empirical evidence” that disclaimers would confuse consumers and fail to make a claim non-misleading.<sup>117</sup> The district court concluded that “disclaimers were ‘constitutionally preferable to outright suppression’” and that “more disclosure rather than less is the preferred approach, so long as commercial speech is not inherently misleading.”<sup>118</sup>

Following the *Whitaker* decision, the FDA has permitted qualified health claims for both dietary supplements and conventional foods under a “credible evidence” standard.<sup>119</sup> The agency has not actually approved such claims; it has instead chosen merely to permit them by exercising its enforcement discretion not to bring enforcement actions against claims that meet the credible evidence standard.<sup>120</sup> The agency has also developed appropriate qualifying language for health claims based upon the level of scientific evidence that supports them.<sup>121</sup>

The details of the FDA’s efforts to address the *Pearson* and *Whitaker* cases in regulating health claims are of less concern to us here than the cases’ implications for the regulation of nutrient content claims. For example, some in the food industry have argued that the FDA’s prohibition of descriptive terms not approved by the agency is an unconstitutional restriction of commercial speech.<sup>122</sup> They argue

<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 14.

<sup>119</sup> CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: FDA’S IMPLEMENTATION OF “QUALIFIED HEALTH CLAIMS”: QUESTIONS AND ANSWERS; FINAL GUIDANCE (May 12, 2006), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053843.htm> [hereinafter GUIDANCE FOR INDUSTRY: FDA’S IMPLEMENTATION OF “QUALIFIED HEALTH CLAIMS”: QUESTIONS AND ANSWERS; FINAL GUIDANCE].

<sup>120</sup> The FDA has not amended its regulations to replace the SSA standard with the credible evidence standard. Instead, it has issued a guidance document explaining that it will employ the credible evidence standard in enforcement discretion decisions that will have the effect of permitting a qualified health claim. 21 C.F.R. § 101.14(c); GUIDANCE FOR INDUSTRY: FDA’S IMPLEMENTATION OF “QUALIFIED HEALTH CLAIMS”: QUESTIONS AND ANSWERS; FINAL GUIDANCE, *supra* note 119.

<sup>121</sup> Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 2003), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm>.

<sup>122</sup> *See, e.g.*, Letter from Alison Kretser, Grocery Mfrs. of Am., to U.S. Food & Drug Admin. (May 4, 2004), *available at* <http://www.fda.gov/hrms/dockets/dockets/94p0390/94P-0390-EC7-Attach-1.pdf>; Letter from Sheryl A. Marcouiller, Senior Food Law Counsel, Kraft Foods to U.S. Food & Drug Admin. (Jan. 18, 2005), *available at* [http://www.fda.gov/ohrms/dockets/dockets/94p0390/94P-0390\\_emc-000012-01.pdf](http://www.fda.gov/ohrms/dockets/dockets/94p0390/94P-0390_emc-000012-01.pdf); Federal Food, Drug, and Cosmetic Act § 403, 21 U.S.C.

that prohibiting such terms bans truthful, non-misleading label claims.<sup>123</sup> These concerns were originally raised in petitions to the FDA prior to *Pearson* and *Whitaker*, and they have been raised subsequently in the wake of those cases.<sup>124</sup> In 1995, the FDA proposed a rule for explicit nutrient content claims that would allow the use of synonyms not listed in FDA regulations so long as “the listed term appear[s] immediately adjacent to (with no intervening material) the most prominent . . . use of the unlisted synonym.”<sup>125</sup> As for implied nutrient content claims, the FDA stated that it believed “the use of unlisted synonyms with implied claims such as terms, statements, or symbols” that were “consistent with a listed term” were permissible under existing regulations.<sup>126</sup> In 2004, following the *Pearson* and *Whitaker* decisions, the FDA reopened the comment period on this proposed rule for explicit nutrient content claims, requesting empirical data “to demonstrate that consumers would understand that unlisted terms that are anchored to defined terms are synonyms of those terms.” The FDA also repeated its earlier suggestion regarding implied nutrient content claims that the use of unlisted statements or symbols consistent with the listed term were permissible under existing regulations.<sup>127</sup>

In addition to raising questions about FDA restrictions on the use of unapproved descriptive terms, the *Pearson* and *Whitaker* cases also raise questions about FDA restrictions on the use of approved terms. Can the FDA prohibit the use of approved descriptive terms in ways other than those defined by the agency? Does the First Amendment protect a food manufacturer’s use of terms such as “low-fat,” “high-fiber,” or “healthy,” so long as these terms are accompanied by adequate qualifying statements? Following *Pearson* and *Whitaker*, the FDA, if challenged, would have to establish that the imposition of exclusive definitions for these terms “directly advances” a “substantial” government interest and that there is a “reasonable fit” between the restriction and the interest it is designed to serve.<sup>128</sup> The reasoning in both *Pearson* and *Whitaker* suggests that preventing consumer

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§ 343(r)(4)(A)(i), (ii) (West 2006) (note process of preapproval).

<sup>123</sup> See, e.g., Letter from Alison Kretser to U.S. Food & Drug Admin., *supra* note 122.

<sup>124</sup> See 69 Fed. Reg. 24,541 (May 4, 2004).

<sup>125</sup> 60 Fed. Reg. 66,206, 66,209 (Dec. 21, 1995).

<sup>126</sup> *Id.* at 66,211 (emphasis added).

<sup>127</sup> 69 Fed. Reg. 24,545.

<sup>128</sup> See *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999) (citations omitted); *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 9 (D.D.C. 2002) (citations omitted).

fraud is a substantial government interest and that exclusive definitions for descriptive terms on explicit nutrient content claims is a sufficiently direct way to advance that interest.<sup>129</sup> Whether there is a reasonable fit between a ban on non-standard uses of approved terms and the prevention of consumer fraud, however, is an open question. The *Whitaker* decision suggests that courts might require the government to “demonstrate with empirical evidence” that qualifying language would confuse consumers and fail to make non-standard uses of approved descriptive terms non-misleading.<sup>130</sup> This is not to say that it would be impossible for the FDA to generate the empirical evidence necessary to justify its exclusive definitions of descriptive terms but only that the agency has not yet done so and that the First Amendment might require it to.<sup>131</sup>

The doctrinal implications of *Pearson* and *Whitaker*, however, may be beside the point. As a matter of practical politics, the food industry has no interest in using *Pearson* and *Whitaker* to dismantle FDA standardization of nutrient content claims. There was widespread support in the food industry during consideration of the NLEA for the creation of government definitions for descriptive terms in nutrient content claims in order to “level the playing field” among competing manufacturers.<sup>132</sup> Thus, as I turn next to my proposal for FDA regulation of nutrient profile labeling, the doctrinal implications of the *Pearson* and *Whitaker* cases may well be less important than crafting the proposal in such a way that industry would be likely to

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<sup>129</sup> *Pearson*, 164 F.3d at 655-56; *Whitaker*, 248 F. Supp. 2d at 10-14.

<sup>130</sup> *Whitaker*, 248 F. Supp. 2d at 5, 7, 10 (citing *Pearson*, 164 F.3d at 659-60).

<sup>131</sup> The FDA’s 2004 reopening of the comment period on its proposed rule for the use of unlisted synonyms reflects that the agency, at that time, lacked such empirical evidence and that it relied on outside sources to provide it. 69 Fed. Reg. 24,545. By the agency’s own account, its 2007 public hearing on nutrient profile labeling failed to produce much in the way of “usable research or other information on the majority of consumer issues listed in the public hearing notice.” FDA Memorandum on Public Hearing, *supra* note 57, at 3. Nevertheless, the FDA has at its disposal the tools to acquire this type of empirical evidence. In the area of health claims, the FDA conducted an empirical study suggesting that consumers do not find it easy to distinguish between different types of qualifying language associated with health claims. See U.S. FOOD & DRUG ADMIN., QUESTIONS AND ANSWERS: QUALIFIED HEALTH CLAIMS IN FOOD LABELING - DRAFT REPORT ON EFFECTS OF STRENGTH OF SCIENCE DISCLAIMERS ON THE COMMUNICATION IMPACTS OF HEALTH CLAIMS (Sept. 28, 2005), available at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm109470.htm>. As discussed in Part II, the FDA is already conducting its own experimental study on consumer reactions to nutrient profile labels and is sponsoring further research by the IOM.

<sup>132</sup> F. Edward Scarbrough, *Perspectives on Nutrition Labeling and Education Act*, in NUTRITION LABELING HANDBOOK 44 (1995).

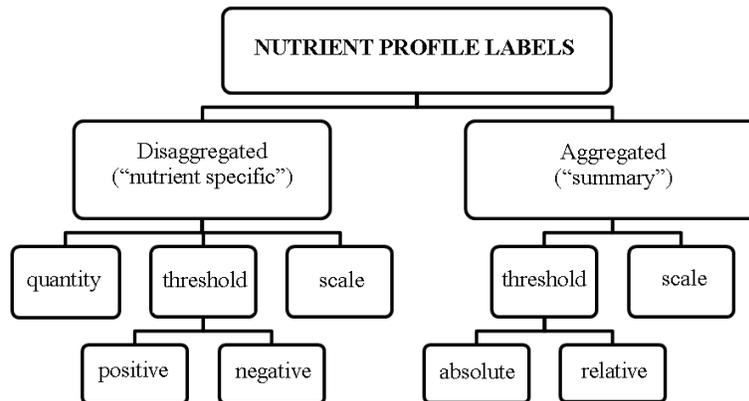
support it in order to maintain the “level playing field” provided by the current regulatory framework for nutrient content claims. If the proposal is sufficiently acceptable to industry, it is unlikely to attract constitutional challenges regardless of their potential for success.

## V. APPLYING NUTRIENT CONTENT CLAIM REGULATIONS TO NUTRIENT PROFILE LABELING

Most nutrient profile labels make nutrient content claims. These claims range from simple quantitative statements about the amount of a specific nutrient or nutrients in a food to complex ratings of the overall nutritional value of a food and its contribution to healthy dietary practices. In this Part, I identify five distinct categories of schemes and discuss how they could each be regulated under the existing regulatory framework for nutrient content claims. I also argue in favor of a regulatory approach that allows for the co-existence of multiple schemes rather than the imposition of a single government-sponsored scheme as proposed by CSPI in its 2004 petition to the FDA.<sup>133</sup>

At this point, it will be helpful to recall the taxonomy of nutrient profile labeling developed in Part I. Based on that taxonomy, Figure 3 divides nutrient profile labels into categories and subcategories that are relevant to regulating them as nutrient content claims.

**Figure 3. Categories of Nutrient Profile Labeling Schemes**



The principal distinction among nutrient profile labels is between those that provide disaggregated nutrient information (what the FDA has termed “nutrient specific” labels) and those that provide aggre-

<sup>133</sup> CSPI PETITION, *supra* note 11, at i.

gated nutrient information (what the FDA has termed “summary” labels).<sup>134</sup>

Within these two principal categories of nutrient profile labels are subcategories based on the gradation employed by different labeling schemes. Labels that provide disaggregated nutrient information may present simple quantitative statements, threshold indicators, or ratings of nutrient content based on a three or more point scale. Labels that provide aggregated nutrient information may be similarly subdivided between labels that employ threshold indicators and labels that present ratings. Labels that present disaggregated nutrient information in terms of thresholds may be further subdivided into labels that provide information that places a product in a positive light and labels that provide information that places a product in a negative light. Labels that present aggregated information in terms of a threshold may employ absolute thresholds of nutritional value or relative thresholds that compare a product to other products within a food group.

These categories are not exhaustive.<sup>135</sup> In the interests of simplicity, I have included categories that cover most, if not all, of the existing nutrient profile labeling schemes currently in use and that will allow for discussion of a range of regulatory issues. The analysis could be expanded to cover other types of schemes that might be developed in the future.

#### A. Disaggregated Nutrient Information

Consider first nutrient profile labels that present disaggregated nutrient information. Nutrient profile labels of this kind that present only simple quantitative statements or indications of threshold amounts of nutrients can be well regulated without any changes to existing FDA regulations governing nutrient content claims. Labels that rate the level of nutrients on a scale raise policy and First Amendment concerns that would best be addressed through modest changes in existing regulations – namely the development of additional definitions for descriptive terms beyond those currently approved by the FDA.

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<sup>134</sup> GUIDANCE FOR INDUSTRY: LETTER REGARDING POINT OF PURCHASE FOOD LABELING, *supra* note 16.

<sup>135</sup> One could, for example, imagine disaggregated threshold schemes that provide *both* positive and negative information or aggregated schemes that use scales to rate foods only relative to other foods within the same food group.

### 1. Simple Quantitative Statements

Nutrient profile labels that present nutrient information in the form of simple quantitative statements concerning the amount of one or more nutrients in the food are express nutrient content claims which existing FDA regulations require to be accurate. General Mills' Nutrition Highlights panel is an example of this type of label (see Figure 4).

**Figure 4. General Mills' Nutrition Highlights Panel**<sup>136</sup>



The inclusion of quantitative information concerning multiple nutrients makes this type of nutrient profile label novel. From a regulatory point of view, however, it falls squarely within the established category of explicit nutrient content claims that present simple quantitative statements concerning the amount of a nutrient in a food.

### 2. Threshold Indicators

Nutrient profile labels indicating that a food contains threshold amounts of individual nutrients also constitute nutrient content claims. Where such labels make explicit claims characterizing the level of nutrients in a food and employ descriptive terms, they may use only terms approved by the FDA, such as “high fiber,” “low sodium,” or “a good source of calcium,” and these terms may be used only as defined by FDA regulations. As we have seen, FDA regulations prohibit the use of unapproved synonyms or alternative meanings of approved terms in explicit nutrient content claims.<sup>137</sup> Thus, a label that characterized as “high” or “low” a number of different nutrients in a food would have to conform to FDA regulations for explicit nutrient content claims using descriptive terms.

Where such labels make implied nutrient content claims, the FDA has indicated that they may include unapproved terms, statements, or symbols so long as these are used in a manner consistent with the de-

<sup>136</sup> General Mills, *supra* note 3.

<sup>137</sup> See discussion *supra* Part III.

definitional standards governing explicit claims.<sup>138</sup> Thus, a nutrient profile label that used a symbol to indicate that a food was high in fiber is permissible as an implied nutrient content claim so long as the level of fiber meets the FDA definition of “high fiber.”

FDA regulation of disaggregated threshold nutrient profile labels as nutrient content claims is unlikely to provoke First Amendment objections from the food industry. With regard to nutrient profile labels that make explicit nutrient content claims, FDA prohibition on the use of unapproved descriptive terms raises no novel First Amendment issues. While the implications of the *Pearson* and *Whitaker* cases for FDA prohibition on unapproved descriptive terms remain unclear, the application of this prohibition to nutrient profile labels does not represent a significant change in the status quo, under which the FDA has, from time to time, expanded the list of approved terms in response to industry petitions and the industry has refrained from bringing First Amendment challenges in court.<sup>139</sup> With regard to the use of symbols that make implied nutrient content claims, FDA regulations permit such symbols so long as they conform to FDA definitions of the approved descriptive terms which they denote. The food industry has traditionally supported these definitional standards and has not brought First Amendment challenges against them.

While nutrient profile labels tend to present information that places products in a positive light, nutrient profile labels can also present information that places products in a negative light, functioning like warning labels, as does the Finnish government’s “high sodium” label.<sup>140</sup> One could imagine a shelf label that warns consumers about high or low levels of individual nutrients, much like low NuVal or Guiding Stars ratings currently do with regard to overall nutritional value.<sup>141</sup> Interestingly, FDA regulations do not include negative descriptive terms like “high sodium,” “low fiber,” or “high in saturated fat” and use of them is, therefore, presumably prohibited. Nevertheless, so long as the label is truthful and not misleading, the FDA would be unlikely to bring an enforcement action against such a warn-

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<sup>138</sup> See discussion *supra* Part IV.

<sup>139</sup> Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period, 69 Fed. Reg. 24,541, 24,545-46 (May 4, 2004) (codified 21 C.F.R. pt. 101) (granting a petition submitted by the National Food Processors Association proposing a way to expand the range available terms).

<sup>140</sup> World Action on Salt and Health, *supra* note 31.

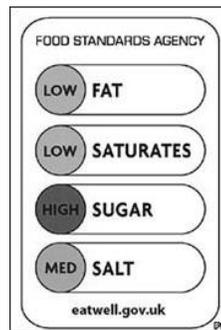
<sup>141</sup> Retail supermarkets might provide warnings on selected foods as a marketing strategy to attract consumers to their stores or to build customer loyalty by projecting an image of health consciousness. Negative Guiding Stars or NuVal ratings may be part of just such a strategy.

ing label. Moreover, in the wake of the *Pearson* and *Whitaker* cases, it is probably unconstitutional for the FDA to prohibit truthful and not misleading nutrient profile warning labels. Should nutrient profile warning labels proliferate, the FDA might consider allowing for them explicitly in its regulations governing nutrient content claims that employ descriptive terms.

### 3. Rating Scales

Nutrient profile labels that rate the level of individual nutrients on a scale are also nutrient content claims. The FSA traffic light label provides an example (see Figure 5).

**Figure 5. FSA Traffic Light Label**<sup>142</sup>



The FSA label uses both descriptive terms – “low,” “medium,” and “high,” – and corresponding symbols – green, yellow, and red dots.

Insofar as a rating scale uses descriptive terms that place the product in a positive light, such as “high fiber,” or “low sodium,” these terms must conform to FDA definitions for approved nutrient content claims using descriptive terms. In many instances, FDA regulations provide for gradation in some nutrient content claims – for example, “a good source of fiber” and “high fiber” or “low sodium,” “very low sodium,” and “sodium free” – so existing regulations would permit a two- or three-tier disaggregated nutrient rating scale for nutrients where the FDA has defined graduated descriptive terms. These restrictions raise no new First Amendment concerns. The use of color-coded symbols to relate ratings constitutes an implied nutrient content claim permitted under FDA regulations provided that any implied

<sup>142</sup> Food Standards Agency, Traffic Light Labelling, <http://www.eatwell.gov.uk/foodlabels/trafficlites> (last visited Oct. 14, 2009).

ratings conform to corresponding definitions for defined descriptive terms.

Insofar as the label uses descriptive terms that place the product in a negative light, such as “high fat,” or “low calcium,” the FDA would likely allow these unauthorized nutrient content claims by exercising its enforcement discretion provided that the claims were truthful and not misleading. And, as was mentioned earlier, outright prohibition of such claims would be vulnerable to First Amendment objections. The use of truthful and non-misleading negative symbols would likely also be allowed by the FDA.

Problems could arise where different negative rating systems employed different standards, which could potentially confuse or mislead consumers. Similarly, “medium” ratings could also create problems in the absence of single standard. An outright FDA ban on negative or medium ratings could elicit a successful First Amendment challenge from industry. The FDA should, instead, promulgate definitions for descriptive terms like “high fat” or “medium sodium.” Promulgating definitions for ratings would protect consumers and, unlike outright prohibition, would be less likely to provoke a First Amendment challenge from an industry that has traditionally supported government definitions of descriptive terms. Moreover, the promulgation of definitions would be more likely to survive the “reasonable fit” standard in the event that anyone brought a First Amendment challenge.

## B. Aggregated Nutrient Information

Some nutrient profile labels present aggregated nutrient information. These types of labels are comparable to use of the term “healthy” and should be regulated as implied nutrient content claims.<sup>143</sup> For labels that use thresholds, the FDA could merely apply existing regulations. By contrast, for labels that use rating scales, I argue that the FDA should develop a graduated definition of “healthy” that would provide minimum standards for rating systems.

### 1. Threshold Indicators

Aggregated nutrient profile labels that employ threshold symbols of approval may be subdivided into absolute and relative schemes.

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<sup>143</sup> See discussion *supra* Part III.

### a. Absolute Schemes

Aggregated absolute threshold schemes suggest that a food satisfies some minimum standard of overall nutritional value, such that it contributes to a healthy diet. The AHA Heart Check mark is an example (see Figure 6).

**Figure 6. The American Heart Association Heart Check Mark<sup>144</sup>**



The AHA explains on its website that the underlying nutrient criteria for its label are based on the Association's dietary recommendations which purport to be consistent with federal dietary guidelines and health recommendations.<sup>145</sup> The Heart Check mark is intended to convey that a particular food is of high nutritional value by these standards.

Aggregated absolute threshold nutrient profile labels like the Heart Check mark are implied nutrient content claims suggesting that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices. The FDA regulations governing this type of implied nutrient content claim include only a definition of various forms of the term "healthy."<sup>146</sup> The FDA has stated that that use of any other term, such as "wholesome" or "natural" employed in regard to a food's nutrient content is prohibited.<sup>147</sup> Thus, one regulatory approach would be to prohibit symbols like the Heart Check mark as unapproved synonyms for the term "healthy."

<sup>144</sup> Am. Heart Ass'n, Nutritional Criteria for Certified Foods, <http://www.americanheart.org/presenter.jhtml?identifier=4973> (last visited Oct. 14, 2009).

<sup>145</sup> *Id.*; *FDA Hearing, Sept. 10, supra* note 34, at 123.

<sup>146</sup> Implied Nutrient Content Claims and Related Label Statements, 21 C.F.R. § 101.65(d) (2009).

<sup>147</sup> Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 59 Fed. Reg. 24,232, 24,236 (May 10, 1994) (codified 21 C.F.R. pt. 101); *see* discussion *supra* Part III.

A second approach to aggregated absolute threshold labels would be to insist that they meet existing standards for “healthy” claims. These labels are, after all, functionally equivalent to the term “healthy” when used in a nutritional context. “[T]he purpose of the ‘healthy’ claim,” explains the FDA, “is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines.”<sup>148</sup> This is precisely what the Heart Check mark is intended to convey and, according to the AHA’s own research, it is also how consumers understand the symbol.<sup>149</sup>

FDA might follow this second approach either by including synonyms and symbols within the list of approved forms of the term “healthy” or by applying the standards specified for “healthy” to all implied nutrient content claims suggesting that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices.<sup>150</sup> In addition to following the FDA’s current policy on “healthy”

<sup>148</sup> See Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 59 Fed. Reg. at 24,233. One might object that the FDA’s definition of “healthy” and its current dietary guidelines are too lax a standard. They do not, for example, recommend limits on sugar consumption. The most appropriate response to this concern would be to improve these standards. It would make less sense to create a new set of standards specifically for nutrient profile labels.

<sup>149</sup> FDA Hearing, Sept. 10, *supra* note 34, at 124. FDA currently regulates the Heart Check mark under the less demanding standard of dietary guidance statements. See Food Labeling; General Requirements for Health Claims for Food, 58 Fed. Reg. 2,478, 2,516 (Jan. 6, 1993) (codified at 21 C.F.R. pt. 20 and 101).

<sup>150</sup> There is a significant ambiguity in FDA regulations concerning the scope of what qualifies as an implied nutrient content claim suggesting that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices. In the “general principles” section of the regulations on nutrient content claims, the regulations state that a description of a food suggesting that it may be useful in maintaining healthy dietary practices is a nutrient content claim only if “made in association with an *explicit* claim or statement about a nutrient.” Nutrient Content Claims, General Principles, 21 C.F.R. § 101.13(b) (2) (2009) (emphasis added). By contrast, a later section on “implied nutrient content claims and related label statements” suggests that such a statement is a nutrient content claim if “made in connection with an *explicit or implicit* claim or statement about a nutrient.” 21 C.F.R. § 101.65(d) (ii); see 59 Fed. Reg. 24,232, 24,236 (emphasis added). Terms like “Smart Choice” and symbols like the Heart Check mark, would not qualify as nutrient content claims under the first definition (unless, somehow, the FDA considered the term or the symbol itself to constitute an explicit claim or statement about a nutrient). Such a term or symbol would likely qualify under the second definition insofar as it constitutes an implied claim or statement about nutrient content unless one argues that this does not qualify as being made “in association” with a claim or statement about nutrient content. Either way, nothing is served by the discrepancy, and the FDA should promulgate a uniform definition that cover additional terms and free-standing symbols in order to bring nutrient profile labels squarely within the regulations.

claims, this approach would also be less likely to provoke First Amendment challenges from industry and more likely to survive such challenges if brought.

Some aggregated threshold labels are based not on specific nutrient thresholds but rather on thresholds for ingredients that constitute major food groups, such as whole grains. For example, the Whole Grain Stamp of the Whole Grains Council indicates that a food contains at least eight grams of whole grain per serving.<sup>151</sup> There are two basic versions of the stamp – the “basic stamp” for products containing both whole grain and non-whole grain ingredients and the “100%” stamp for products containing only whole grain ingredients.<sup>152</sup> Both versions of the stamp indicate the number of grams of whole grain per serving. Figure 7 presents an image of the stamp.

**Figure 7. The Whole Grain Stamp of the Whole Grains Council<sup>153</sup>**



Whole grains are associated with nutrients such as fiber, iron, magnesium, vitamin B, and vitamin E,<sup>154</sup> and since the stamp indicates that a food contains whole grains, the stamp could be considered an implied nutrient content claim. Accordingly, foods labeled with this type of symbol of approval could be subject to FDA standards for use of the terms “a good source of,” “contains,” and “provides.” The FDA originally treated whole grain claims as implied nutrient content claims about fiber.<sup>155</sup> In light of more recent “scientific evidence that

<sup>151</sup> Whole Grains Council, Whole Grain Stamp, <http://www.wholegrainscouncil.org/whole-grain-stamp> (last visited Feb. 5, 2010).

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> Whole Grains Council, Whole Grains 101, <http://www.wholegrainscouncil.org/whole-grains-101> (last visited Feb. 5, 2010).

<sup>155</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid,

suggests that the health benefits of whole grains are based on more than their fiber content,” however, the agency has begun to reconsider how to categorize whole grain claims, as well as other claims about major food groups that imply aggregated nutrient information.<sup>156</sup> In a 2006 draft guidance, the agency suggested that it would permit simple quantitative statements regarding the amount of whole grain in a product but not descriptive statements such as “high” or “excellent source.”<sup>157</sup> The Whole Grain Stamp satisfies this standard.

The problem with regulating the Whole Grain Stamp as an implied nutrient content claim is that for most whole grain products, such as breads and cereals, no single serving would meet the mandatory FDA nutrient content thresholds for all of the nutrients contained in whole grains. Given that the *Dietary Guidelines for Americans* recommend consumption of whole grains, perhaps it makes more sense to treat the Whole Grain Stamp as a dietary guidance statement or a generic claim, permitted under current regulations provided that it is truthful and not misleading.<sup>158</sup> More generally, where nutrient profile labels imply aggregated nutrient information based on claims about major food groups – such as whole grains, vegetables, fish – and are consistent with the federal government’s dietary advice, it makes sense to allow them provided that they are truthful and not misleading.<sup>159</sup>

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and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,374 (Jan. 6, 1993) (codified at 21 C.F.R. pt 5 and 101); Letter from Margaret O’K. Glavin, Assoc. Comm’r for Regulatory Affairs, Food & Drug Admin., to Stuart M. Pape, Patton Boggs, LLP (Nov. 8, 2005), available at <http://www.fda.gov/ohrms/dockets/dockets/04p0223/04p-0223-pdn0001-vol5.pdf> [hereinafter Glavin Letter].

<sup>156</sup> Glavin Letter, *supra* note 155, at 2; U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE: WHOLE GRAIN LABEL STATEMENTS (Feb. 17, 2006), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059088.htm> [hereinafter DRAFT GUIDANCE: WHOLE GRAIN].

<sup>157</sup> DRAFT GUIDANCE: WHOLE GRAIN, *supra* note 156.

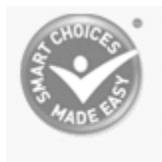
<sup>158</sup> U.S. DEP’T OF AGRIC., DIETARY GUIDELINES FOR AMERICANS 25 (2005), available at <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/DGA2005.pdf>.

<sup>159</sup> The FDA has not yet promulgated regulatory standards for dietary guidance statements beyond the requirement that, like all label statements, they be truthful and not misleading. The agency has issued a 2003 Advanced Notice of Proposed Rulemaking explaining that, unlike its authority over nutrient content claims, the FDCA does not grant the FDA authority to require pre-approval of dietary guidance statements. 68 Fed. Reg. 66,047. The 2003 ANPRM also requests comments on how such statements should be evaluated for scientific validity. 68 Fed. Reg. 66,048.

### b. Relative Schemes

Aggregated relative threshold labels highlight products within a food category that have comparatively better overall nutritional value, although they may be foods of low nutritional value. For example, as already mentioned, PepsiCo places its Smart Spot on Baked! Cheetos and Tropicana Twister Diet Soda to indicate that, because of their relatively lower fat and sugar content, these are healthier products when compared to other snack foods and soft drinks manufactured by PepsiCo (see Figure 8).<sup>160</sup>

**Figure 8. PepsiCo's Smart Spot**



Similarly, the Smart Choices logo designates foods that are, comparatively, “better for you” such as Cocoa Krispies and Froot Loops (see Figure 9).<sup>161</sup>

**Figure 9. The Smart Choices Logo<sup>162</sup>**



Insofar as aggregated nutrient profile labels are functionally equivalent to “healthy” claims, these relative threshold labels are pro-

<sup>160</sup> See PepsiCo, *supra* note 36; see also *FDA Hearing, Sept. 10, supra* note 34, at 75, 80.

<sup>161</sup> Smart Choices Program, *Helping Guide Smart Food and Beverage Choices*, <http://www.smartchoicesprogram.com/index.html>; see Marion Nestle, *The Not-So-Smart Choices Story Continues...*, *FOOD POLITICS*, <http://www.foodpolitics.com/?s=eileen+kennedy> (quoting excerpts from an e-mail letter sent to alumni by Dr. Eileen Kennedy, dean of the Friedman School of Nutrition Science and Policy at Tufts University, defending the validity of the Smart Choices Program); see also Neuman, *For Your Health, Froot Loops*, *supra* note 13.

<sup>162</sup> Smart Choices Program, *supra* note 4.

hibited by current FDA regulations. The agency has prohibited use of the term “healthy” as a relative claim, explaining that:

[t]he usefulness of a food labeled ‘healthy’ is not based on how it compares to a similar food, but on how it contributes to achieving a total diet consistent with dietary recommendations. In contrast, the purpose of comparative claims is to distinguish those foods that contain modified levels of the specified nutrient when compared to the level of that nutrient in an appropriate reference food. Thus, the purpose of a “healthy” claim is significantly different from that of a comparative claim. While both types of claims can be beneficial to consumers in structuring their diets, they do different things. Therefore, the agency considers it inappropriate to define “healthy” as a comparative claim.<sup>163</sup>

This view would spell the end of aggregated threshold schemes that make relative claims.

One might argue in defense of relative schemes that the stated purpose of programs like PepsiCo’s Smart Spot or Smart Choices is not to promote baked potato chips, diet soda, or Froot Loops as healthy foods but rather to help chip, soda, and cereal consumers make *marginally* healthier choices. Moreover, one might also argue that an outright ban on aggregated relative threshold labels that are truthful and not misleading would violate the First Amendment.

Relative threshold labels have a very high potential to mislead consumers. On their face, nothing distinguishes relative threshold labels from absolute threshold labels. Neither the text nor the symbol in the Smart Spot and the Smart Choices labels indicates that the foods they recommend are only marginally better than other, similar, foods of low nutritional value. Moreover, manufacturers could avoid the potential for confusion with an equally effective relative nutrient content claim that disaggregates nutrients and uses relative terms such as “less” and “reduced” accompanied by explicitly named reference foods.<sup>164</sup> Of course, it is true that aggregation might simplify food comparisons that involve complex tradeoffs between nutrients, for example, less fat but more sugar. In practice, however, aggregated relative labels like Smart Spot and Smart Choices recommend foods based not on a complex weighing of tradeoffs, but on simple calculations of lower fat or lower sugar content. And even where an aggre-

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<sup>163</sup> Final Rule, 59 Fed. Reg. 24,232, 24,233-24,234 (May 10, 1994) (codified at 21 C.F.R. § 101 (2009)).

<sup>164</sup> 21 C.F.R. § 101.13(j).

gated relative threshold label would simplify complex tradeoffs between less nutritious foods, the potential for confusion with absolute threshold claims arguably justifies requiring relative claims to be disaggregated. As for potential First Amendment objections, this approach is not an outright ban on relative nutrient content claims but rather a requirement that they be disaggregated. While one might respond that this approach constitutes an outright ban on aggregated relative nutrient content claims, it permits essentially the same information so long as the information is presented in a disaggregated form.

## 2. Rating Scales

Aggregated nutrient profile labels that rate the nutritional value of foods on a scale could also be regulated under the FDA's rules governing nutrient content claims, although doing so would require changes in the FDA standard for "healthy" claims. Examples of aggregated rating labels include the Hannaford Brothers' Guiding Stars label and the NuVal Nutritional Scoring System (see Figures 10 and 11).

**Figure 10. Hannaford Brothers' Guiding Stars Label<sup>165</sup>**



**Figure 11. The NuVal Nutritional Scoring System<sup>166</sup>**



<sup>165</sup> Guiding Stars, *supra* note 35.

<sup>166</sup> NuVal Nutritional Scoring System, <http://www.nuval.com> (last visited Oct. 14, 2009).

Unlike aggregated threshold schemes, aggregated rating schemes are not easily assimilable into the existing regulatory category of implied nutrient content claims suggesting that a food, because of its nutrient content, may be helpful in maintaining healthy dietary practices. As we have seen, FDA regulations define a threshold that divides foods into two categories: foods that qualify as “healthy” and foods that do not. And, as we have also seen, the FDA has rejected use of the term “healthy” in a relative sense that would allow for comparisons between foods of low nutritional value. By contrast, rating schemes divide foods into more than two categories, and they seek to facilitate comparisons between the overall nutritional value of both more nutritious and less nutritious foods among all foods and within food groups.

One might argue that insofar as aggregated rating labels present some foods of low nutritional value as healthier than other foods of low nutritional value – just like aggregated relative threshold labels – they should be prohibited as relative “healthy” claims. Rating labels, however, are distinguishable from relative threshold labels. In the previous section, I suggested two reasons that justify prohibition of aggregated relative threshold labels. First, relative threshold labels are easily misunderstood as making claims about high nutritional value in an absolute sense. By contrast, rating labels that rate all foods along a spectrum from low to high nutritional value are not likely to mislead consumers the way relative threshold schemes are. High ratings indicate high nutritional value in an absolute sense. Only foods with high nutritional value will be labeled with high ratings. Foods of low nutritional value will not be labeled with high ratings. Accordingly, while foods like baked chips and diet soda may be rated higher than other similar foods, these foods will not have high ratings that could mislead consumers into thinking that such foods are of high nutritional value.<sup>167</sup>

The second reason I suggested for prohibiting aggregated relative threshold labels is that differentiating between nutritionally better and worse foods of low nutritional value can effectively be accomplished through the use of disaggregated relative nutrient content claims for individual nutrients, such as “lower sodium” or “reduced fat.” By contrast, aggregated rating schemes provide information that cannot be conveyed by disaggregated relative nutrient content claims. Rating

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<sup>167</sup> This argument does not apply to aggregated rating schemes that do not rate all foods. Aggregated rating schemes that rate only less healthy foods might well award high ratings to foods that are not of high nutritional value, making them potentially misleading to consumers. For that reason, I would argue that they should be prohibited.

foods along a spectrum rather than dividing them into two groups offers consumers more opportunities to compare foods both among all foods and within food groups. There are significant nutritional differences among foods that meet the threshold definition of healthy and among foods that do not, and these differences are invisible in threshold schemes. Disaggregated relative nutrient content claims for individual nutrients cannot capture these comparisons since they merely compare a food to a reference food. Moreover, ratings can provide a scale along which to compare many foods to each other.

Aggregated rating schemes are not without problems. For one thing, eating only the most highly rated foods might not provide enough fat in one's diet in schemes where the presence of fat in a food lowers its rating. Moreover, rating systems may have a hard time accounting for the nutrition implications of eating foods in combination. Given the complex interactions between foods, the components of a meal analyzed separately may generate a different nutrient profile rating than the meal as a whole. This is not to say that aggregate rating schemes are not useful but only that rating the nutrition content of foods in the aggregate is a complex business.

I propose that the FDA promulgate multiple threshold definitions for overall nutritional value, for example providing three threshold definitions that would create a four-point scale: (1) foods below the bottom threshold, (2) foods between the bottom and middle thresholds, (3) foods between the middle and top thresholds, and (4) foods above the top threshold. This would require adding further gradation to the FDA's current definition of "healthy," as it has already done for some single nutrient claims, such as "low sodium," "very low sodium," and "sodium free."<sup>168</sup> Thus, food ratings in a scheme like Hannaford Brothers' Guiding Stars would have to meet the corresponding FDA threshold definitions – for example, a food labeled with three stars would have to meet the FDA's top threshold definition, a food labeled with two stars would have to meet the FDA's middle threshold definition, and so on. For schemes with a higher level of gradation, like NuVal's one to one-hundred ranking, the FDA could employ the same four-point scale. Foods rated by NuVal in the top quartile (100-76) would have to meet the FDA's top threshold definition, foods in the NuVal second quartile (75-51) would have to meet the FDA's middle threshold definition, and so on.

Calibrating nutrient profile rating schemes to graduated FDA threshold definitions of overall nutritional value would provide con-

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<sup>168</sup> SHAPIRO, *supra* note 49, at 182 (note that "sodium free" does not mean zero sodium).

sistency among schemes and make them consistent with the federal government's dietary guidelines and health recommendations. This regulatory approach would also allow for variation among schemes in terms of gradation and rankings. Those who design nutrient profile labeling schemes could experiment with greater and lesser levels of gradation, and rankings could vary so long as they met or exceeded minimum FDA threshold levels.

One might object that imposing standards that employ tiers with cutoff points between them undermines the attempt of more complex rating schemes like NuVal to express nutrient value in continuous terms on a more graduated scale. Clear cutoff points would fail to reveal significant differences between foods at either extreme of the same tier, and they would exaggerate minor differences between foods just on either side of the cutoff point dividing two tiers.

The purpose of my proposal to formulate a four-tiered definition of "healthy" is not to create an FDA nutrient profile rating system to displace private-sector rating systems like Guiding Stars or NuVal. The purpose is merely to provide an easily understandable system of minimum thresholds to prevent abuse. Thresholds should be set in such a way as to prevent high ratings for foods of low nutritional value – like Froot Loops and diet soda – while allowing for variation in different approaches that are consistent with these minimum thresholds. A government regulatory tool that employs tiers and cutoff points need not interfere with private sector efforts to develop more complex nutrient rating schemes, so long as those schemes satisfy minimum standards that prevent ratings that are false or misleading.

The details of this regulatory proposal – for example, how many tiers to use, which nutrients to include, and where to set cutoff points—could be worked out by FDA professional staff with input from the IOM and private researchers under contract with the agency. Working out such details is, of course, no easy task, but it is well within the FDA's expertise. The agency has, for many years, been in the business of setting minimal thresholds for nutrient content claims, both disaggregated and aggregated, in order to promote public health and provide clear guidance for what constitutes false or misleading claims.

### C. Minimum Standards are Preferable to a Single FDA-Sponsored Scheme

I have proposed that the FDA regulate nutrient profile labels by setting minimum standards to ensure that they are not false or misleading. This is consistent with the FDA's traditional approach to regulating nutrient content claims. By contrast, CSPI has advocated

that the FDA develop and impose on the food industry “a simple, uniform science-based system [that] would bring consistent and reliable information to the marketplace and help consumers choose more healthful diets.”<sup>169</sup> The FSA’s Traffic Light labeling scheme is a voluntary version of this same regulatory approach, one that would require the FDA to develop its own nutrient profiling system.

The high level of complexity involved in designing nutrient profiling systems gives rise to two reasons to prefer a regulatory approach that merely sets minimum-thresholds for nutrient profile labels. First, there is little reason to suppose that government policymakers will be able to create a system that is superior to those developed by research scientists in academia and industry. Disagreement among experts in industry and academia as to the best approach to nutrient profiling – even after millions of dollars of investment and years of research – is significant and ongoing.<sup>170</sup> Setting minimum standards is a less complex task that is more likely to generate consensus among experts, who do agree on many basic principles of nutrition, and among food companies eager to maintain a “level playing field.”<sup>171</sup> Setting minimum standards is a common regulatory tool well within the expertise of the agency and likely to elicit few complaints about the agency going beyond its statutory mandate under the NLEA.

Second, allowing for experimentation and competition among private-sector groups is likely to advance knowledge in the areas of nutrient profiling and food labeling more effectively than the development and imposition of a single, centralized government scheme. The most effective role for government in this area is not to supplant private sector experimentation and competition but rather to police them. Minimum government standards will create space for genuine experimentation and competition aimed at advancing knowledge while eliminating profit-driven research and the reduction of nutrient profile labeling to just another marketing strategy. There is also reason to believe that market incentives, under certain circumstances, will produce high quality scientific information. While allegations of conflict of interest and “junk-science” surround manufacturer-sponsored front-of-package labels, such as Smart Choices, the same is not true of shelf labels developed by or for retail stores.<sup>172</sup> The Guid-

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<sup>169</sup> CSPI PETITION, *supra* note 11, at i, 2.

<sup>170</sup> See generally V. Azais-Braesco et al., *Nutrient Profiling: Comparison and Critical Analysis of Existing Systems*, 9 PUB. HEALTH NUTRITION 613, 613-22 (2006).

<sup>171</sup> MARION NESTLE, *FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH* 29 (2002); Scarbrough, *supra* note 132, at 44.

<sup>172</sup> See Accidental Hedonist, *For a Healthy Breakfast...Cocoa Krispies???*

ing Stars and NuVal labels have been singled out for the scientific integrity of their ratings, even among critics of nutrient profiling generally.<sup>173</sup> One reason may be that retail supermarkets are more interested in attracting consumers into their stores than in selling any particular type or brand of food, including their own their store brands. Whereas manufacturers have an incentive to adopt nutrient profiling schemes that favor their products – regardless of the product’s nutritional value – retail supermarkets draw customers into their stores by offering them reliable nutrient profile labels that, for some consumers, enhance their shopping experience.<sup>174</sup>

## VI. RESPONSES TO OBJECTIONS

In Part V, I argued that the existing FDA framework for regulating nutrient content claims can address concerns about nutrient profile labeling related to consumer confusion and the reliability of nutrition information. I proposed additional gradation in the FDA’s definition of the term “healthy” in order to provide regulatory standards for aggregated nutrient profile labeling schemes that rate foods on a scale based on their overall nutritional value. In this Part, I address three potential objections to this proposal. First, my proposal assumes that federal nutrition standards are an appropriate basis for judging the accuracy of nutrient profile ranking schemes. One might question whether federal nutrition standards are the most accurate measure of overall nutritional value or even whether such a measure is possible. Second, one might object that mandatory government standards will squelch debate, thus impeding experimentation and innovation. Third, one might object that nutrient profile ranking schemes are a marketing tool for industrially processed foods and that rather than

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(Sept. 8, 2009), [http://www.accidentalthedonist.com/index.php?title=for\\_a\\_healthy\\_breakfast\\_cocoa\\_krispies&more=1&c=1&tb=1&pb=1](http://www.accidentalthedonist.com/index.php?title=for_a_healthy_breakfast_cocoa_krispies&more=1&c=1&tb=1&pb=1) (referring to the Smart Choices Program as “junk science”) (last visited Nov. 14, 2009); *see also* Nestle, *supra* note 161; Press Release, Mike Adams, “Smart Choices” Food Label is Marketing Fraud; Tufts University Involvement Questioned (Opinion), (Sept. 25, 2009), <http://www.prlog.org/10353784-smart-choices-food-label-is-marketing-fraud-tufts-university-involvement-questioned-opinion.html> (last visited Nov. 14, 2009).

<sup>173</sup> *See* Martin, *supra* note 24; Martin, *supra* note 7; Alex Jung, *Will New Food Labels Make Americans Thinner?*, AlterNet (Oct. 3, 2007), [http://www.alternet.org/story/64219/will\\_new\\_food\\_labels\\_make\\_americans\\_thinner/](http://www.alternet.org/story/64219/will_new_food_labels_make_americans_thinner/).

<sup>174</sup> Reliable nutrient profile labeling can be an effective marketing strategy for retail stores insofar as it contributes to a store’s image and provides a “service-based” strategy for attracting consumers. For an analysis of the strategies employed by retail stores to attract consumers, *see* BARBARA E. KAHN & LEIGH MCALISTER, *GROCERY REVOLUTION: THE NEW FOCUS ON THE CONSUMER* 89-110 (1997).

modifying existing regulations to permit nutrient profile labels, the FDA should prohibit them altogether as unauthorized nutrient content claims. I shall address each of these objections in turn.

#### A. Basing Government Nutrition Standards on Scientific Consensus

There are at least two reasons to question whether federal nutrition standards are an appropriate basis for regulating the accuracy of nutrient profile rating schemes. One reason is that political considerations unrelated to nutrition science influence federal nutrition standards. In *Food Politics*, Marion Nestle describes the food industry's many successful efforts to quash or blunt government dietary recommendations that would negatively impact food sales.<sup>175</sup> Nestle catalogues instances of food companies and industry associations waging intensive lobbying campaigns, giving research funding to influence university academics who serve as independent experts on government advisory panels, providing financial support to professional organizations to obtain endorsements, and suppressing critics using libel litigation.<sup>176</sup>

Yet, despite how troubling a portrait of federal nutrition policy-making Nestle paints, her criticisms do not necessarily lead to the conclusion that we ought not to rely on FDA and USDA nutrition standards. From a regulatory point of view, one must ask what the institutional alternatives are. Regulation always requires a choice between imperfect institutional alternatives of the market, legislatures, courts, and administrative agencies.<sup>177</sup> Nestle's critique offers reason to believe that unregulated markets are unlikely to produce nutrition information that is more accurate than federal administrative agencies. Moreover, for all of their susceptibility to industry influence, administrative agencies enjoy a measure of insulation from the political pressures that influence legislation.<sup>178</sup> And while courts may similarly enjoy a measure of insulation from political pressures, judges deal only with particular issues that are raised in litigation and are, as a matter of training and temperament, unsuited to promulgate general

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<sup>175</sup> NESTLE, *supra* note 171, at 93-171.

<sup>176</sup> *Id.*

<sup>177</sup> *See generally*, NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY (1996); Peter H. Schuck, *Why Regulating Guns Through Litigation Won't Work*, in *SUING THE GUN INDUSTRY: A BATTLE AT THE CROSSROADS OF GUN CONTROL & MASS TORTS* 225, 227-30 (Timothy D. Lytton ed., 2005).

<sup>178</sup> *See generally*, DAVID E. LEWIS, PRESIDENTS AND THE POLITICS OF AGENCY DESIGN (2003).

and highly technical standards as compared to administrative agencies.<sup>179</sup> In the end, concerns about political influence on federal administrative policymaking in the area of nutrition standards would be best addressed by reforming the administrative process rather than by rejecting agency standards altogether. Nestle herself recognizes this and offers an agenda of reforms in the conclusion to *Food Politics*.<sup>180</sup>

A second reason to question whether federal nutrition standards are an appropriate basis for regulating nutrient profile rating schemes is that nutrition science is, at best, an inexact science. As Nestle explains, nutrition research entails a number of inherent limitations.<sup>181</sup> Epidemiological data can provide evidence of associations between consumption of particular nutrients and health conditions on the level of an entire population. Associations, however, are not definitive proof of causation. Moreover, research into individual consumption and health conditions is complicated by the difficulty of obtaining accurate information about what individuals actually consume (as opposed to what they report) and by the impossibility of isolating individual nutrient intake as a causal factor from other factors such as overall diet, lifestyle, and environmental impacts. Animal studies are only a proxy for human studies and do not replicate the real life conditions in which humans consume nutrients. All of this is not to say that nutrition science is entirely unreliable but only that, when done carefully, most of the time produces only general and tentative conclusions about the relationship between individual nutrients and health conditions. Moreover, different interpretations of findings lead nutrition scientists to disagree among themselves as to many of these conclusions.

In perhaps the best comparative study of nutrient profile rating schemes to date, researchers found significant discrepancies in how the same foods were ranked by four schemes that were each peer-reviewed by scientific experts. V. Azais-Braesco, C. Goffi, and E. Labouze, French nutrition scientists, compared the four schemes with each other by rank ordering the nutritional scores of 125 foods under each of the four schemes.<sup>182</sup> While Azais-Braesco et al. found that all of the schemes generally ranked fruits and vegetables higher than foods high in fat and sugar, they also found significant discrepancies due to differences in the underlying algorithms related to the choice of nutrients and how much weight particular nutrients were given. For

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<sup>179</sup> See Schuck, *supra* note 177, at 234-35.

<sup>180</sup> NESTLE, *supra* note 171, at 368.

<sup>181</sup> *Id.* at 381-85.

<sup>182</sup> Azais-Braesco et al., *supra* note 170, at 613-22.

example, avocados were ranked 23, 46, 113, and 101 depending upon the scheme, and bran cereal was ranked 6, 16, 18, and 85.<sup>183</sup>

Azais-Braesco et al.'s analysis also illustrates the difficulty of evaluating the accuracy of any particular scheme. In comparing different schemes, they organized the food rankings into quintiles and asked a panel of 12 nutrition experts to rank the same foods from one to five "according to their own knowledge and experience of [each food's] contribution to a balanced diet."<sup>184</sup> The group of experts was composed of "10 experienced scientists in nutrition, sitting on official expert committees, and two operational dietitians."<sup>185</sup> To begin with, there was variation among the experts in their rankings, which the authors attributed to differences in "the expertise and knowledge of each expert, as well as his/her personal or cultural point of view."<sup>186</sup> Second, even when expert rankings were aggregated, by recording the median expert classification for each food, significant differences remained between the experts and all of the schemes. Most importantly, Azais-Braesco et al. point out that there was no reason to believe that this aggregated expert opinion provided a measure of accuracy. As Azais-Braesco et al. put it, "[c]omparisons between classifications . . . should be interpreted with caution: none of it, including the expert partitioning, can be considered an absolute reference."<sup>187</sup> Comparative analysis, they explain, is "useful for examining the nutrient profiling systems relative to one another, but not relevant for stating that one system is more accurate than another."<sup>188</sup> The fundamental problem with any attempt to evaluate schemes is that differences among schemes may merely reflect different views about nutrition and nutrition science that are subject to legitimate professional disagreement among nutrition scientists.

These findings might lead one to question whether any standard – government or otherwise – can provide a means of assessing the accuracy of nutrient profile rating schemes, or even if it makes sense to talk in terms of accuracy when it comes to nutrient profile rating. If peer reviewed schemes and experts cannot agree on how to rank 125 foods on a scale of one to five, what confidence can one have in a government standard?

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<sup>183</sup> These discrepancies can be accounted for by different treatment of fat and sugar in each of the schemes. *Id.* at 618-21.

<sup>184</sup> *Id.* at 616.

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* at 621.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

This kind of scientific uncertainty is not peculiar to nutrition regulation. It is a regular feature of regulation. Regulatory agencies grapple with scientific uncertainty by relying on their own in-house experts, inviting public comment on regulatory proposals, and consulting panels of independent experts. The FDA relies on the many nutrition experts within its ranks, solicits comments on proposed nutrition regulations, and commissions studies by the IOM and other panels of independent experts. Setting government standards for nutrient profile rating could begin with a search for areas of scientific consensus. The study by Azais-Braesco et al. reveals not only variation but also a measure of consensus among peer-reviewed nutrient profile schemes and between the schemes and the panel of experts. For example, all of the schemes and the panel ranked oranges, peaches, strawberries, melon, tomatoes, spinach, broccoli, carrots, green beans, and tofu in the top quintile and chocolate chip cookies, filled wafer biscuits, and Mars bars in the bottom quintile.<sup>189</sup> Ranking by quartiles instead of quintiles would likely reduce disparities even more. Government regulatory standards could be formulated to conform to whatever consensus exists with the help of agency nutritionists, public comments, and an IOM study. For example, multiple government threshold definitions of “healthy” could be calibrated to ensure that the top threshold was set low enough so that oranges and broccoli satisfied it and the bottom threshold was set high enough so that cookies and Mars bars did not satisfy it. Where consensus does not exist, threshold definitions could be set low enough to allow for differences among schemes that met standards for scientific rigor, such as peer review. Standards could be updated periodically to account for developments in food science and nutrient profile rating and to adjust to changes in scientific consensus. Such a system would still allow for a great deal of variation among schemes. Its purpose would be not to arrive at a gold standard for nutrient profile rating but rather to protect consumers from ratings that might lead them to believe that foods like chocolate chip cookies and Mars bars are foods of high overall nutritional value or are helpful in shaping a healthy diet.<sup>190</sup>

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<sup>189</sup> *Id.* at 618-19.

<sup>190</sup> If it seems implausible that anyone would attempt to convince consumers that foods like these are healthy, see the recent attempt by the dean of the Friedman School of Nutrition Science and Policy at Tufts University to argue that Froot Loops are a healthy choice, Neuman, *For Your Health, Froot Loops*, *supra* note 13.

### B. Imperfect Government Nutrition Standards Are Better than None

Regulating nutrient profile rankings of overall nutritional value according to multiple threshold definitions of “healthy” would tie ranking schemes to federal dietary guidelines and health recommendations. This would limit the ability of nutrient profile labeling schemes to promote alternative approaches to nutrition or to incorporate advances in nutrition science unless and until they were included in federal guidelines. Concern about the negative impact of government dietary advice is perhaps best illustrated by controversy over the government’s thirty-year campaign to reduce consumption of dietary fat. Michael Pollan suggests in *In Defense of Food* that when government dietary guidelines began to encourage a diet lower in fat and higher in carbohydrates in the 1970s, they “effectively closed off debate” on the link between dietary fat and chronic disease.<sup>191</sup> Critics of the guidelines argue that this shift has resulted in less healthy dietary patterns and increases in obesity, Type II diabetes, and heart disease. According to Pollan, the voices of critics were largely drowned out by the government’s campaign against fat and the food industry’s enthusiastic development and marketing of low-fat products.<sup>192</sup> Pollan asserts that even in the face of mounting scientific evidence questioning the link between dietary fat and chronic disease, the government has been slow to change course.<sup>193</sup>

While Pollan’s critique is compelling, one must be careful not to overstate the power of government dietary guidelines to suppress debate. There is no dearth of alternative dietary approaches. Perhaps the most well known is the Atkins Nutritional Approach. This low-carbohydrate, high-protein diet has been around since the early 1970s.<sup>194</sup> By the height of its popularity in the 2000s, millions of Americans followed the Atkins approach, and the food industry promoted it with an extraordinary array of low-carb products.<sup>195</sup> Government endorsement of a particular dietary approach does not seem to have ended debate or suppressed alternatives. Advocates for alternatives receive government and industry support for research and are

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<sup>191</sup> MICHAEL POLLAN, *IN DEFENSE OF FOOD: AN EATER’S MANIFESTO* 45 (2008).

<sup>192</sup> *Id.* at 40-50.

<sup>193</sup> *Id.* at 40-41.

<sup>194</sup> TheHistoryOf.net, *The History of the Atkins Diet - A Revolutionary Lifestyle!* (Sept. 10, 2008), <http://www.thehistoryof.net/history-of-the-atkins-diet.html>.

<sup>195</sup> Wikipedia, *Atkins Diet*, [http://en.wikipedia.org/wiki/Atkins\\_diet#cite\\_ref-8](http://en.wikipedia.org/wiki/Atkins_diet#cite_ref-8) (last visited Oct. 14, 2009).

able to influence the government's views through the regulatory process by submitting comments to proposed regulations and participating on expert panels. Admittedly, requiring that nutrient profile rating schemes conform to federal dietary guidelines would inhibit the use of food labels as a means of challenging the guidelines and promoting alternative approaches. But meaningful debate over competing approaches to nutrition, diet, and health is more likely at academic conferences, industry meetings, and within the regulatory process, than on food labels. While the slow pace of change within administrative agencies charged with promulgating dietary guidelines and health recommendations is a source of frustration to reform advocates like Pollan, careful deliberation within the regulatory process helps to mitigate the often extreme swings in dietary advice dispensed by private sector experts in an area especially prone to faddism. Moreover, providing no government standard at all for industry claims about nutrition is unlikely to improve the overall quality of dietary advice available to consumers.

### C. Beyond Nutritionism

Critics of nutrient profile labeling have suggested that it perpetuates an unhealthy approach to food and diet that overemphasizes the nutrient content of foods.<sup>196</sup> "Nutritionism," explains Michael Pollan, is a reductionist ideology that views foods as essentially the sum of their nutrient parts and sees the purpose of eating as primarily a means of promoting physical health. From the perspective of nutritionism, industrially processed foods that contain the appropriate quantity of desirable nutrients are just as good, and potentially even better, than whole foods.<sup>197</sup> Nutrient profile labels, critics suggest, promote highly processed foods so long as they are sufficiently fortified with good nutrients and/or formulated in ways that reduce or replace bad nutrients.<sup>198</sup> But better eating, argue these critics, is not a matter of optimizing one's nutrient intake by consuming reformulated industrially processed foods. Instead, individuals should avoid processed foods in

<sup>196</sup> See generally Marion Nestle, *FOOD POLITICS*, <http://www.foodpolitics.com/> (last visited Feb. 5, 2010); Fooducate, *Why Coke's New Front-of-Package Calorie Label is BAD*, <http://www.fooducate.com/blog/> (last visited Oct. 23, 2009).

<sup>197</sup> POLLAN, *supra* note 191, at 27-32.

<sup>198</sup> See, e.g., Marion Nestle, *Food Labeling: Yet Another Update*, *FOOD POLITICS* (Oct. 14, 2009), <http://www.foodpolitics.com/?s=smart+choices>; *FOOD POLITICS*, *supra* note 196; Fooducate.com, *Six Reasons "Smart Choices" Food Labeling Won't Help Shoppers* (Aug. 7, 2009), <http://www.fooducate.com/blog/2009/08/07/six-reasons-smart-choices-food-labeling-wont-help-shoppers/>.

favor of whole foods and adopt a more relaxed, less health-obsessed attitude toward food that takes into account the social and environmental implications of what and how we eat.<sup>199</sup> Increasingly detailed nutrient profile labeling, one might argue, serves the nutritionist agenda of the processed food industry at the expense of human health and environmental sustainability. Accordingly, one might conclude that, rather than permitting nutrient profile rating schemes by modifying existing regulations, the FDA should prohibit such schemes as unauthorized nutrient content claims.<sup>200</sup>

It is unclear, however, that prohibiting nutrient profile rating schemes would be an effective strategy to shift federal nutrition policy away from nutritionism toward a more wholistic approach to food. Nutrient profile labels, in all of their forms, simplify the nutrient information that is already available to consumers on the Nutrition Facts panel and the ingredient list. For consumers who want nutrient information and who use it to make decisions, well regulated nutrient profile labels at the very least make that information more accessible and useable. Prohibiting the labels would not discourage individuals from following government dietary advice but would simply make it more difficult to do so. For consumers uninterested in following government dietary advice, permitting the labels is unlikely to make them focus more on the nutrient content of the foods they consume. So it is unlikely that allowing nutrient profile labeling would either increase or decrease nutritionism among consumers.

The case against nutritionism is more than just a narrow critique of food label regulation. It is also a call for a new direction in food policy altogether. Perhaps nutrient profile labeling could help to advance this goal. The value of nutrient profile labeling lies first in its capacity to condense and simplify information about the complex tradeoffs in comparing the overall nutritional value of different foods and second in product improvement as manufacturers seek to improve the nutrient profile of their foods. The more holistic approach to food championed by Pollan calls on people to consume whole foods, mostly plants, and foods produced in ways that minimize the use of natural resources and pollutants.<sup>201</sup> Nutrient profile labels can promote this approach. The Whole Grain Stamp helps consumers identify and choose less processed foods. Vegan symbols help consumers identify plant foods. And the NuVal rating system favors naturally occurring

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<sup>199</sup> POLLAN, *supra* note 191, at 183-200.

<sup>200</sup> My consideration of this approach leaves aside, for the purposes of discussion, potential First Amendment limitations on an outright ban of nutrient profile labels.

<sup>201</sup> POLLAN, *supra* note 191, at 1.

nutrients over nutrients added through fortification.<sup>202</sup> More complex profile labeling schemes could assist consumers in comparing the environmental impact of foods, which involves complex tradeoffs between variables such as carbon footprint and water footprint.<sup>203</sup> For example, foods that are grown locally may require less fossil fuels for transportation to market but require more water to grow them than would be the case in other places. These issues of environmental impact fall outside of the scope of nutrient content labeling, and are beyond the expertise and jurisdiction of the FDA. Nevertheless, insofar as profile labeling could be a useful tool in promoting a broader, more environmentally sensitive, food policy, FDA experience regulating nutrient profile labeling is likely to be valuable. Thus, the real problem with nutrient profile labeling from the point of view of nutritionism critics is the focus on nutrients, not profile labeling itself as a policy tool. While profile labeling is currently aimed at educating consumers about the nutrient content of foods, it offers a valuable tool to promote other food policy goals, such as a more environmentally-conscious food policy.

### CONCLUSION

Just as my proposal – relying on the existing FDA framework for regulating nutrient content claims and developing additional gradations of the FDA standard for “healthy” foods – is modest, so too are my ultimate conclusions. In the end, nutrient profile labeling is not a sign of any significant change in the general direction of U.S. food policy, which remains focused on nutrients and personal health. Nor does nutrient profile labeling inevitably result in a clash of symbols adding to consumer confusion. If well regulated, nutrient profile labeling is a means of facilitating current food policy. And for advocates of change, nutrient profile labeling may also provide a useful tool for promoting alternatives.

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<sup>202</sup> See, e.g., NuVal, *supra* note 37 (explaining the role of the different types of nutrients in the NuVal Nutritional Scoring System); see also *FDA Hearing Sept. 11, supra* note 9, at 21.

<sup>203</sup> See generally JAMES E. MCWILLIAMS, *JUST FOOD: WHERE LOCAVORES GET IT WRONG AND HOW WE CAN TRULY EAT RESPONSIBLY* (2009).